Public Health Assessment GUIDANCE MANUAL (Update)

January 2005

U.S. Department of Health and Human Services
Public Health Service
Agency for Toxic Substances and Disease Registry
Atlanta, Georgia

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Foreword

In the United States and its territories, thousands of abandoned industrial and commercial facilities and hazardous waste disposal sites exist. Some of these sites may have the potential to adversely affect public health. The mission of the Agency for Toxic Substances and Disease Registry (ATSDR) is *to serve the public by using the best science, taking responsive public health actions and providing trusted health information to prevent harmful exposures and disease related to toxic substances.* The ATSDR public health assessment process serves as a mechanism to help ATSDR sort through the many hazardous waste sites in its jurisdiction and determine when, where, and for whom, public health actions should be taken. Through this process, ATSDR finds out whether people living near or at a hazardous waste site are being exposed to toxic substances, whether that exposure is harmful, and what must be done to stop or reduce any exposure.

This manual is a revision of ATSDR's 1992 Public Health Assessment Guidance Manual. The revised manual builds upon the process described in the 1992 manual and draws from the lessons learned through conducting public health assessments for nearly two decades. More detailed guidance on many of the procedures used to identify hazards and needed public health actions is presented in the manual. New information and techniques that reflect advances in science and technology, including tools and resources available to health assessors, are also presented. Advancements in geographical information systems, computational modeling techniques, exposure investigation approaches, and toxicologic knowledge, for example, enable a more sophisticated analysis of environmental data and exposures than was previously possible.

The manual emphasizes a team approach and the importance of careful planning, coordination of scientific analyses, and communication throughout the public health assessment process. ATSDR recognizes that effective collection, analysis, interpretation, and dissemination of public health assessment information often requires the cooperation and coordination of multi-disciplinary teams of scientists, health communication specialists, health educators, and/or medical professionals. Good communication with other governmental agencies, tribes, the community, and other stakeholders is critical and integral to the process.

This Public Health Assessment Guidance Manual is just one tool available to the health assessment team. It is not intended to supplant the professional judgment or discretion of the health assessor (or public health assessment team) in compiling and analyzing data, drawing conclusions, and making pubic health recommendations. Instead, the manual is intended to serve as a uniform tool to help discriminate and prevent poor professional judgement calls, and to provide a logical approach to the team in evaluating the public health implications of hazardous waste sites, while still allowing the health assessor to develop new approaches to the process and apply the most current and appropriate science and methodology. The public health assessment process adapts to changing scientific technology and public health procedures to remain dynamic.

ATSDR is committed to updating the manual as new technical information becomes available. The agency welcomes comments from users of the manual.

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Chapter 1
Introduction

The Agency for Toxic Substances and Disease Registry (ATSDR) determines public health implications associated with hazardous waste sites and other environmental releases. This work supports ongoing site investigations conducted by other agencies, addresses community health concerns, and results in recommendations for preventing harmful exposures and conducting additional scientific study. ATSDR has developed a methodology for evaluating the public health implications of exposures to environmental contamination—the public health assessment process.

ATSDR has written this manual to provide guidance to new and experienced health assessors when performing the variety of tasks associated with the public health assessment process. The manual presents specific approaches, methods, and resources that can be used to:

- Evaluate environmental exposures associated with a hazardous waste site.
- Assess the potential for adverse health effects resulting from environmental exposures at a site.
- Recommend sound public health actions based on the scientific evaluation of health and environmental data.
- Involve communities near a site and respond to their health concerns.
- Organize and write a public health assessment document to convey the findings of the assessment.

To provide a foundation for this document, this introductory chapter discusses:

- Why ATSDR conducts public health assessments (Section 1.1).
- The key elements of the public health assessment process (Section 1.2).
- The overall purpose and goal of this guidance manual (Section 1.3).
- How the manual is organized (Section 1.4).

1.1 ATSDR's Mandate and Mission

Congress established ATSDR in 1980 under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as the Superfund law. This law set up a fund to identify and clean up our country's hazardous waste sites. The U.S. Environmental Protection Agency (EPA) and individual states regulate the investigation and cleanup of site-related contamination. Under the Superfund law, ATSDR is charged with assessing the presence and nature of health hazards to communities living near Superfund sites, helping prevent or

reduce harmful exposures, and expanding the knowledge base about the health effects that result from exposure to hazardous substances.

In 1984, amendments to the Resource Conservation and Recovery Act of 1976 (RCRA)—which provides for the management of hazardous waste storage, treatment, and disposal facilities—authorized ATSDR to conduct public health assessments at these sites when requested by EPA, states, tribes, or individuals. ATSDR was also authorized to assist EPA in determining which substances should be regulated and the levels at which substances may pose a threat to human health. The passage of the Superfund Amendments and Reauthorization Act of 1986 (SARA) broadened ATSDR's responsibilities in the areas of public health assessments, establishment and maintenance of toxicologic databases, information dissemination, and medical education. ATSDR also conducts public health assessments when petitioned by concerned community members, physicians, state or federal agencies, or tribal governments.

CERCLA, as amended by SARA (104 [i][6][f]), requires that, at a minimum, ATSDR consider the following factors when evaluating the public health impact (or risk) associated with site exposures:

- The *nature and extent of contamination* at a site.
- The *demographics* (size and susceptibility) of the site population.
- The *exposure pathways* that may exist at a site (to what extent people contact site contaminants).
- *Health effects and disease-related data* associated with the observed levels of exposure.

Since its inception, ATSDR has continued to improve its approach to evaluating public health hazards in light of evolving science. The agency has refined its mission and goals to practice the best science and meet the needs of site communities. ATSDR's current mission and goals are reflected in the box below.

ATSDR's Mission

To serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related to toxic substances.

ATSDR's Goals

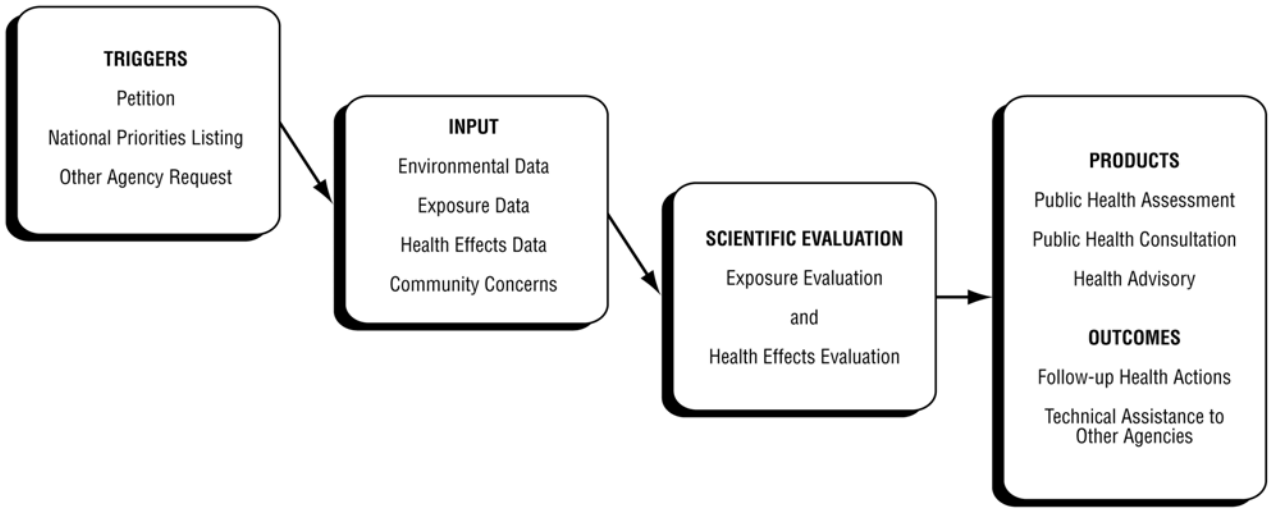
- *Evaluate human health risks from toxic sites and releases and recommend timely, responsive public health actions.*
- *Ascertain the relationship between exposure to toxic substances and disease.*
- *Develop and provide reliable, understandable information for affected communities and tribes and for other stakeholders.*
- *Build and enhance effective partnerships.*
- *Foster a quality work environment at ATSDR.*

1.2 The Public Health Assessment Process

ATSDR has developed a method to evaluate the public health implications of exposures to environmental contamination. This method is called the *public health assessment* process. The public health assessment process serves as a mechanism for identifying appropriate public health actions for particular communities. The process may be triggered by a site's listing on the National Priorities List or a specific request (or petition) from a community member or another government agency. The purpose of the process is to find out whether people have been, are being, or may be exposed to hazardous substances and, if so, whether that exposure is harmful, or potentially harmful, and should therefore be stopped or reduced. The process also serves as a mechanism through which the agency responds to specific community health concerns related to hazardous waste sites. Figure 1-1 (next page) illustrates the process, which is briefly summarized below.

The public health assessment process involves the evaluation of multiple data sets. These include available **environmental data**, **exposure data**, **health effects data** (toxicologic, epidemiologic, medical, and health outcome data), and **community health concerns**. Starting early in the assessment process, ATSDR begins to gather relevant scientific data to support the assessment. ATSDR also needs to learn what people in the area know about a site and site-related exposures and what concerns they may have about its impact on their health. Therefore, ATSDR actively gathers information and comments from the people who live or work near the site, including area residents, civic leaders, health professionals, and community groups. Throughout the public health assessment process, the agency communicates with the public about the purpose, approach, and results of its public health activities.

Figure 1-1. Basic Components of the Public Health Assessment Process



The public health assessment process involves two primary scientific evaluations—the exposure evaluation and the health effects evaluation.

- **Exposure Evaluation:** Exposure assessment is the hallmark of the public health assessment process. ATSDR scientists review environmental data to see how much contamination is at a site, where it is, and how people might come into contact with it. Generally, ATSDR does not collect its own environmental sampling data but reviews information provided by federal and state government agencies and/or their contractors, potentially responsible parties, and the public. When adequate environmental or exposure information is not available to evaluate exposure, ATSDR will indicate what further environmental sampling may be needed and may collect environmental and biologic samples when appropriate.

- **Health Effects Evaluation:** If the exposure evaluation shows that people have or could come into contact with hazardous substances, ATSDR scientists evaluate whether this contact may result in harmful effects. ATSDR uses existing scientific information, which can include the results of medical, toxicologic, and epidemiologic studies and data collected in disease registries, to determine what health effects may result from exposures. ATSDR recognizes that children, because of their behavior, size and growing bodies, may be particularly vulnerable to site-related exposures. Developing fetuses also may be more vulnerable to such exposures. Thus, the impact to children is considered first when evaluating the health threat to a community. The health impacts to other potentially high-risk groups within the community (such as the elderly, the chronically ill, and people who may have higher exposure potential) also receive special attention during the evaluation.

The public health assessment process is iterative and dynamic and may lead to a variety of products or outcomes. The findings may be communicated in *public health assessment* or *public*

health consultation documents, or an issued *public health advisory* (if there is an urgent health threat). All of these products serve as an aid for developing public health actions. The audience for such items often includes environmental and public health agencies, communities, and ATSDR itself.

In addition to products developed by the agency, there are other possible outcomes of the public health assessment process. During the course of the process, ATSDR may identify the need to prevent or better define exposures or illnesses in a particular community. ATSDR's response to such a need might include follow-up health actions such as, initiating an *exposure investigation* (to better define site exposures), recommending a *health study* (to identify elevated illness or disease rates in a site community), or working with the community to implement a *health education* program. ATSDR may also provide technical assistance to other agencies in response to their requests.

The public health assessment process enables ATSDR to prioritize and identify additional steps needed to answer public health questions. The science of environmental health is still developing, and sometimes information on the health effects of certain substances is not available. When this is the case and certain questions cannot be answered, ATSDR will suggest what further research studies and/or health education services are needed.

Public health assessments are conducted by agency health assessors, often supported by a multi-disciplinary team of scientists, health communication specialists, health educators, and/or medical professionals. ATSDR solicits and evaluates information from local, state, tribal, and other federal agencies; parties responsible for operating or cleaning up a particular site; and the community. All of these stakeholders play an integral role in the public health assessment process. ATSDR promotes a team approach to ensure that information used in the assessment is accurate and up-to-date and that community concerns are identified and addressed, and to foster cooperative efforts in implementing recommendations and public health activities.

Chapter 2 of this guidance manual provides a more in-depth description of the various elements and products of the public health assessment process.

1.3 Purpose of This Guidance Manual

This manual is intended to serve primarily as a "how to" guide for the new health assessor and other site team members, and a reference and resource for the more experienced health assessor. For this reason, the "you" used throughout the guide refers to the health assessor. The manual may also be helpful to the public and other end users of ATSDR products.

The public health assessment guidance manual provides guidance on how to effectively obtain, compile, and interpret environmental health data, and how to put that information into meaningful perspective. It presents the methods and tools health assessors can use to answer the critical question: *Are exposures occurring and, if so, are they likely to result in adverse health effects under site-specific conditions?* Specifically, it presents approaches to help you understand whether, and to what extent, people are being exposed to site-related chemical or radioactive contamination, as well as the extent to which physical hazards pose a threat.

The manual also repeatedly encourages cooperative efforts among multi-disciplinary teams in evaluating data and drawing public health conclusions and establishing and maintaining good two-way communication with the community. Each chapter provides tips and/or examples on how to effectively communicate scientific information, significant findings, and other information gained through the evaluation process.

The guidance is prescriptive where possible but also presents flexible evaluation tools and approaches that will enable you to address unique circumstances that may be encountered at individual sites. It cannot be emphasized enough that *each site is different*. Therefore, not all of the elements of the public health assessment process described in this manual apply to all sites. The resources you will need and your level of evaluation will vary. Some sites are more complex and may require extensive data gathering and evaluation of multiple substances and exposure pathways. Others may require only a focused review of a single pathway with little contamination.

Professional judgment, as noted throughout this manual, plays an important role in guiding public health assessments. However, the application of the approaches described in this manual, the use of multi-disciplinary teams, and internal and external review of all public health assessment documents foster the development of consistent, scientifically-defensible products and outcomes.

This manual is just one of many resources available to health assessors, but should serve as a foundation from which to build your assessments. Experience and consultation with peers also will be invaluable in conducting your assessments.

1.4 Organization of the Guidance Manual

This manual is organized as shown below. An overview of the public health assessment process is presented first (Chapter 2). Guidance on how to collect pertinent data (Chapter 3) and how to involve and effectively communicate with the community (Chapter 4) is presented next (both of these activities are performed throughout the public health assessment process). Guidance on the components of the two primary scientific evaluations in a public health assessment—the exposure evaluation and the health effects evaluation—is provided in Chapters 5–8. Lastly, guidance on how to draw conclusions and make recommendations is presented in Chapter 9. Each chapter guides the health assessor through the process being discussed, then offers suggestions for presenting public health assessment information and writing a public health assessment document. Supplemental guidance and additional examples are provided in the appendices.

Overview

Chapter 2 (Public Health Assessment Overview) highlights the various components of the public health assessment process. It provides the information needed to understand the overall process: why it exists, how an assessment is conducted, and how the findings are communicated. It also explains the distinct difference between ATSDR's public health

assessment process and the quantitative "risk assessment" process used by regulatory agencies.

Data Collection and Involving the Community

Chapter 3 (Obtaining Site Information) describes the sources and types of information generally needed to support public health assessments, answer public health questions, and prepare public health assessment documents.

Chapter 4 (Involving and Communicating With the Community) focuses on how to involve a site community in the public health assessment process and describes effective ways to communicate public health conclusions, including responses specific to health concerns expressed by the community.

Exposure Evaluation

Chapter 5 (Evaluating Environmental Contamination) describes how to evaluate whether available environmental data are of sufficient quality to evaluate exposures and whether the data adequately characterize the spatial and temporal extent of environmental contamination.

Chapter 6 (Evaluating Exposure Pathways) explains the criteria used for determining whether people are being exposed to site-related contaminants and understanding who is being exposed, for how long, and under what conditions. Gaining this knowledge will drive your health effects evaluation.

Health Effects Evaluation

Chapter 7 (Screening Analysis) describes screening methods used to evaluate which site-specific exposure pathways and detected substances need to be studied further. The chapter introduces the basis for and use of ATSDR health-based comparison values and other appropriate screening values. It also describes how to estimate site-specific exposure doses.

Chapter 8 (In-depth Analysis) explains when and how ATSDR performs more in-depth evaluations for the pathways and substances identified in the screening analysis as requiring further evaluation. Specifically, this chapter describes how health assessors integrate and weigh exposure, toxicologic, epidemiologic, health outcome, and medical data when evaluating implications of exposures.

Conclusions and Recommendations

Chapter 9 (Determining Conclusions and Recommendations) describes the criteria used to draw public health conclusions, make recommendations, and outline specific public health actions that may have occurred, may be in progress, or may be planned.

In addition, several appendices are included to supplement chapter-specific guidance.

Chapter 2
Public Health Assessment Overview

This chapter introduces the public health assessment process and serves as a road map to the rest of the manual. It provides an overview of the various steps in the process, introduces the multi-disciplinary team approach that you will use for most of your public health assessments, and describes the specific role of the health assessor and team leader and how various team members fit into the process. Throughout this manual, the public health assessment process will be distinguished from the public health assessment document. Henceforth, the acronym "PHA" will be used exclusively to refer to the PHA *document* (whereas, the public health assessment process can result in either a PHA or a PHC).

ATSDR partners may find that some discussions in this chapter, and the manual in general, are not necessarily relevant to their particular procedures (e.g., use of affiliated offices to manage different aspects of the public health assessment), but the process as a whole applies to all health assessors from within or outside ATSDR. This chapter addresses the questions:

- What is a public health assessment? (Section 2.1)
- When is a public health assessment conducted? (Section 2.2)
- Who conducts public health assessments? (Section 2.3)
- What is the role of the community in a public health assessment? (Section 2.4)
- How is the public health assessment conducted? (Section 2.5)
- What products and public health actions result from the assessment process? (Section 2.6)
- What is the format for public health assessment documents? (Section 2.7)

2.1 What Is a Public Health Assessment?

2.1.1 Definition and Purpose

A public health assessment is formally defined as:

> *The evaluation of data and information on the release of hazardous substances into the environment in order to assess any [past], current, or future impact on public health, develop health advisories or other recommendations, and identify studies or actions needed to evaluate and mitigate or prevent human health effects* (42 Code of Federal Regulations, Part 90, published in 55 Federal Register 5136, February 13, 1990).

A public health assessment is conducted to determine whether and to what extent people have been, are being, or may be exposed to hazardous substances associated with a hazardous waste site and, if so, whether that exposure is harmful and should be stopped or reduced. The public

health assessment process enables ATSDR to prioritize and identify additional steps needed to answer public health questions, and defines follow-up activities needed to protect public health.

There are a number of goals of the process that you should keep in mind throughout your assessment. These are:

- Evaluate site conditions and determine the nature and extent of environmental contamination.
- Define potential human exposure pathways related to site-specific environmental contaminants.
- Identify who may be or may have been exposed to environmental contamination associated with a site (past, current, and future).
- Examine the public health implications of site-related exposures, through the examination of environmental and health effects data (toxicologic, epidemiologic, medical, and health outcome data).
- Address those implications by recommending relevant public health actions to prevent harmful exposures.
- Identify and respond to community health concerns and clearly communicate the findings of the assessment.

2.1.2 Factors to Be Considered in All Public Health Assessments

By law, ATSDR is required to consider certain factors when evaluating possible public health hazards. Specifically, the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act (SARA) (104 [i][6][f]) requires that, at a minimum, public health assessments consider the following factors. This manual describes an approach to conducting public health assessments that incorporates each of them.

- *Nature and extent of contamination*—What is the spatial and temporal extent of site-related contamination? Have contaminants migrated off site? What media have been and/or continue to be affected (e.g., water, soil, air, food chain [biota])?
- *Demographics (population size and susceptibility)*—Who is being exposed, and do any special populations need to be considered (e.g., children, women of child-bearing age, fetuses, lactating women, the elderly)?
- *Pathways of human exposure (past, current, and future)*—How might people be exposed to site-related contamination (e.g., drinking water, breathing air, direct skin contact)? What are the site-specific exposure conditions (e.g., duration, frequency, and magnitude of exposure)?

- *Health effects and disease-related data*—How do expected site-specific exposure levels for the identified hazardous substances compare with the observed health effect levels (from toxicologic, epidemiologic, and medical studies), and with any available recommended exposure or tolerance limits (e.g, water quality standards)? How do existing morbidity and mortality data on diseases compare with observed levels of exposure?

2.1.3 How Does a Public Health Assessment Differ From a Risk Assessment?

ATSDR's public health assessments differ from the more quantitative risk assessments conducted by regulatory agencies, such as EPA. Both types of assessments attempt to address the potential human health effects of low-level environmental exposures, but they are approached differently and are used for different purposes. One needs to understand these differences to know how to interpret and integrate the information generated by each of these assessments.

- *The quantitative risk assessment* is used by regulators as part of site remedial investigations to determine the extent to which site remedial action (e.g., cleanup) is needed. The risk assessment provides a numeric estimate of theoretical risk or hazard, assuming no cleanup takes place. It focuses on current and potential future exposures and considers all contaminated media regardless if exposures are occurring or are likely to occur. By design, it generally uses standard (default) protective exposure assumptions when evaluating site risk.

- *The public health assessment* is used by ATSDR to identify possible harmful exposures and to recommend actions needed to protect public health. ATSDR considers the same environmental data as EPA, but focuses more closely on site-specific exposure conditions, specific community health concerns, and any available health outcome data to provide a more qualitative, less theoretical evaluation of possible public health hazards. It considers past exposures in addition to current and potential future exposures.

The general steps in the two processes are similar (e.g., data gathering, exposure assessment, toxicologic evaluation), but the public health assessment provides additional public health perspective by integrating site-specific exposure conditions with health effects data and specific community health concerns. ATSDR's public health assessment also evaluates health outcome data, when available, to identify whether rates of disease or death are elevated in a site community, especially if the community expresses concern about a particular outcome (e.g., cancer).

Remedial plans based on a quantitative risk assessment represent a prudent public health approach—that of prevention. By design, however, quantitative risk assessments used for regulatory purposes do not provide perspective on what the risk estimates mean in the context of the site community. The public health assessment does. The process is more exposure driven. The process identifies and explains whether exposures are truly likely to be harmful under site-specific conditions and recommends actions to reduce or prevent such exposures.

2.2 When Is a Public Health Assessment Conducted?

Three situations can trigger a public health assessment:

- *A site is proposed to be placed on the EPA National Priorities List (NPL).* ATSDR is required by law to conduct a public health assessment at all sites proposed for or listed on EPA's NPL.

- *ATSDR receives a "petition" to evaluate a site or release.* Both CERCLA, as amended by SARA, and the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous Solid Waste Amendments of 1984, allow individual and concerned parties (e.g., community members, physicians, state or federal agencies, or tribal governments) to petition ATSDR to conduct public health assessments. ATSDR has promulgated regulations describing the petitioned public health assessment process (42 Code of Federal Regulations, Part 90, published in 55 Federal Register 5136, February 13, 1990). After the initial information gathering, ATSDR decides whether a public health assessment should be conducted. Not every petition results in a public health assessment.

- *ATSDR receives a request from another agency.* State and federal regulatory agencies and state, local, and tribal health departments may request that ATSDR use its public health evaluation expertise to provide a technical consultation for a proposed or completed action. In these cases, ATSDR may be asked to evaluate data (e.g., a sampling plan, a remediation alternative) for the degree to which it is protective of public health. This type of evaluation is often conducted as an abbreviated public health assessment.

2.3 Who Conducts Public Health Assessments?

ATSDR staff and its government partners (i.e., state health departments, tribal governments, and other government organizations that have received funding through ATSDR's cooperative agreement program) are responsible for conducting public health assessments, for communicating the findings of their evaluations to the public, and for involving the community and responding to community health concerns. The process may require the coordination and cooperative efforts of ATSDR's Division of Health Assessment and Consultation (DHAC) with other offices and divisions within ATSDR; other local/county, state, and federal government agencies; tribes; and the community.

Early in the process, the team leader—generally you, the health assessor—establishes a team composed of individuals who contribute to the site-specific technical and communication needs of the site. Experience has shown that a team approach is very effective, especially at more complex sites. The mix of the team will depend on the nature and complexity of site issues and may change over the course of the assessment as more information becomes available. Team members may include scientists (e.g., engineers, environmental or public health scientists, geologists, toxicologists, epidemiologists, health physicists), communication specialists, health educators, and/or medical professionals.

Those who support the assessment will vary from site to site. Regional representatives from the agency's Division of Regional Operations should be included on site teams. The regional

representative is a vital link between ATSDR; federal, state, and tribal partners; and the community. For many sites, your team may require a health communication specialist to ensure that appropriate community involvement and outreach mechanisms are established. Where tribal issues are identified or if assistance is needed in identifying tribal concerns, ATSDR's Office of Tribal Affairs (OTA) will be contacted (see Appendix A for policies governing ATSDR's relationship with tribal governments and Section 4.2.3 for further information about OTA). When environmental justice concerns exist, the National Center for Environmental Health (NCEH)/ATSDR's Office of Director/Environmental Justice may become involved (see Section 4.2.4). In addition, activities and recommendations throughout the public health assessment process may require input and support from other NCEH/ATSDR offices or divisions, such as the Office of Communication, Division of Health Education and Promotion, the Division of Health Studies, and the Division of Toxicology. For some sites, ATSDR's Washington, D.C. office may need to be involved or kept informed. For ATSDR partners, many of the tasks often undertaken by separate divisions within ATSDR will be conducted by the health assessor and local team members.

Figure 2-1 illustrates the individuals and groups that may play a role in the public health assessment process.

2.4 What Is the Role of the Site Community?

Communities often play an important role in the public health assessment process. For a particular site, the community generally consists of people who live and work at or around the site. The community may include, for example, residents, site or facility personnel, members of local action groups, local officials, tribal members, health professionals, and local media.

Community members are a resource for and a primary audience and beneficiaries of the public health assessment process. They can provide important information and ideas that may prove valuable input to the public health assessment. For example, they can often supply site-specific information that might otherwise not be documented. As you conduct your assessment, community members may also want to know what the process involves, what they can and cannot expect, what conclusions you reach, and in general how ATSDR and the public health assessment process can help address their concerns. The relationship you build with the community through your public involvement and communication activities will influence how much community members trust you and thus, ultimately, how they react to your public health messages and recommendations. For all these reasons, effective involvement of and communication with the community is important throughout the public health assessment process.

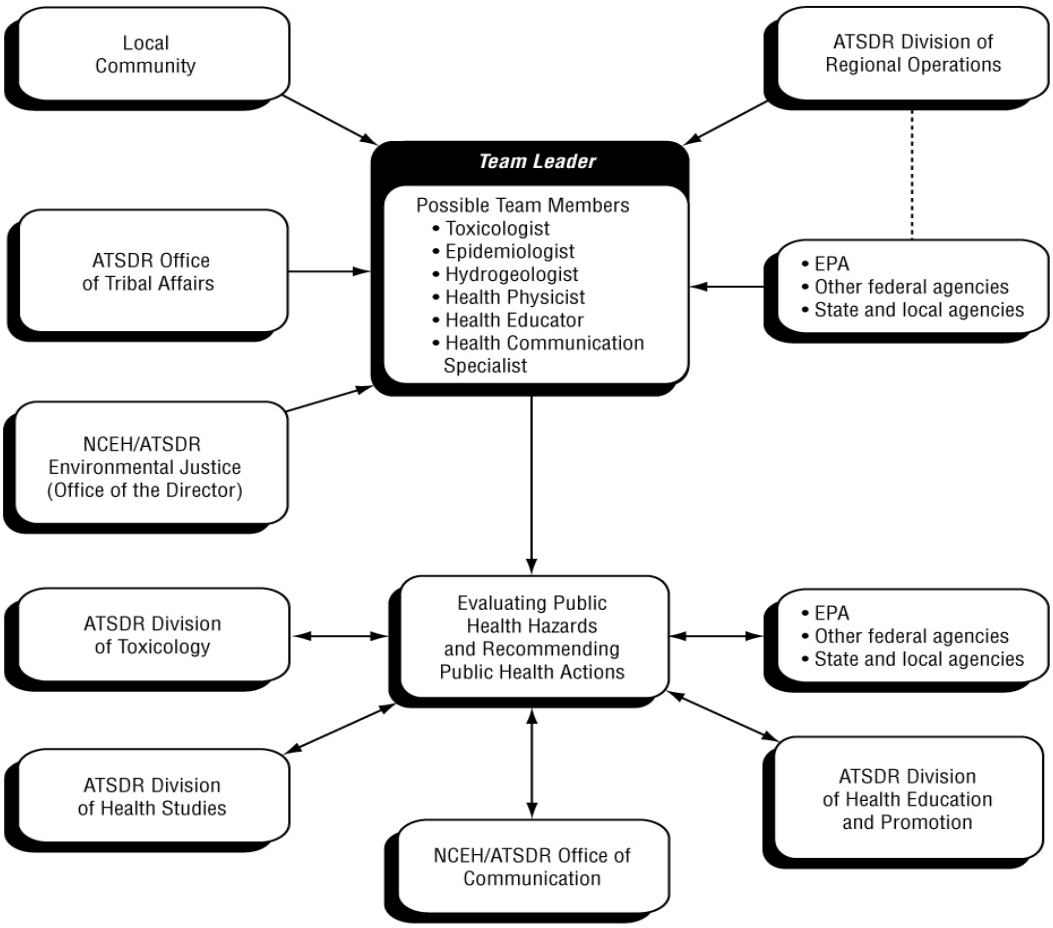


Figure 2-1. Types of NCEH/ATSDR Staff and External Partners That May Be Involved in Supporting a Public Health Assessment

Since 1990, ATSDR has embraced the philosophy of continuous improvement of and increased attention to its community involvement and health education efforts, which include identifying and reaching out to the concerned public; informing and educating; promoting interaction and dialogue; involving communities in planning, implementing, and decision-making; providing opportunity for comments and input; and collaborating in developing meaningful partnerships.

Chapter 4 provides guidance on how to plan for and conduct community involvement activities. By reading Chapter 4 before the subsequent chapters, which provide guidance on the technical aspects of the public health assessment process, you will be better able to incorporate public involvement and basic communication principles into all the activities you perform at a site.

2.5 How Is a Public Health Assessment Conducted?

The public health assessment process involves multiple steps, but consists of two primary technical components—the *exposure evaluation* and the *health effects evaluation.* These two components lead to making conclusions and recommendations and identifying specific and appropriate public health actions to prevent harmful exposures.

Integral to the entire process are effective fact finding and thorough scientific evaluation. Identifying and understanding the public health concerns of the site community—as well as involving and effectively communicating with the public—is another important component of the process. Good communication among ATSDR, other agencies, and the community is essential throughout the public health assessment process.

The exposure evaluation involves studying the environmental data and understanding if and under what conditions people might contact contaminated media (e.g., water, soil, air, food chain [biota]). The information compiled in the exposure evaluation is used to support the health effects evaluation, which includes a screening component, a more detailed analysis of site-specific exposure considerations and of the substance-specific information obtained from the toxicologic and epidemiologic literature. An additional consideration, although not always available, is an evaluation of health outcome data for the community of interest.

The specific steps in the process are summarized below and detailed in Chapters 3 through 9. Figure 2-2 maps out the overall public health assessment process.

The evaluation is an iterative, dynamic process that considers available data from varying perspectives. The process is not always linear. In reality, many activities may occur simultaneously and/or require repeated efforts. Further, because sites are different, not every aspect of the public health assessment process described in this manual will apply to all sites.

Another very important point to remember about the process is that public health assessment teams should not wait to complete the entire step-by-step assessment process before recommending an action to address a public health hazard. Instead, the team should immediately focus its efforts on the public health hazard, confer with all stakeholders, and coordinate and implement appropriate actions to minimize exposures and protect public health.

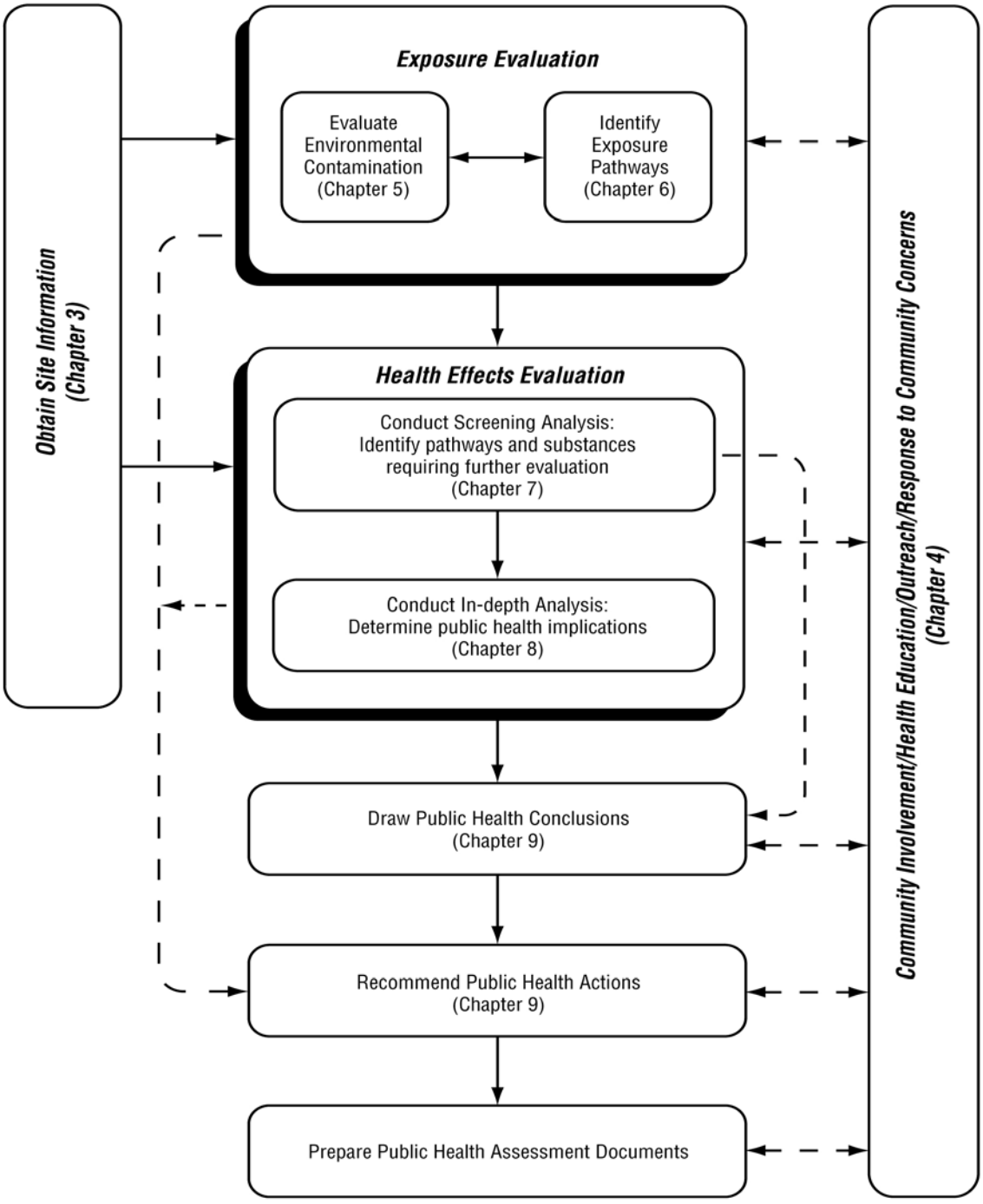


Figure 2-2. Overview of the Public Health Assessment Process

The public health assessment process often requires the consideration of multiple data sets. It is the health assessor's job to sort through this information and identify key information that will help determine whether people are being exposed to site-related contaminants at sufficient levels to result in adverse health effects. As you do so, you should identify data gaps and limitations, such as the need for further environmental sampling.

2.5.1 Getting Started

Once assigned a site to evaluate, your first step is to establish an overall understanding of the site and begin to identify the most pertinent issues. You need to quickly gain some baseline information about your site. Once you start to build an information base, you can start developing a strategy for conducting the public health assessment.

To help ensure a consistent approach across sites, the following steps should be followed:

- *Initiate site scoping*. Perform an initial review of site files and general sources of site information (e.g., summary reports, petition letters, media reports, EPA summaries on the Web). Identify any past ATSDR activities or activities conducted by ATSDR's partners. The ATSDR regional staff are an important contact for site information at this initial step. Initial scoping efforts will help you identify the type of environmental, exposure, and community health concern information you may need to pursue. Identify and communicate with site contacts (e.g., state agencies, tribal governments, facility representatives) to learn about site environmental conditions, the status of site investigations, and the involvement of other stakeholders.

  During site scoping you will also determine when to conduct the site visit. The site visit should be viewed as a prime opportunity for meeting with the local community and gathering pertinent site information, in addition to providing you with first-hand knowledge of current site conditions.

- *Define roles and responsibilities of team members (internal and external)*. Identify core team members as early as possible. As described in Section 2.3, the mix of the team and each member's responsibility will depend on site issues. Establishing the team early will foster better communications throughout the public health assessment process.

- *Establish communication mechanisms (internal and external)*. Establish government agency, tribal, site, community, and other stakeholder contacts early in the process. Develop a schedule for team meetings, start considering how to present the findings of your assessment, and develop health communication strategies. This requires understanding the information needs of your audience. Adequate communication with the local community is an important part of the public health assessment process. Therefore, a strategy to develop and maintain communication with the community should be developed early in the process.

- *Develop a site strategy*. As you move forward, be mindful of the various steps in the public health assessment process (see Figure 2-2) and develop a strategy for completing these tasks. Each of these steps are summarized in the sections below and detailed in subsequent chapters of this manual. During the planning stages, you will need to begin to identify the tools and resources that might be needed to evaluate the site, communicate your findings, and implement public health actions. Careful planning will provide a strong foundation for all subsequent activities.

  Based on information obtained during site scoping, develop an approach that focuses on the most pertinent public health issues. Identify site priorities both in terms of potential exposures and community health concerns. Establish aggressive but realistic time lines for the various components of your site-specific evaluation. Note that your strategy may change over time. Remember that the public health assessment process is iterative. The information you gain as you conduct your public health assessment may generate new information and perspectives that may prompt you to revise your strategy.

2.5.2 Collecting Needed Information

Throughout the public health assessment process, you and other site team members will collect information about the site. Figure 2-3 illustrates the type of information that supports the assessment.

Information gathering generally occurs throughout the public health assessment process, but the initial collection of information is typically the most intensive. In the early phases of information collection, described in detail in Chapter 3, you are building the foundation of site-specific information and data for the rest of your activities at the site. As mentioned above, you will be collecting information about community health concerns, exposure pathways, and environmental contamination, as well as identifying any site-specific health outcome data. Information sources typically include interviews (in-person or via telephone); site-specific investigation reports prepared by EPA, other federal agencies, and state, tribal, and local environmental and health departments; and site visits.

Gathering pertinent site information requires a series of iterative steps, including gaining a basic understanding of the site, identifying data needs and sources, conducting a site visit, communicating with community members and other stakeholders, critically reviewing site documentation, identifying data gaps, and compiling and organizing relevant data to support the assessment.

2.5.3 Exposure Evaluation: Evaluating Environmental Contamination Data

Critical to the public health assessment process is evaluating exposures. One component of this evaluation is understanding the nature and extent of environmental contamination at and around a site. During this step, described in detail in Chapter 5, you will evaluate the environmental contamination data obtained to determine what contaminants people may be exposed to and in what concentrations. As part of this evaluation, you will be assessing the quality and representativeness of available environmental monitoring data and determining exposure point

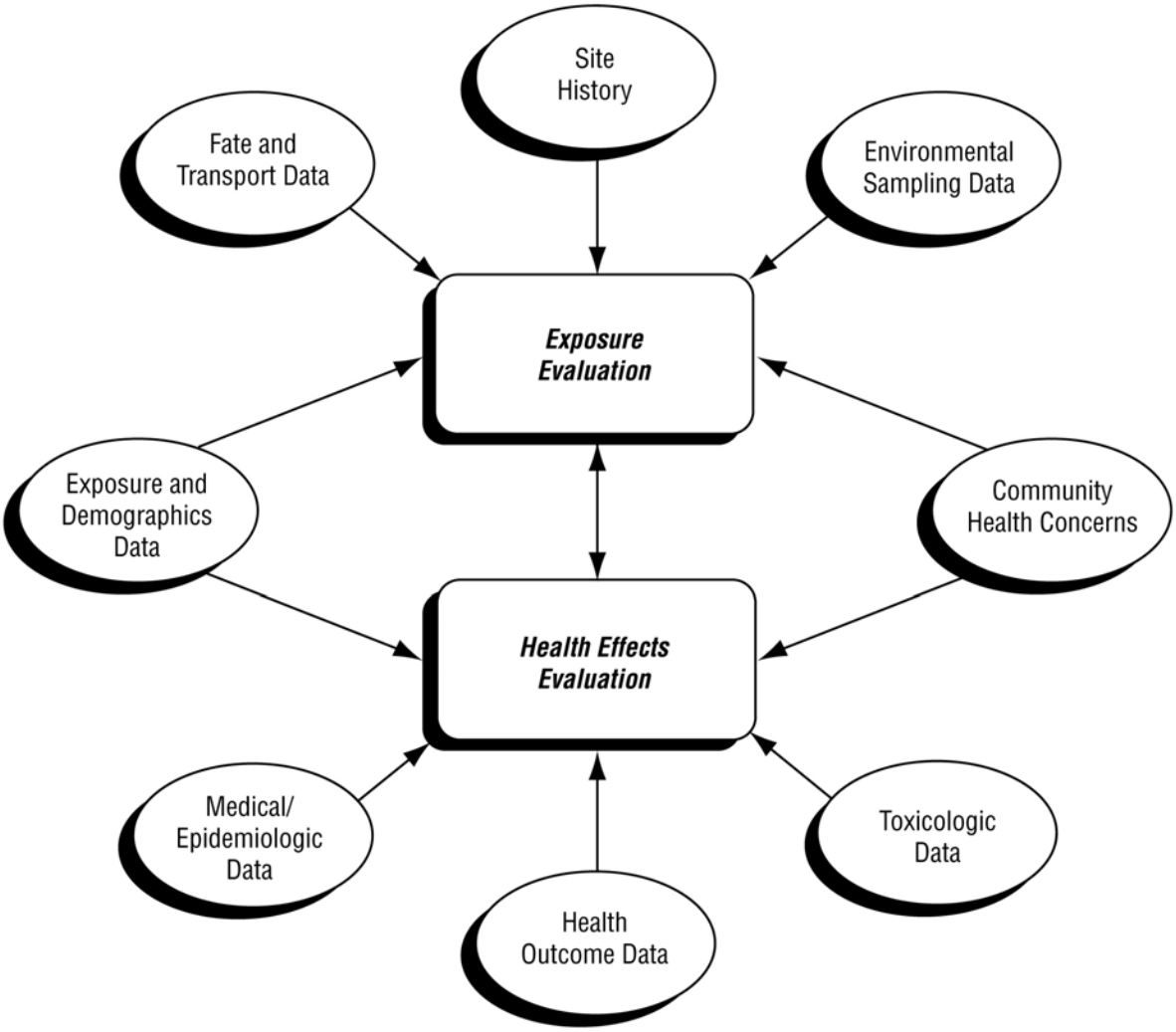


Figure 2-3. Information Needed To Evaluate Exposures and Health Effects

concentrations. This is an important way to ensure that any public health conclusions and recommendations for the site are based on appropriate and reliable data. In some cases, further environmental sampling may be recommended to fill a critical data gap. While sampling data are preferred for public health assessments, mathematical modeling techniques are sometimes used to estimate environmental concentrations either temporally or spatially (see Section 5.2). Evaluation of environmental contamination data typically proceeds simultaneously with the exposure pathway evaluation.

2.5.4 Exposure Evaluation: Identifying Exposure Pathways

During the exposure pathway evaluation, described in detail in Chapter 6, you will evaluate who may be or has been exposed to site contaminants, for how long, and under what conditions. You will consider past, current, and potential future exposure conditions. This involves identifying and studying the following five components of a "completed" exposure pathway:

- A *source* of contamination.
- A *release mechanism* into water, soil, air, food chain (biota) or transfer between media (i.e., the fate and transport of environmental contamination).
- An *exposure point or area* (e.g., drinking water well, residential yard).
- An *exposure route* (e.g., ingestion, dermal contact, inhalation).
- A *potentially exposed population* (e.g., residents, children, workers).

The overall purpose of this evaluation is to understand how people might become exposed to site contaminants (e.g., via drinking affected water or by coming in contact with contaminated soils) and to identify and characterize the size and susceptibility of the potentially exposed populations. If all of the elements described above are identified, a completed pathway exists. If one or more components are missing or uncertain, a potential exposure pathway may exist. For completed or potential exposure pathways, you will evaluate the magnitude, frequency, and duration of exposures.

As you evaluate exposure pathways, you should constantly remind yourself: *If no completed or potentially completed exposure pathways are identified, no public health hazards will exist.* If, as a result of your evaluation, you conclude there are no exposure pathways, then you will not need to perform further scientific evaluation. You will, however, need to explain your rationale for excluding each exposure pathway you deem incomplete and should communicate the conclusion of an incomplete pathway to the public at the earliest point possible. Additional community concerns not related to potential exposure pathways may be addressed in the community concerns section of the written public health assessment or the public health action plan (see Section 2.7).

When complete environmental or biologic data are lacking for a site, you may determine that an *exposure investigation* is needed to better assess possible impacts to public health. These exposure investigations, often conducted by ATSDR or cooperative agreement partners, may

include environmental sampling, measurements of current human exposure (e.g., biologic monitoring), and/or using a variety of fate and transport models linked with geographic information systems to estimate past (dose reconstruction) or predict future exposure concentrations. The results of an exposure investigation are used to support the public health assessment process.

2.5.5 Health Effects Evaluation: Conducting Screening Analyses

Screening is a first step in understanding whether the detected concentrations to which people may be exposed are harmful. The screening analysis, described in detail in Chapter 7, is a fairly standard process ATSDR has developed to help health assessors sort through the often large volumes of environmental data for a site. It enables you to safely rule out substances that are not at levels of health concern and to identify substances and pathways that need to be examined more closely. For completed or potential exposure pathways identified in the exposure pathway evaluation, the screening analysis may involve:

- Comparing media concentrations at points of exposure to health-based "screening" values (based on protective default exposure assumptions).

- Estimating exposure doses based on site-specific exposure conditions that you will then compare with health-based guidelines.

2.5.6 Health Effects Evaluation: Conducting In-Depth Analyses

For those pathways and substances that you identify in the screening analysis as requiring more careful consideration, you and site team members will examine a host of factors to help determine whether site-specific exposures are likely to result in illness and whether a public health response is needed. In this integrated approach, described in detail in Chapter 8, exposures are studied in conjunction with substance-specific toxicologic, medical, and epidemiologic data. Through this in-depth analysis, you will be answering the following question: *Based on available exposure, toxicologic, epidemiologic, medical, and site-specific health outcome data, are adverse health effects likely in the community?* You will be considering not only the potential health impacts on the general community, but also the impact of site-specific exposures to any uniquely vulnerable populations (e.g., children, the elderly, women of child-bearing age, fetuses, and lactating mothers) in the community.

2.5.7 Formulating Conclusions and Recommendations and Developing a Public Health Action Plan

Upon completing the exposure and health effects evaluations, you will draw conclusions regarding the degree of hazard posed by a site (described in detail in Chapter 9)—that is, you will conclude either that the site does not pose a public health hazard, that the site poses a public health hazard, or that insufficient data are available to determine whether any public health hazards exist. The process also involves assigning a "hazard conclusion category" for the site or for an individual exposure pathway. After drawing conclusions (which occurs throughout the public health assessment process), you will develop recommendations for actions, if any, to prevent harmful exposures, obtain more information, or conduct other public health actions. These actions will be detailed in a Public Health Action Plan, which will ultimately be part of the

public health assessment document (or possibly public health consultations) you develop for the site, as described in Section 2.6. Note that some public health actions may be recommended earlier in the process (see Section 2.6).

2.6 What Products and Actions Result From the Public Health Assessment Process?

2.6.1 Products

You may develop various materials during the public health assessment process to communicate information about the assessment. For example, the team may develop outreach materials, as described in Chapter 4, to communicate the status and findings of your assessment to the site community. If you identify imminent health hazards during the assessment process, you may issue a *health advisory* that alerts the public and appropriate officials to the existence of a public health threat and identifies measures/actions that should be taken immediately to eliminate the health threat (see Chapter 9 for more information about health advisories). Whether and when to produce these materials or advisories and in what format is up to the judgment of the site team and their management.

At the end of the assessment process, you will prepare a report that summarizes your approach, results, conclusions, and recommendations. This report may be either a *public health assessment document (PHA)* or a *public health consultation (PHC).*

- A PHA may be prepared to address various exposure situations and/or community health concerns. It may address multiple-chemical, multiple-pathway exposures or it may address a single exposure pathway. Regardless of the focus of the PHA, all of the CERCLA-required elements must be included in the PHA.

- A PHC is generally prepared to describe the findings of an assessment that focuses on one particular public health question (e.g., a specific exposure pathway, substance, health condition, or technical interpretation). For example: Will community members be harmed by drinking water from private wells around the site? Is a proposed site-specific sampling plan adequate to collect data to use in a public health evaluation? Such assessments often are more time critical, necessitating a more rapid and therefore limited response than assessments that result in a PHA. While some PHCs include a presentation of all the elements required in the PHA (i.e., a comprehensive exposure pathway and health effects evaluation), discussions are often limited to answering the question at hand.

A PHA is generally produced for all NPL sites. For petitioned sites, you may produce either a PHA or a PHC depending on site-specific issues and information needs. Sometimes, an assessment of a single issue at a petitioned site may evolve into a more multifaceted assessment that results in a PHA. Regardless of the document prepared, the overall assessment process, as described in this manual, is generally the same.

2.6.2 Public Health Actions

As stated earlier, during the public health assessment process, you will not only evaluate whether a site poses a public health hazard, but also identify public health actions. *Actions may be recommended at any appropriate point in the assessment process*. Some recommended actions may be initiated before the completion of the PHA, such as certain health education activities or efforts to obtain additional exposure data. Other actions may begin during the assessment process but end after the release of the PHA for a site (e.g., health studies or research). Community involvement continues to be important as you identify and communicate public health actions.

In its role as an advisory agency, ATSDR may recommend actions to be undertaken by ATSDR staff, and also actions that the agency feels are appropriate for EPA; other federal agencies; state, tribal, or local governments; the community; and others to undertake to protect public health from site hazards. Ideally, the site team works cooperatively when developing public health actions to judge the usefulness and feasibility of recommended actions.
Public health actions vary from site to site and may include:

- *Actions to reduce exposures.* If current harmful exposures are identified, removal or clean-up actions may be recommended. This will generally involve working with the appropriate federal, state, or tribal agencies.

- *Exposure investigations*. As part of your exposure evaluation, you may determine that critical exposure data are missing. In such cases, the site team may recommend environmental or biologic sampling to better define the extent, if any, of harmful exposures (see Section 6.7).

- *Health education.* Throughout the public health assessment process, you may identify the need for education within a community. For example, ATSDR's Division of Health Education and Promotion or the appropriate local health department may educate health professionals about special diagnostic techniques for possible site-related illnesses identified during the public health assessment process.

- *Health services*. Site conditions may identify the need for certain community health interventions, such as medical monitoring or psychological stress counseling. Referrals may be made to health care providers (e.g., community health centers or local health departments) when health services are needed that may improve the overall health of the community. ATSDR does not have the legal authority to provide medical care or treatment to people who have been exposed to hazardous substances, even if the exposure has made them ill. ATSDR works with health care agencies to address community health care needs.

- *Health studies/health surveillance.* Public health assessments are not epidemiologic or health studies. However, during the public health assessment process, you may identify an exposed population for whom a site-specific epidemiologic or health study should be considered (e.g., disease- and symptom-prevalence studies, cluster investigations). An epidemiologist should be involved with evaluating the need and feasibility of any such study. ATSDR's Division of Health Studies or comparable local agency should be involved in designing, implementing, and interpreting any such study.

- *Research.* Knowledge gaps that you identify concerning the toxicity of substances identified at a site or release under review may trigger substance-specific research, computational toxicology, or expanded efforts in developing ATSDR toxicological profiles.

2.7 What Is the Format for Public Health Assessment Documents?

This section describes the content and format guidelines for PHAs and PHCs. Communicating the findings of your assessment in an organized, clear, and concise way is equal in importance to conducting a scientifically sound evaluation. As you prepare a public health assessment document, you will make many choices about how to organize material within each section, how much detail to provide, whether to use a question-and-answer format in various sections, and so on.

While ATSDR has developed the minimum requirements presented below to ensure consistency and completeness, the agency encourages health assessors to remain flexible while fulfilling these requirements. You should use the most appropriate site-specific approach, based on the knowledge, expectations, and information needs of your audience. The suggested format provides a framework for documenting the findings of the public health assessment. Subsequent chapters provide more detail on the type of information that you may need to consider and include in each section of the document.

General PHA Format

Primary sections

- Summary
- Purpose and health issues
- Background
- Discussion[1]
- Community health concerns
- Conclusions
- Recommendations
- Public health action plan

Preparers of report
References

Tables
Figures

Appendices

- Additional background materials
- More in-depth technical discussions
- Glossary (including conclusion category summary)
- Response to public comments

[1]A separate discussion on child health considerations is required in all PHAs.

Generally, PHAs include the sections and appendices described below. Additional sections may be included as you judge appropriate if the information may be helpful in communicating the findings. The main body of the document should be long enough to fully address pertinent issues. Narratives should be concise and relevant to those issues.

The primary sections of a PHA are:

- *Summary*. In this section, you will summarize the most important conclusions and recommendations of the PHA. This section should be as simple, clear, and concise as possible, since it will be one of the most frequently read sections of the document. As appropriate, you may include a brief summary of previous public health evaluations of the site and/or a brief explanation of the planned future public health evaluations of the site. Do not include any technical information, conclusions, or recommendations that are not addressed in the main body of the document.

- *Purpose and Health Issues*. In this section, you should explain what the PHA will and will not discuss. This section focuses the discussion for the rest of the PHA by posing the question(s) that will be addressed in the PHA. This section may include a brief overview of the health concerns voiced by the site community, with reference to a later section in the PHA that addresses those concerns.

- *Background*. This section should contain all pertinent "factual" information and data needed to frame or lead into the Discussion section. Typically in this section, you will present the site description, site history, demographics, land use, and natural resource use as it relates to the issues presented in the *Purpose and Health Issues* section. Do not include any information not directly relevant to the issue(s) being discussed in the PHA (though you may place it in an appendix if you judge it important to make the information available to the reader).

- *Discussion.* In this section, report the findings of your exposure and health effects evaluations. Describe what is known (and not known) about environmental exposures to site-specific contaminants. Clearly describe site-specific exposure conditions (or how people may contact site contaminants). Then discuss how site-specific exposure levels compare with health-based screening levels; if screening levels are exceeded, then explain how site-specific exposure levels (and conditions) compare to levels shown to cause harm in relevant scientific studies. Describe how the integration of pertinent exposure and health effects data leads you to your overall conclusion—that is, explain/state whether site-specific conditions are likely to result in adverse health effects. This discussion should provide support for and help to justify the conclusions that you will present in the subsequent *Conclusions* section. You must also include a distinct subsection within the *Discussion* section that discusses child health issues.

  You can use different formats for the *Discussion* section depending on the site. In some cases, you may wish to discuss public health issues on an exposure pathway-by-pathway basis. In others, a question-and-answer format might work better. You may provide varying levels of technical detail as appropriate to the site, but, you should always strive to keep the text clear and simple and use appendices as appropriate to provide more detailed technical discussions. Also, you should use *tables, figures, and maps* whenever possible to facilitate the understanding of written text.

- *Community Health Concerns.* In this section, present answers to any health questions the public may have about the site. A question-and-answer format is often most appropriate. You can include the *Community Health Concerns* section either as a separate section in the PHA or as a subsection of the *Discussion* section, depending on which is most appropriate to the optimal logic and flow of the document.

- *Conclusions.* In this section, briefly present the conclusions of the public health assessment process. If you have reached more than one conclusion, you may want to present your conclusions as a list, starting with the conclusion(s) that directly address the issues presented in the *Purpose and Health Issues* section. Include a statement that assigns a hazard conclusion category (see Section 2.5.7 and Chapter 9) to the site, time period (e.g., past, current, or future), or exposure pathway, as appropriate. While you should not reiterate large portions of previous sections, you must support each conclusion with a brief but adequate discussion of available data and information. This summation should follow logically from the relevant portions of the *Discussion* section.

- *Recommendations.* In this section, you will describe recommendations that the site team has developed based on the conclusions reached about the site, as described in the *Conclusions* section. Generally, the most effective way to communicate recommendations is to organize them as a list and to begin each recommendation with an action word (e.g., provide, monitor, restrict, obtain, inform, etc.). Again, ATSDR makes public health recommendations; it does not make specific risk management decisions. Ideally, communication among ATSDR and parties responsible for implementing the recommendations will have been ongoing throughout the public health assessment process. Such communication will help identify actions needed to implement the recommendations.

- *Public Health Action Plan.* Every PHA must include a public health action plan (PHAP) indicating the specific actions that are warranted. The PHAP should present actions that have been completed as well as those that are ongoing or planned. Discussion with the entities (e.g., other agencies) who will ultimately be responsible for conducting specific actions is required ahead of time.

In addition to the main text of the document you must include the *preparers of the report*, *references*, and various *appendices*. While your text should be written as clearly and concisely as possible when relaying the findings of the assessment, the use of various technical terms will likely be unavoidable. You should, therefore, include a glossary of terms in all PHAs. The “plain language” glossary developed by ATSDR should be used as a starting point (see Appendix B). As mentioned, you will need to assign a conclusion category to your site and the exposure situations evaluated. A summary of the five ATSDR conclusion categories must be included in all PHAs, either as part of your glossary or as a stand-alone list.

For the final version of the PHA, you will have gathered public comments. An appendix will be dedicated to listing these comments and explain how the PHA responds them. The format and content of the appendix will depend on the number and nature of the comments you have received; the responses will be based on the judgment of the site team. For example, if comments

are few in number or represent unique issues, you will likely present each comment more or less verbatim. In other cases, you may choose to summarize like comments or edit comments to more succinctly present expressed concerns or questions. When doing so, be careful not to eliminate specific points made or question asked by the commenters. To facilitate your response and present it effectively, group comments by major theme or by section of the PHA (e.g., site history, groundwater issues, conclusions). In your responses, focus on addressing technical issues raised by commenters, explaining how and why ATSDR took a certain approach or drew a particular conclusion. If the comment points out an error or introduces new information, acknowledge any error, review any new data, and explain how ATSDR may have revised its assessment in light of that information. (Section 4.7.1.3 in Chapter 4 provides additional guidance in responding to public comments.)

Like the PHA, the PHC has certain minimum requirements as set forth by agency policy (May 27, 1995). The PHC should include, at a minimum, the following:

- Summary[1]
- Background/Statement of Issues
- Discussion
- Conclusions
- Recommendations
- PHAP, if applicable
- Response to Public Comments, if applicable
- References
- Appendices (as required)

In preparing PHAs and PHCs, your text should be written in as clear and understandable a way as possible. The box below contains a few tips for effective communication. Many of these tips are elaborated upon in subsequent chapters.

[1]A summary is optional in a PHC, but recommended when the PHC is lengthy or technically complex.

Communication Tips for Preparing PHAs and PHCs

- Tell the story
- Consider your audience(s).
- Be concise (do not include anything that does not add to the story).
- Use "plain" language where possible to describe the evaluation and conclusions.
- Use the active voice.
- Clearly communicate the following concepts:
    - — Public health assessments are exposure-driven. Remember, exposure must occur to allow the potential for adverse health effects.
    - — Simply being exposed to a hazardous substance does not make it a hazard—the magnitude, frequency, timing of exposure (e.g., pregnant female, fetal development), duration of the exposure, and the toxicity characteristics of individual substances affect the degree of hazard, if any.
- Think perspective. Put available environmental and health effects data in to meaningful perspective for the community.
- The language should not unnecessarily alarm the reader, nor should the health assessor downplay concerns/exposures.
- Write a simple summary that will capture key points and give bottom lines.
- Keep conclusions focused and be sure that recommendations parallel the conclusions.
- If information is unavailable and, as a result, no conclusions can be drawn, simply state this fact.
- Reference all statements of fact—make it clear what are judgments and opinions.

Chapter 3
Obtaining Site Information

This chapter describes the information needed to conduct a public health assessment and how to obtain that information. Gathering pertinent site information requires a series of iterative steps. The process involves gaining a basic understanding of the site; identifying data needs and sources; conducting a site visit; communicating with community members and other stakeholders; critically reviewing site documentation; identifying data gaps; and compiling and organizing relevant data to support the assessment.

Data are collected throughout the public health assessment process to respond to community concerns (Chapter 4), support the exposure assessment (Chapters 5 and 6) and health effects evaluation (Chapters 7 and 8), and, ultimately, to draw public health conclusions with appropriate recommendations to prevent any harmful exposures (Chapter 9).

Figure 3-1 illustrates the basic information-gathering process. The following subsections detail the key components of this process:

- What information is needed? (Section 3.1)
- How is information obtained? (Section 3.2)
- Identifying information gaps (Section 3.3)
- Documenting relevant information (Section 3.4)
- Recognizing confidentiality and privacy issues (Section 3.5)

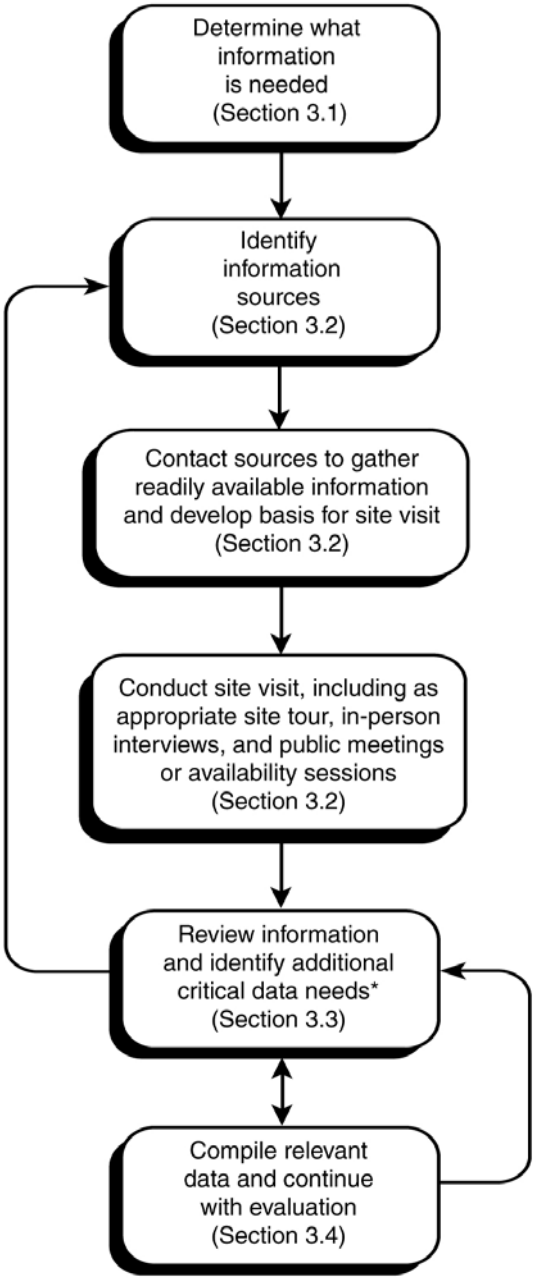
As information is obtained, you will need to sort through it to identify what is most relevant for conducting the public health assessment. Each new source or set of information will likely cause you to refine your information search. In addition, you will need to identify possible information gaps and determine mechanisms to fill critical information needs.

3.1 What Information Is Needed?

This section describes the basic types of information you will look at when conducting a public health assessment and why each is important. You will not be collecting all this information at once. Rather, specific information needs will evolve as you learn more about the site and identify the issues requiring further study.

In general, you will need the following information:

- Site background information (including site operations and history, relevant regulatory actions, area land use and natural resources, tribal resource uses, presence of a tribal reservation or tribal land, and demographics).



*Evaluation procedures are described in Chapter 5 (Environmental Data) and Chapter 6 (Exposure Pathways)

Figure 3-1. The Basic Iterative Information-Gathering Process for a Public Health Assessment

- Community health concerns (including the nature of the concerns and the population[s] affected) and other community-supplied information, such as surveys.

- Environmental contamination information (including chemical and radiological data, as well as documentation, where possible, on the quality and reliability of the data).

- Exposure pathway information (including information on how people come in contact with contamination).

- Substance-specific information (including chemical and physical) properties that may affect a substance's fate in the environment or within the human body).

- Health effects data (including toxicologic, epidemiologic, medical, and health outcome data).

These types of information will support the evaluations described in the remaining chapters of this guidance manual and will enable you to develop a *site conceptual model*—a model of how people may or may not be coming into contact with site-related contaminants. Though it is better to err on the side of collecting more information than will ultimately be deemed useful, you will need to use professional judgment to determine the information most relevant to the assessment. Only those facts necessary to evaluate exposures and health implications should ultimately be considered and presented in the written public health assessment. Each piece of information should be collected with the intent of helping you evaluate whether site-specific conditions may be associated with exposures and if identified exposures might be associated with adverse health effects.

Site-specific circumstances will drive the amount of information that may be available. At some sites, such as Superfund sites under remediation, much documentation will exist. At other sites, background information and environmental data may be very limited. The more specific your knowledge about the site and its potential hazards, the more accurate and definitive your conclusions will be.

The checklist in Figure 3-2 summarizes general information to be considered by the health assessor. Not all the information described in this checklist is necessary to perform every public health assessment. On the other hand, for some sites, additional information may be needed. However, this checklist serves as a good starting point and guide. Appendix C provides another checklist that may be helpful throughout the public health assessment process; this "community check list" was developed by the Community/Tribal Subcommittee of ATSDR's Board of Scientific Counselors and expands upon some of the basic data needs presented in Figure 3-2.

Sections 3.1.1 through 3.1.6 discuss, in more detail, the type of information that should be considered in the public health assessment process. Section 3.2 describes the primary sources of this information and how to obtain it.

Figure 3-2. Basic Data Needs for Conducting a Public Health Assessment

Background Information

Site Description

- Site name(s) and address.
- Site boundaries.
- Site maps–current and historical (e.g., site plans, aerial photographs, U.S. Geological Survey [USGS] maps, photographs that depict site conditions, areas of contamination, proximity to populated areas, and site use).
- Physical hazards.
- Contact person(s) (local/county, state, tribal, and federal).

Site Operations and History

- Current and past site-related activities (dates of operation, process description, significant events, and estimated number of people involved).
- Current and past hazardous waste treatment, storage, and disposal practices.
- Current and past site use (industrial, military or energy facility, landfill, surface impoundment).

Regulatory History and Activities

- Current CERCLA or RCRA status of the site.
- Site investigation results.
- Permit and compliance information.
- Site remedial activities (past, current, and future) and actions taken to address contaminant releases.
- Types of institutional controls planned or in place.

Land Use and Natural Resources Information

- Types of barriers or signs to prevent public access.
- Residential, commercial, and industrial land use on or near the site, including schools.
- Estimated frequency and types of recreational activities on or near the site (e.g., dirt biking, camping, hunting, fishing, and swimming).
- Children's play areas on or near site, both designated playgrounds and informal play areas.
- Planned and proposed future land use or development.
- Location and purveyors of public water supplies (groundwater and surface water, including number of users).
- Location of nearby private drinking water wells.
- Surface water uses downstream of the site.
- Drainage systems on and in the vicinity of the site.
- Agriculture, aquaculture, animal husbandry, hunting, fishing, and tribal activities near the site.

Demographic Information

- Types, sizes, locations, and levels of activities of populations residing on or near the site (worker, residential, recreational).
- Indicators of sensitive populations in the vicinity of the site (e.g., schools, nurseries, hospitals, retirement homes).
- Ethnic identity, age, gender distribution, and socioeconomic status of potentially affected populations.

Community Health Concerns and Information

- Records of health and environmental complaints by the public about the site (e.g., petition letters, public meetings, public availability sessions).
- Logs of actions taken by federal, state, or local agencies at or near the site in response to health concerns, complaints, or community issues.
- Information from the community, gathered during meetings or health studies.
- Environmental justice, tribal member concerns, or cultural issues.

Environmental Contamination Information

- Summary of current and historical sampling data for all media.
- List of substances analyzed for, tested for and not found (data gap analysis), and detected (by medium).
- Range of detected concentrations; date and location of maximum concentration.
- Sampling and analytical methods used, including detection limits.
- QA/QC documentation.

Exposure Pathway Information

- Contaminant sources (e.g., landfill, drums, spills, effluents, air emissions from operations).
- Description of physical barriers to prevent pollutant transport (e.g., pollution control equipment, liners, slurry walls, fences, dikes, point of entry treatment systems on drinking water supplies such as granulated activated carbon or reverse osmosis treatment systems).

Exposure Pathway Information (continued)

- ❑ Topography, geology and hydrogeology information.
- ❑ Description of upstream (surface water) or other nearby off-site activities that may contribute to contamination.
- ❑ Affected media, including groundwater, surface water, soil/sediment, air, and food chain (biota).
- ❑ Exposure point (e.g., drinking water supplies, residences, recreational areas, workplace).
- ❑ Exposure route (e.g., human activities that would result in ingestion, dermal, and/or inhalation exposures).

Health Outcome Data

- ❑ Relevant health outcome databases (e.g., morbidity/mortality data, cancer incidence, birth defects data).
- ❑ Any site-specific community health records and/or health studies.

Substance-Specific Information

- ❑ Information on chemical and physical properties of environmental contaminants of concern.
- ❑ Toxicologic and epidemiologic data.
- ❑ Biologic and physiologic data.

3.1.1 Background Information

Becoming familiar with the site, its setting, and its history is usually one of the first steps in the public health assessment process. Background information about the site is key to understanding the nature, magnitude, and extent of contamination. Background information also assists in identifying potentially exposed populations. This information will support detailed exposure evaluations to be conducted later in the assessment process.

The types of background information you will need include site description, site history and operations, regulatory history and activities, land use and natural resources information, and demographic information, as listed in Figure 3-2.

3.1.1.1 Site Description

Obtaining descriptive information about key geographic and other physical features of the site lays the initial foundation for understanding potential associated exposures. A site description may include the following components:

- The *site name and address or geographic location*, including its relationship to entities such as towns and cities, and information on climatic and geologic conditions (e.g., floodplains, locations of major surface water bodies).

- The *site boundaries*, including any fenced areas. This allows on- and off-site areas to be delineated.

- The *location of the site within the community*, including a map showing the distance from the site to the closest residence or potential future residence. This will provide insight about the population potentially affected by the site.

- *Visual representations* of the site, such as site plans, U.S. Geological Survey (USGS) quadrangle maps or other topographic maps, aerial photographs, and satellite images. Such visual tools may indicate the size of site operations, possible extent of surface contamination, conduits for and barriers to potential contaminant transport, and land use near the site, including distances to populations, schools, hospitals, and tribal lands near the site. If possible, collect global positioning system (GPS) data to support future site mapping.

- Any *physical hazards* (such as stacked drums, accessible chemical products, unexploded ordnance, pits, dams, dikes, and unsafe structures) at the site that may constitute a public health concern.

- *Contact information* (such as site representatives; local, state, tribal, and federal officials involved with site activities; community members).

3.1.1.2 Site Operations and History

Information about a site's current and past operations and historical development often indicates the types of contaminants that may be present, the possible extent of contamination, and the

possible magnitude of human exposure. Obtaining information on the following aspects of site operations and history may be useful:

- The *current and past activities* conducted at a site, including process descriptions and associated wastes generated. These activities indicate the potential contaminants of concern at the site.

- Current and past *hazardous waste treatment, storage, and disposal practices*. These practices provide information on the potential for releases of contaminants to the environment.

- *Dates of specific site operations*. These dates indicate periods during which contaminant releases may have occurred, potentially influencing the extent of contamination and contaminant migration.

- *Uses of the site* (past, current, and planned future, if different), including all areas where the public or workers may be or could have been exposed to contaminants. This site usage provides information about exposure potential.

- Any *significant events* in the site's history (such as changes in site size/boundaries, site ownership, and development of the site, or fires, explosions, and other non-routine events) that may affect the types, rates, and times of contaminant releases.

3.1.1.3 Regulatory History and Activities

Certain (but not all) information about a site's regulatory history may assist you in evaluating a site's public health implications. You may have to sort through many regulatory documents, focusing on information in them that is relevant to public health exposures. For example, a detailed understanding of a site's permitting history may not be directly relevant to understanding site exposures, but a general understanding of the operational processes and types of regulated emissions/effluents permitted at a site may allow you to relate certain environmental contaminants to site operations. In addition, permit applications may provide useful information if limited historical data end up being available. Those activities associated with environmental releases, site investigations, and remedial actions will be most pertinent. Listing the names of all the site owners, for example, is not necessary when documenting regulatory history in the PHA. However, knowledge of different owners will help you understand site activities and processes as you are reviewing the site history.

Information about a site's past, current, and future regulatory status that may contribute to your understanding of the site's potential hazards includes:

- Information on the current *Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)* or *Resource Conservation and Recovery Act (RCRA) status* of the site (e.g., is the site on EPA's National Priorities List [NPL], and why?).

- *Results of any site investigations* that have been conducted.

- Types of *permits* (air, water discharge, hazardous waste) held and *compliance information and monitoring data* available for the site.

- *Actions taken* by EPA, state agencies, or site operators to address contaminant releases from the site.

- *Remedial activities and other risk management strategies* implemented, planned, or proposed (including past, current, and future monitoring practices and/or institutional controls).

3.1.1.4 Land Use and Natural Resources Information

A review of land use and natural resources at and near a site provides valuable information about the types and frequency of the surrounding population's activities and the probability for human exposure. Land use in the area can affect the degree of contact with contaminated soil, water, air, waste materials, plants, and animals. (Guidance for evaluating site-specific exposures is provided in Chapter 5). Further, you will need information about past, current, and planned or proposed future land use to evaluate how site conditions and exposure scenarios may have changed or may change over time. Photographs (including aerial photographs) and maps indicating site conditions, proximity to populated areas, and area land uses are often helpful tools.

The following specific information may be useful:

- *Site accessibility* (including the presence, integrity, and suitability of warning signs, fences, gates, and other security measures, as well as any physical signs that people or animals have gained access to the site).

- *Residential, commercial, and industrial land use* on or near the site and the *types and levels of activities* (residential, recreational, and occupational) of potentially exposed populations. (Different types of activities can affect whether people are exposed and the frequency and duration of exposure).

- *Schools* (including daycare operations; elementary, middle, and high schools; children's athletic or recreational facilities).

- *Other nearby industrial sites*, including any CERCLA or RCRA sites, that may contribute to contamination and/or exposure.

- *Waste and disposal sites* such as landfills, surface impoundments and smaller sources of contamination (e.g., junk yards, gas stations, etc.) that do not necessarily represent industrial sites but can still contribute to contamination and/or exposure.

- *Recreational uses* of the site (such as dirt biking, camping, fishing, and hunting) and areas around or near the site (such as parks, playgrounds, and beaches).

- Planned or proposed *future use* of the site and proposed land transfers.

- *Locations of public and private water supplies*—including groundwater wells or surface water intakes (particularly hydraulically downgradient or downstream of the site) used on-site or off-site for drinking water, agriculture, or commercial purposes—and their distances from the site.

- *Surface water use* (e.g., swimming areas, boating areas, and commercial, sport, or subsistence fishing).

- Locations of any *drainage systems* (e.g., springs, creeks, drainage ditches) that may be conduits for contamination.

- Nearby *agricultural areas* (e.g., crops, orchards, gardens, feedlots, pastures, dairy farms, bee hives) and the market/consumption patterns for these foods (home, local, regional, commercial, or subsistence).

- *Biota* (plants and animals) potentially affected by the site (such as fish and game) and patterns of human consumption of these biota (e.g., tribal populations preparing and using food in traditional ways may experience increased exposure to contamination).

3.1.1.5 Demographic Information

Demographic information helps identify and define the size, characteristics, locations (distance and direction), and possible susceptibility of known populations related to the site. Demographic information alone does not define exposure. However, since demographic data sets do provide information on *potentially* exposed populations, they can provide important information for determining site-specific exposure pathways. Keep in mind that demographic data may be dated (e.g., the national census is conducted once every 10 years) and thus may not accurately reflect more recent changes in the numbers and/or types of populations in an area. Population estimates for certain areas may be available between census years, but the source and applicability of intercensal or postcensal data need to be reviewed prior to use.

The following demographic information should be collected:

- A description of *residential populations* residing near or on the site, as well as people who may be exposed at nearby businesses, schools, and recreational areas.

- The *location and distance* from the site or contaminated areas to nearby residents and the *size* of the population within a specific radius of the site.

- Information on *age, gender distribution, ethnicity, and socioeconomic status* in the potentially affected community to assist in identifying susceptible or particularly vulnerable populations and assist in interpreting relevant health outcome data.

- Information on the *stability* or *transient nature* of the population (e.g., length of residency, age changes, etc.) which may require looking at older censuses/ demographics for past periods.

As a baseline, you should summarize the demographic information for the area within a default 1-mile radius around the site boundaries. Other distances may be more appropriate or applicable depending on site-specifics (e.g., where air dispersion of contaminants is the main issue at the site, wind patterns might be such that your radius should be smaller or larger than 1-mile, or, if surface water contamination is a concern and an area is particularly flat or sloped, your radius could change). More specific temporal and spatial descriptions should be collected whenever possible for likely exposure scenarios.

Section 3.2 and the resource list at the end of the chapter provide detailed information on how and where to obtain pertinent demographic data.

3.1.2 Community Health Concerns

Understanding community health concerns related to a site or environmental release is an important component of the public health assessment process and ATSDR's overall mission. Community health concerns, therefore, need to be investigated and understood to the greatest extent practical. It is important to gather this information early in the process.

The nature and degree of community concerns will vary from site to site. For example, at some sites residents may express great concern about excess cancers in their neighborhood; at other sites residents may simply be looking for assurances that site-related contamination is not affecting them.

Types of information to gather include:

- Records of *environmental and health complaints* made by the public, including documentation of when these concerns were voiced. Focus on obtaining information related to potential site-specific impacts on people's health or well-being.

- Information about *actions taken* by federal, state, or local agencies (such as health departments), and responsible parties in response to health concerns, complaints, or issues.

- Health and other information obtained through *individual and community meetings* or through *community health studies*.

- Information obtained on local *environmental justice, tribal member concerns, or community interest groups* and issues that may reflect unique cultural concerns.

- History of government involvement and community response to past involvement.

- Community expectations for ATSDR involvement.

Once you have identified a community health concern, try to determine how many people share the concern (by determining the frequency and number of complaints received by a local health department or community group, for example).

One of the primary means of gathering this information is through communications with the community during site visits (as discussed in Section 3.2.5 and Chapter 4). Methods for identifying and responding to community concerns, such as holding public meetings and responding to community concerns in PHAs and PHCs, are detailed in Chapter 4.

In addition to public health concerns, community members are usually good sources of information about human activities on or near the site, such as children's play areas, locations along streams frequented by children and fisherman, locations of local "swimming holes," etc. Community members can often provide some historic information about sites that are not captured in government reports, such as frequency of flooding events when unplanned contaminant releases may have occurred (see example in box below) or frequency of site fires.

Example of the Value of Interviewing Community Members

During review of historical environmental data at a closed landfill site, a health assessor noted elevated (above background) levels of cadmium, lead, and other metals in a small pond across the road from the site. The pond had no known drainage connection to the landfill. In interviewing residents living adjacent to the landfill, the health assessor learned of the effects of heavy rainfall on the storm water flow pattern from the site during the landfill operating period. According to residents, during high rainfall events, storm water would flow from the landfill, across their yards, across the road, and into the pond. Residents reported storm water depositing mud and other debris in their yards and the street. As a result of this information, the health assessor recommended surface soil sampling of the affected residential yards, connected the contamination of the pond to the landfill, and identified an exposure point that might not have otherwise been evaluated.

3.1.3 Environmental Contamination Information

Environmental contamination data enable you to evaluate the nature and extent of environmental contamination and the magnitude of potential exposures. Environmental contamination data will provide you with the information needed to answer questions about: to what contaminants people might be/have been exposed; when and for how long people might be/have been exposed to the contaminants of concern; the likelihood of exposure to different levels of contaminants; and how reliable the data are on which you will base your conclusions. This information will be used with exposure and toxicologic data to evaluate possible health implications of exposures. Efforts should focus on obtaining as extensive a data set as possible for those media for which past, current, or potential future exposures exist.

The following type of information should be obtained for each contaminated medium (i.e., groundwater, soil, surface water, sediment, air, and/or food chain [biota]):

- The *specific substances identified* at and near the site (on-site and off-site sampling data).
- The *concentrations* of the substances found, including naturally occurring background conditions (e.g., metals in soil).
- The *location* and *sample depth* (i.e., 3-dimensional location) where the substances were found (including maps, where possible).
- The *dates* when the samples were collected.
- *Sampling collection and analysis methods* used, including detection limits.
- *Field measurements*, such as conductivity and field pH (as opposed to laboratory pH, field pH measurements of monitoring wells and water supply wells often yield important information on how representative and useful the particular water sample at a given location may be).
- *Quality assurance/quality control (QA/QC) data*, to ensure that the resulting data are adequate for assessing possible human exposures (i.e., that the data are of sufficient quality and are representative of area contamination). More extensive information on desirable QA/QC procedures is presented in Chapter 5.

Table 3-1 provides an overview of the key information on environmental contamination that you should gather. ATSDR's guidance manual entitled *Environmental Data Needed for Public Health Assessments* (ATSDR 1994) provides more in-depth guidance on specific data needs. If necessary information is not available, you should take into account any assumptions you end up making in your evaluation, and will need to qualify your evaluation as appropriate when presenting it in the PHA.

Table 3-1. Contamination Information Needed by Environmental Medium*

Environmental Medium	Type of Information To Collect
Groundwater	• Locations and descriptions of any known or suspected sources of groundwater contamination. • Location, depth, and use of known and potentially contaminated wells. • Substances and concentrations detected in site monitoring wells, in water supply wells, and at tap water sources, if available. • Vertical and lateral extent of the contaminant plume (if known) and of any leachate (if present and known). • Location of liners or slurry walls (e.g., for landfills), if any. • Background conditions.

Table 3-1. Contamination Information Needed by Environmental Medium*

Environmental Medium	Type of Information To Collect
Surface water/sediment	• Substances and concentrations identified. • *Surface water:* Surface water sample results at the site and from upstream and downstream of the site. • Locations of National Pollutant Discharge Elimination System (NPDES) effluents from the site. • Locations of any dikes present. • *Sediment*: Sampling results of stream channel, impoundment, drainage ditches, streams, and/or dredged sediments (if present). • Background conditions.
Soil	• Substances and concentrations identified. • Contaminant concentrations before and after any removal or remedial actions. • Separate sample results for surface (ideally top 3 inches, though EPA methodology defines surface soil as 0-12 inches) and subsurface soils. • Depth of samples. • Sample type(s) (e.g., grab vs. composite). • Background conditions.
Air (ambient, stack, soil gas, indoor air, and dust)	• Substances and concentrations identified from sampling results of air releases on site (production processes, stack emissions, monitoring stations, and soil gas, including buried utility lines) and off-site monitoring (including indoor air, if any). • Results of air modeling (if performed) of on-site air releases to potential off-site air exposure points and deposition areas, and of on-site stack and/or fugitive emissions. • Measurements of any flammable and explosive gases. • Gas pressure measurements. • Stack testing or trial burn results (if any). • Air permits held. • Background, local, and (if possible) site-specific meteorologic conditions. • Descriptions of other potential contaminants found indoors (e.g., stored chemicals or solvents, cleaners, lead paint, tobacco smoke).
Food chain (biota)	• Substances and concentrations identified from sampling results for edible portions of plants and/or animals on-site and/or off-site. • Information from local fish advisories such as prohibition of eating certain fish because of known contaminant concentrations.
Physical hazards	• Information about the existence or lack of barriers to the site, such as fences, gates, or warning signs. • Descriptions of any existing confined spaces, industrial equipment, electric hazards, open pits, sinkholes, stored materials, unexploded ordnance or other explosive hazards, and/or wires/ropes/chains. • Known or suspected presence of methane or other flammable gases at the site.
Radiologic parameters	• Radionuclides identified and their concentrations (from field and laboratory measurements). • Smear (removable surface radiation), air, soil, water, gamma radiation data, and radon sampling results (if any).

Source: ATSDR 1994.

*Chapters 5 and 6 discuss how this information is used in the public health assessment process.

In some cases, estimated or calculated environmental data obtained from models may be the only available information (e.g., air concentrations estimated from air dispersion models). Although environmental measurements (sampling data) are always preferred to estimated and calculated numbers (modeled data), modeling data should be examined if they provide additional perspective on site-related conditions. In such cases, you should obtain information about the assumptions used in and uncertainties of the model as well as information about the quality of any computer models used. Chapter 5 discusses how environmental and modeled data are evaluated in the public health assessment process and where and how this information is presented in the PHA.

Environmental data may be available in many different forms (e.g., laboratory reports, summary tables, CD-ROMs, microfiche, or databases). Obtaining environmental sampling data electronically can save you much time because you can often analyze the electronic data in spreadsheets, import the data into geographic information system (GIS) formats, and so on without having to manually enter the data. Such data are often available from EPA and other government agencies or their contractors, or site owners and their contractors.

3.1.4 Exposure Pathway Information

Because adverse health impacts can only occur if people are exposed to contaminants, much of the information you seek should ultimately address some aspect of an exposure assessment, such as contamination sources, contaminant fate and transport, affected environmental media (i.e., water, soil, air, food chain [biota]), exposure points, exposure routes, and potentially exposed populations—elements of a completed exposure pathway. Much of the information about sources, affected media, and exposure points and populations can be gathered through the review of site background information discussed above. However, exposure routes (how contaminants get from a source to a potentially exposed population) are influenced, if not dictated, by the fate and transport of contaminants in the environment. Additional site-specific information that you may need to evaluate contaminant fate and transport includes local geologic, topographic, and climatic conditions. (Methods for evaluating exposure pathway information are detailed in Chapter 6.)

Fate- and transport-related information varies somewhat from one medium to another and may include the following.

- *Topography*, the relative steepness of slopes and elevation of the site, may affect the direction and rate of water runoff, rate of soil erosion, and potential for flooding.

- *Soil types and locations* (e.g., sandy, organic) influence percolation, groundwater recharge, contaminant release, and transport rates.

- *Ground cover/vegetation* of the site greatly influences the rates of rainwater infiltration and evaporation and soil erosion, as well as the accessibility of contaminants to people.

- *Local climate conditions*, such as annual precipitation, affect the amount of moisture contained in the soil and the amount of percolation, as well as the water runoff and

groundwater recharge rates. Temperature conditions affect rates of contaminant volatilization and the frequency of outdoor human activity.

- *Meteorologic* factors, such as wind speed, may influence dispersion and volatilization of airborne contaminants and soil erosion rates.

- *Groundwater hydrology* (e.g., depth, direction, and type of flow) and geologic composition affect the direction and extent of contaminant transport in groundwater.

- *Locations of surface-water bodies* and planned and unplanned use of those water bodies may significantly affect the migration of contaminants off the site and into other media.

- Frequency of *flooding* events may significantly affect the migration of contaminants off the site and into other media (see the box in Section 3.1.2).

Table 3-2 lists the types of contaminant transport information you may need to collect for each environmental medium.

3.1.5 Health Outcome Data

Health outcome data can provide information on various aspects of the health of people living on or near a site. It may reveal whether people living or working near a site are experiencing adverse health effects at a rate higher than would be expected to occur. Health outcome data can constitute a key source of information for conducting public health assessments. However, site-specific health outcome data are rarely available or of sufficient quality to enable you to link health outcomes with site-related exposures. Whether you should evaluate health outcome data depends on a number of factors. The criteria for deciding whether and what health outcome data should be obtained are discussed in Chapter 8.

Health outcome data that may be obtained can include:

- Morbidity data (e.g., incidence of cancer, birth defects, or other diseases from state or county disease registries).

- Mortality data (e.g., death certificates).

- Disease information from community health records, healthcare provider agencies, and individuals (e.g., community health centers, private physicians).

- Health statistics from community health studies.

Table 3-2. Site-Specific Information That May Be Needed To Evaluate Contaminant Fate and Transport*

Environmental Medium	Type of Information
Groundwater	• Hydrogeology (e.g., types of aquifers and soils/sediments/bedrock, hydraulic conductivity). • Geochemistry. • Precipitation, infiltration rates. • Recharge sources, discharge areas, influent and discharge streams/seeps. • Groundwater flow direction, depth to aquifer, aquifer thickness. • Well location. • Groundwater uses.
Surface water/sediment	• Precipitation, temperature. • Influent and discharge streams. • Point and nonpoint source discharge areas. • Stormwater drainage system locations. • Surface water uses. • Soil and sediment type(s), permeability, particle size. • Floodplains.
Soil	• Physical and chemical properties of soil (e.g., soil type, organic content, permeability, pH). • Topography (as it affects soil erosion/runoff, e.g., slope). • Vegetative cover. • Precipitation. • Site activities.
Air	• Topography (valleys, hills). • Predominant wind direction and speed. • Precipitation, temperature. • Existing air pollution conditions.
Food chain/biota (plants, animals)	• Plant and animal species consumed. • Soil type (e.g., as it affects plant uptake). • Wildlife migration patterns. • Feeding habits of wildlife/livestock.
Waste materials (e.g., exposed wastes, liquids, drums, mine tailings)	• Waste type. • Approximate time waste materials have remained on site. Climate (can affect waste degradation).

*Chapter 5 describes when this type of information may be needed and how it is used in the public health assessment process.

When examining health outcome data, it is important to also obtain information about the source and type of information, relevance to the populations of concern at the site, and a possible contact person for each study, in addition to the study findings. Remember, health outcome data will not prove cause and effect. Cause and effect may be addressed through long-range epidemiologic studies.

In consultation with an epidemiologist, you need to determine the extent to which health outcome data can help support or refute public health conclusions (see Chapter 8). Health outcome data may point to the need for additional, focused environmental or health effects data collection, as in an exposure investigation.

3.1.6 Substance-Specific Information

The need for information on specific substances may be identified as you move through the public health assessment process. Once you have reviewed the site-specific information and gained an understanding of what hazardous substances are present and of potential concern, you may seek information on substance-specific properties to support your exposure pathway analysis and health effects evaluations.

Specifically, you may need the following:

- General information on the chemical and physical properties of environmental contaminants within the media of concern.
- Substance-specific toxicologic and epidemiologic data.
- General substance-specific biologic and physiologic data.

With the support of toxicologists, epidemiologists, hydrologists, and/or other specialists on your team, this information will help you more fully evaluate the nature and extent of contamination and the likelihood of adverse health effects. The specific type and sources of these types of data are detailed in Chapters 6 and 8. ATSDR's Toxicological Profiles can provide much of this information and are therefore a good starting point.

3.2 How Is Information Obtained?

ATSDR relies largely on information and environmental data already collected as part of regulatory investigations in its public health assessments. Information sources include government agencies, on-line resources, the community, and site owners and responsible parties, as discussed below.

Once you gain a basic understanding of the site, its history, regulatory status, and environmental health issues, you will need to identify and communicate with site-specific contacts in an effort to obtain data to conduct a public health evaluation.

Primary sources or mechanisms through which site-specific information can be obtained include:

- Health and environmental agencies.
- Internet resources (e.g., for background information, maps, demographic data, health outcome data, published literature).
- Community members and other stakeholders (e.g., petitioners, nearby residents, community groups or tribal members).
- Site owners and "potentially responsible parties" (PRPs), including their contractors.
- Site visit (e.g., for visual observations and personal communications).

The site visit, typically conducted early in the public health assessment process, should be viewed as a prime opportunity for meeting with the local community and gathering pertinent site information (see Section 3.2.5).

3.2.1 Government Agencies

Government agency staff and documents are a primary source of site-related information and other materials that may support the public health assessment process. This includes federal, state, local, and tribal agencies that regulate site operations and oversee or conduct environmental or health investigations or monitoring. Governmental organizations that maintain databases of relevant environmental or health data also may be a good primary source of information.

These agencies also may assist in other ways, such as identifying local contacts (including additional stakeholders and elected or appointed officials), participating in site visits, reviewing draft documents, posting notices of public meetings to be held, providing information on community networks, and sharing mailing lists.

For example, EPA oversees many hazardous waste sites, including NPL and RCRA sites. In such cases, the EPA Remedial Project Manager, On Scene Coordinator (for sites in the removal program), and community relations staff can be a valuable resource for:

- Providing site background and status information.
- Providing the site's Administrative Record, which contains a listing of all site-related documents.
- Identifying community contacts and existing information distribution channels.
- Developing a plan for joint public meetings and communication mechanisms.
- Responding to community requests for information.
- Minimizing the release of conflicting information to the public. When multiple agencies are involved, the agencies should communicate with each other to help ensure that information released to the public from different agencies does not conflict or cause confusion.

Similar information may be available from state agencies involved with a site.

Table 3-3 lists various agencies and the types of site information they may be able to provide. Table 3-4 lists some of the types of documentation that may contain relevant data for the public health assessment which are available through government agencies.

Table 3-3. Information Available Through Government Agencies

Agency	Possible Information
Federal Agencies:	
ATSDR Regional Representatives	ATSDR and EPA site files; names of state, local, and tribal contacts.
EPA Superfund/CERCLA Program	Site history; community concerns and community involvement activities; environmental monitoring data; any remedial activities; contact names for other agencies and possibly community members.
EPA RCRA Program	Site history; RCRA permit information; community concerns and community involvement activities; environmental monitoring data; any remedial or corrective actions; contact names for other agencies and possibly community members.
U.S. Department of Energy (DOE) U.S. Department of Defense (DOD)	Site history; environmental monitoring data; restoration program activities; cleanup schedules; future land uses.
Indian Health Service (IHS)	Tribal concerns/IHS environmental health programs in the site area.
Tribal governments	Specific tribal concerns related to the site.
Fish and Wildlife Service	Natural resource uses and possibly food chain (biota) concerns.
National Oceanic and Atmospheric Administration (NOAA)	Climatic information (e.g., wind direction, rainfall).
Soil Conservation Service (SCS)	Soil information (e.g., soil types, erosion); regional agricultural pesticide use.
U.S. Department of Agriculture	Soil information; regional agricultural practices.
U.S. Geological Survey (USGS)	Geologic and hydrologic information (e.g., contour maps, well locations, topographic maps).
U.S. Department of Commerce	Maps and census data for the area around the site (available as Summary Tape Files or Internet).
State Agencies:	
Health Department	Reported health concerns; health outcome data; public meeting records; names of local contacts.
Environmental	Reported contaminant releases; environmental monitoring data; specific concerns at and near the site; information on ongoing/planned remedial actions.
Emergency response	Reported historic or chronic releases from the site and surrounding industries.
Local and County Agencies:	
Health department, hospitals, clinics	Health concerns or complaints; available disease/cancer registries or disease clusters in the area.
Water department	Location and depth of municipal supply wells (current and historical); compliance monitoring results; private well location and use; location of surface water intakes; types of treatment systems in place, currently and historically.
Library	City directories with names and addresses of residents who live or may live near a site; collections of historical information about a site/company, especially if the company was a major employer in the area. Also, libraries often serve as information repositories for site investigation reports, etc.

Table 3-3. Information Available Through Government Agencies

Agency	Possible Information
Planners	Demographic information; past, present, future development.
Environmental	Contamination concerns or complaints; environmental monitoring data.
Local game wardens	Fishing and hunting activities.
Extension services	Information on local soil conditions, plants.

Table 3-4. Useful Government Sources of Information

- Administrative Record
- EPA's National Priorities List (NPL) Site "Scoring" Package
- Preliminary Assessment/Site Inspection
- Remedial Investigation/Feasibility Study (RI/FS) or RCRA Facility Investigation (RFI)
- Record of Decision (ROD)
- Human Health Risk Assessment
- Community Involvement/Relations Plan
- Fact Sheets
- Pesticide Management Plans
- Food Consumption Surveys
- Environmental Monitoring Data
- Toxics Release Inventory (TRI) [1]
- Aerometric Information Retrieval System (AIRS)
- Water Supply Data
- Well Drilling Logs for Private or Public Water Supplies
- Geology/Hydrology Studies (USGS)
- Soil Surveys (Soil Conservation Service)
- Meteorological Data (NOAA)
- Fish/Shellfish/Wildlife Studies or Advisories
- Local Health Studies
- Wellhead Protection Plans

[1] TRI can sometimes provide supplemental information about contamination found in on- or off-site environmental media and may suggest additional sampling needs, though there are limitations to its usefulness. TRI includes information on: the annual amount of estimated releases of more than 300 selected toxic chemicals into the environment (reported by air, water, and land) by specific facilities; the types of chemicals that each listed company manufactures, processes, or otherwise uses; and the amounts of chemicals stored on site and/or transferred to waste sites. Several limitations of TRI data should be noted, including: reported releases are only estimates provided by facilities to EPA; data are reported on a volume basis and do not reflect concentrations of chemicals in environmental media; chemical releases are reported only since 1987 (when TRI was initiated); only certain chemicals are included; and only certain facilities (manufacturing and federal facilities with more than 10 full-time employees) are required to report releases to the TRI.

3.2.2 Internet Resources

Internet resources may be particularly helpful in the early stages of the information collection process. Information often can be obtained more easily and quickly from the Internet than from traditional sources. Examples of available Internet information include Superfund site summaries, databases (e.g., census data and EPA's Toxics Release Inventory), and site maps. A more extensive listing of Internet resources is provided at the end of this chapter.

Keep in mind that anyone can post information on the Web, and that not all posted information is reliable. Therefore, be sure to pay close attention to the sources of all information obtained from the Internet, as well as all other sources, and assess their reliability.

3.2.3 Community Members and Other Stakeholders

The community associated with a site can be broadly defined as the population living on and around the site. Community members and community-based organizations are excellent sources of information about the site and about community health concerns (including site-specific issues, the nature of the concerns, local behavioral patterns that may influence exposure, and the degree to which the community is involved).

Working with the community involvement specialists or health educators on your team, as well as the regional representative, you can often initially identify a few key individual community or organization contacts by reading through government site files and/or talking with staff from different government agencies. These community contacts can often suggest additional people in the community whom you could contact. Some of the individuals and community groups that you might want to contact include (but are not limited to):

- Individual site petitioner(s) (if any) and/or local residents, particularly community leaders.
- Site-specific advisory boards.
- Tribal organizations/leaders.
- Religious organizations.
- Local medical society and other healthcare providers.
- Fishing, hunting, agricultural, conservation, and industrial organizations.
- Media (print, electronic).
- Community organizations.
- Local community environmental groups.
- Staff at universities or other area academic institutions.

- School principals and school nurses.
- Labor unions.
- Staff of local institutions and facilities near the site (e.g., child-care centers, prisons).

You should request meetings with some of these community members during your site visit to learn more about community concerns. These community contacts often can provide you with valuable information about the site, ways to obtain site data, the level of community interest, and the best strategies for interacting with the community. You can begin determining the types and extent of concern within a community by noting the nature and number of questions that residents ask. Again, work with health communication specialists to facilitate your interactions with the community.

You may also want to review local/community newspapers, including on-line archives, to identify historical information and health concerns. These sources might fill some information gaps in available site records.

3.2.4 Site Representatives

Developing an open relationship with site representatives, including site owners, PRPs, and their contractors is very important. You should brief all site representatives or their designated contractors on ATSDR's role to gain their cooperation in obtaining needed site information. Some documents listed in Table 3-4 may be obtained from site representatives.

At federal facilities or other large industrial facilities, possible contacts include representatives of the public affairs office; occupational medicine, industrial hygiene, or public health professionals; civil engineering and/or water department staff; natural resources and pest management staff; facility environmental engineers or remedial program managers; staff representing other environmental programs; housing office staff; historians; and people responsible for environmental or public health cases or issues. *In addition, at federal facilities, coordination with a federal agency's principal point of contact is typically required. Procedures and protocol developed by ATSDR should be consulted and followed (for example, see ATSDR's, Memorandum of Understanding between ATSDR and the U.S. Department of Defense).*

3.2.5 Conducting the Site Visit

A site visit is an invaluable piece of the public health assessment process. The site visit provides you with an opportunity to:

- See the site to determine activities and possible exposure points.
- Identify current conditions at the site.
- Gather extensive information about the site.
- Meet with site representatives, state and local officials, tribes, community members, and other sources of information (e.g., local physicians or community leaders).

- Establish contacts to facilitate future information requests.

- Confirm previously gathered site information.

Site visits and regulatory reports often provide much of the necessary site background information. Meeting with members of the community and other contacts during the site visit is an important means of obtaining relevant documents and gathering additional information.

3.2.5.1 Before the Site Visit

To prepare for the site visit, you should review any site-specific information you have gathered early on: site background information (including maps), community health concerns, relevant environmental and health outcome data, and demographics, noting what information has already been made available to the public about the site (e.g., TRI data, site-related reports, etc.). You should also review the types of information still needed and prepare a list of information needs and questions to pursue during your site visit.

Site visits are usually conducted by a small team including the health assessor, the regional representative, and a health communications specialist. The team makeup may vary, however, depending on site issues. Coordination is important to a successful site visit. Before the trip, you should meet with the other members of the site team and make arrangements to:

- Coordinate with the appropriate site or facility representatives to schedule site visit activities.

- Brief all contacts with whom the team will be meeting individually about the purpose of the visit.

- Send the contacts written confirmation of the site visit meeting dates, times, and places.

- Determine the type of meeting best suited for the community (public meeting, public availability session, and/or meetings with individuals) and arrange for the meeting(s) to be held during the site visit (see Chapter 4).

- Invite representatives of relevant agencies (EPA, state and local health and environmental departments, tribes) to appropriate meetings or visits.

- Develop informational materials (such as press releases and fact sheets) (see Chapter 4).

The health assessor/site-team leader should determine if it is necessary to enter any restricted areas (e.g., “hot zones”). If so, all participants in the site visit should make sure their health and safety training is up to date and that the required approval forms have been completed (e.g., safety check-off list, site health and safety plan, travel requisitions).

3.2.5.2 During the Site Visit

A tour of the site and its environs is an invaluable part of all site visits. Remember, the site visit is a critical component of your data collection activities. While touring the site, you should

Important Information Can Be Gained From Visual Examination of a Site

Examining the site area for signs of children playing is one of the more important reasons for a site scoping visit. For example, at one petitioned site, a health assessor observed children's toys in a drainage ditch connected to a wood treatment lagoon. Subsequent sampling of the drainage ditch and discussion with local parents revealed several local children had skin rashes and other problems that may have been related to playing in the drainage ditch where high levels of polycyclic aromatic hydrocarbons were found in soil and water.

identify as much as possible any contamination source areas, the locations/proximity of private wells, physical hazards, warning signs or fences, potential exposure points (see example in box above), and approximate distances to places where people live and work. You should also ask the questions you prepared prior to the visit and collect any relevant documents and data sets. You are encouraged to take photographs during the site visit (with permission) and use a map to record the location and direction of physical features. Although physical hazards and any visible releases should be photographed or noted, be sure to use professional judgement to stay out of danger. All members of the site team attending the site visit are responsible for adhering to ATSDR and other applicable health and safety requirements.

During the site visit, you should also meet with community members, local and state officials, and tribal representatives as arranged prior to the visit. Again, you should come to these meetings prepared with questions and requests to obtain missing information, working closely with the health communication specialist on your team.

Document the findings of your site visit in detailed notes written during the visit. Field observations should be distinguished from information conveyed at meetings. Record concerns and issues accurately and objectively, without interpretation. List possible sources for additional needed data.

3.2.5.3 After the Site Visit

After conducting the site visit, you need to review and compile the information gathered. Consider a team debriefing meeting to evaluate information obtained during the site visit, define lessons learned, and begin developing site priorities and an action plan. See Section 3.4 for methods and tools for documenting and summarizing pertinent site information.

As with other steps in the information gathering process, you may identify additional data needs and may need to make additional contacts and possibly perform additional file reviews.

3.3 Identifying Information Gaps

Throughout the public health assessment process, you will continue to identify different types of information needed to support the assessment. As mentioned previously, data collection is an iterative process and will often require networking and follow-up inquiries.

As the process evolves and information needs are refined, you may find that some of the needed information simply does not exist. Health assessors are encouraged to use available information to the greatest extent possible in drawing public health conclusions. If there is missing or limited information, you should proceed by clearly identifying in your report (i.e., the PHA or PHC) what information is not known and how this lack of information may affect conclusions.

In some cases, you may believe that the missing information is significant in terms of assessing public health implications at the site, and may recommend that additional sampling or studies be performed to address the data gaps. If you find yourself in this situation, it is important to keep the public informed about the status of the public health assessment activities during the process.

Methods for evaluating the adequacy of the available information are described in the chapters that follow.

3.4 Documenting Relevant Information

Health assessors may benefit from using checklists when compiling site information. After you have collected as much of the needed information as possible about a site, the next step is to identify which information is most relevant to the public health assessment process and compile it in a meaningful way. For future reference, you may need to prepare a site visit report that lists all the people contacted during the trip; summarizes each meeting and its outcome; describes any environmental monitoring conducted; summarizes key site issues, important observations, and conclusions; and identifies remaining data gaps and other recommended actions.

Often the first step in organizing the information collected is to develop a Site Summary Table, as shown in Table 3-5, particularly for large sites where much information needs to be organized. For example, some Superfund sites and/or DOD and DOE sites might have numerous separate "areas of concern," each with different possible exposure situations and environmental conditions.

Compiling data in such a manner helps you sort out and organize the information collected and determine what is most important for assessing exposures and possible health hazards. After developing the Site Summary Table, you will be ready to begin a more in-depth evaluation of exposure pathways and environmental data, as described in Chapters 5 and 6.

Of utmost importance when documenting information is to clearly reference all information sources.

Table 3-5. Sample Site Summary Table

Site	Site Description/Waste Disposal History	Investigation Results/Environmental Monitoring Results	Corrective Activities and/or Current Status	Exposure Conditions
Storage Area #1	42-acre area located along the railroad yard in the northeastern portion of the site. Since 1942, incoming raw materials have been sorted here for distribution to the appropriate receiving facility. No hazardous wastes were produced here, but some of the incoming raw materials were classified as hazardous. The area is fenced.	**Groundwater:** No volatile organic compounds (VOCs), semivolatile organic compounds (SVOCs) or inorganics were detected above health-based comparison values (CVs). **Surface Soil:** Arsenic (7.3 parts per million [ppm]) and iron (34,000 ppm) were detected above CVs. Soils naturally contain low levels of arsenic. Background concentrations range from 1 to 40 ppm with a 5 ppm average. Iron is an essential nutrient.	A RCRA (Resource Conservation and Recovery Act) Feasibility Investigation (RFI) has been completed. Draft report recommends no further action. No further action planned.	No past, current, or anticipated future use of groundwater in site area. Access to the area is restricted. No children or other trespassers likely to access area.
Former Fire Training/ Landfill Burn Area	Fire Training Area is a gravel pit 30 feet in diameter located northwest of the Main Test Area. Wastes were burned in this area approximately 20 times per year from 1973 to 1978. Liquids drain from the burn area via a pipe into a small pond to the west.	**Shallow Groundwater:** The following VOCs were detected above CVs (maximum concentrations are in parentheses): TCE (680 ppb), PCE (15 ppb), 1,1-DCE (300 ppb). Cadmium detected slightly above background and its CV (44 ppb). Other metals detected at background levels and/or below CVs. **Deep Groundwater:** 1,1-DCE (150 ppb), methylene chloride (9 ppb) were detected above CVs in on-site wells.	RFI is complete. Long-term monitoring of groundwater is ongoing.	Shallow groundwater is not used as a drinking water source. Private wells (deep groundwater) were used in the past (prior to 1978) in residential areas upgradient of the site.
Pesticide Handling Area	Located in the north central part of the site. A new Pesticide Storage building that is used to store and mix pesticides and herbicides replaced an old building in 1984. Reportedly, all liquid from the sumps is recycled, and no discharge, spills, or releases have been reported. The area is fenced.	**Groundwater:** No pesticides were detected above CVs. **Surface Soil:** Aldrin (0.0483 ppm), chlordane (4.92 ppm), and dieldrin (1.1 ppm) were detected above CVs.	RFI is complete. Remediation of pesticide residues reportedly conducted on old facility and surrounding area before construction of new facility. Resampling of soils is planned (date).	No past, current, or anticipated future use of groundwater in site area. Access to the area is restricted. No children or other trespassers likely to access area.

Sources: ABC Consulting 1996, 1998

3.5 Confidentiality and Privacy Issues

Some of the data collected during the public health assessment process may be considered confidential or private and may contain sensitive personal information. These include:

- *Biologic/medical data* (e.g., medical records, individual health outcome information, ATSDR Records of Activity [AROAs], and written logs that document an individual's medical condition). Typically, medical confidentiality issues arise as part of health studies or health surveillance activities that might evolve from the public health assessment process. Health assessors should be cautious before accepting or reviewing medical information containing personal identifiers (e.g., names, addresses, social security numbers). Medical facilities and state health departments generally have strict requirements pertaining to the handling of such confidential medical information. Before handling any data in which confidentiality may be an issue, you should consult with your supervisor, the assigned medical officer, or legal counsel. Health assessors are not typically required to handle this type of information as part of the public health assessment process and would more likely be reviewing environmental and exposure data and aggregate health outcome data (e.g., from cancer registries).

- *Names of homeowners* identified on maps (e.g., location of residences or private wells linked with environmental sampling data).

- *Graphical displays of health outcome data* (e.g., GIS maps) that may identify locations where a person with a particular illness or disease resides.

- *Summaries of health information* (e.g., informal door-to-door surveys conducted by community members) that might identify people with a particular health condition, especially if information is collected from a relatively small geographic area.

Information that needs to be presented in order to answer public health questions should be presented in such a fashion so that it protects the confidentiality or identity of the people involved. It is important that any such sensitive information not be disclosed in written products or in other communications (e.g., meetings, telephone calls). Further guidance is provided in ATSDR's "Confidentiality and Privacy Issues Related to Public Health Assessments and Health Consultations" (2001).

References

ATSDR. 1994. Environmental data needed for public health assessments: a guidance manual. Atlanta: US Department of Health and Human Services. March 1994.

ATSDR. 2001. Confidentiality and privacy issues related to public health assessments and health consultations. Draft guidance document. Atlanta: US Department of Health and Human Services. May 24, 2001.

Other Resources

The resources listed below are all on-line. No list of on-line resources is comprehensive or static: new resources are constantly being changed or added. All links were current at the time of publication.

Compendia of Resources

http://www.atsdr.cdc.gov/atsdrhome.html, ATSDR's Web site, includes documentation on a wide range of agency activities and technical information that may be used to support public health assessment activities, including ATSDR's toxicological profiles, exposure registry information, ATSDR activities at hazardous waste sites (including PHAs released by ATSDR and its partners), and various technical reports. It also includes links to other credible science resources.

http://www.cdc.gov/elecinfo.htm. *CDC and ATSDR Electronic Information Resources for Health Officers* catalogs some of CDC's more important information resource offerings which make public health information accessible via computer, automated telephone systems, and electronic media (diskette and CD-ROM).

Site Information

http://www.epa.gov/superfund/sites/npl/npl.htm provides a listing of EPA National Priorities List (NPL) Superfund sites and an overview of their site status.

Maps/GIS

http://gis.cdc.gov/atsdr/default.asp. The Geographic Analysis Tool for Health and Environmental Research (GATHER) is ATSDR's interactive map server. It provides maps of site boundaries for selected hazardous waste sites, including geographic features and selected population data, as well as access to additional maps and spatial analyses created by GIS.

http://www.mapblast.com/ and http://www.mapquest.com produce area maps that include locations of hospitals, schools, and other features of interest.

http://terraserver.homeadvisor.msn.com allows users to view aerial photographs, satellite imagery, topographical maps, and GIS maps, some of which can be ordered online.

http://www.terrafly.com/ provides aerial photographs similarly to TerraServer, but also allows the user to enter street addresses (instead of just geographical coordinates).

http://www.ngdc.noaa.gov/seg/topo/state.shtml provides topographic maps of each state made available by the National Oceanic and Atmospheric Administration.

http://mapping.usgs.gov and http://earthexplorer.usgs.gov/ provide access to satellite images, aerial photographs, maps, and digital data from the U.S. Geological Survey.

http://www.topozone.com provides access to USGS maps at 1:25,000, 1:100,000, or 1:200,000 scale.

Demographics

http://www.census.gov/, http://quickfacts.census.gov/, and http://factfinder.census.gov/servlet/BasicFactsServlet provide selected demographic and economic information collected by the U.S. Census Bureau.

http://tiger.census.gov/cgi-bin/mapbrowse-tbl can generate maps that include features such as streets, water bodies, and Indian reservations based on information from the U.S. Census Bureau.

http://www.amshomefinder.com/index_community.html generates community profiles including information about area schools and hospitals, as well as selected demographic information.

http://sedac.ciesin.org/demog lists resources for U.S. demographic data from the Center for International Earth Science Information Network (CIESIN).

http://www.cast.uark.edu/local/hunt/index.html is a guide to mostly on-line and mostly free U.S. geospatial and attribute data.

http://www.geolytics.com. CensusCD can be purchased at this Web site.

http://www.oseda.missouri.edu/plue/geocorr accesses MABLE/Geocorr V3.0, a geographic correspondence engine.

http://mcdc2.missouri.edu/websas/xtabs3v2.html will generate 1990 demographic profiles for states, counties, ZIP codes, or census tracts.

Environmental Pollution

http://www.epa.gov/tri/ contains EPA's Toxics Release Inventory (TRI).

http://www.scorecard.org was developed by Environmental Defense using data from TRI to provide information about sources of environmental releases by county.

http://www.epa.gov/enviro/html/multisystem_query_java.html is the access point for data from EPA's "Envirofacts Warehouse," which includes information about EPA-regulated facilities and their hazardous waste, air, water discharge, and other permits. The Web site also has a "Maps on Demand" service that will provide maps showing EPA-regulated facilities, schools, water bodies, hospitals, ZIP code boundaries, etc.

http://hq.environmental.usace.army.mil/programs/fuds/fuds.html, from the U.S. Army's Defense Environmental Restoration Program, provides information about formerly used defense sites.

http://www.epa.gov/superfund/programs/risk/datause/partb.htm contains EPA's guidance for the usability of environmental pollution data.

http://www.epa.gov/quality/qs-docs/g4hw-final.pdf contains data quality objectives developed by EPA for hazardous waste site investigations.

Local Health

http://www.cdc.gov/nchs/fastats/. The National Center for Health Statistics site includes data on health status, lifestyle, and exposure to unhealthy influences, the onset and diagnosis of illness and disability, birth and death rates, and the use of health care nationally and by state in an A to Z format.

http://www.cdc.gov/other.htm lists state health departments.

Local/State Contacts and Local News

http://www.dogpile.com provides information about local contacts, including the names, addresses, and phone numbers of government officials (such as city managers and water departments), by city and state.

http://www.50states.com/news/ provides a list of local newspapers by state.

Local Organizations

http://www.nativeweb.org/sitemap.html lists Native American organizations.

http://www.igc.apc.org/envjustice/maps/continen.html lists locations of environmental justice groups in North America.

Chapter 4
Involving and Communicating With the Community

The community associated with a site is both an important resource for and a key audience in the public health assessment process. Community members can often provide information that will contribute to the quality of your scientific assessment. In turn, they will want to know

- What the public health assessment process involves.
- What conclusions you reach.
- How ATSDR and the public health assessment process can help address their health concerns.
- How they can become involved in the process.

ATSDR has embraced the philosophy of continuous improvement of and increased attention to its community involvement efforts. The practice of community involvement requires earnest, respectful, and continued attention.

One of the keys to the success of the public health assessment process lies in the ability to establish clear expectations, communicate effectively, and place the community at the center of its response.

The relationship the team builds with the community will influence how much community members trust you and thus, ultimately, how they react to your public health messages and recommendations. For all these reasons, effective community involvement is an important part of the public health assessment process.

The purpose of this chapter is to provide information on how to involve the community in the public health assessment process. As a health assessor, it is important for you to have a good understanding of the purpose, approaches and tools for involving the community, and to work effectively with your team to promote community participation during the public health assessment process. This will help your site team initiate and maintain good two-way communication between ATSDR and the community.

This chapter is not intended to provide all information about conducting community involvement, health communication, or health promotion activities. Rather, it describes the tools and resources for an effective site-specific approach. If additional information is needed, contact the health communication involvement or health education specialist on your team. ATSDR partners may find that some discussions in this chapter are not necessarily relevant to their particular procedures (e.g., use of ATSDR's Community Involvement Branch), but the process of effective community involvement is the same.

Note that community involvement strategies and activities are site-specific—dependent on the community, the site, the possible public health hazard, available resources, and other issues. Not all community involvement activities occur at all sites. Strategies can change over time based on input from the community and other stakeholders throughout the public health assessment

process. For each site, the team will need to make judgments about which community involvement activities are appropriate based on the site situation, and possibly based on resource availability.

Figure 4-1 shows the general components of the community involvement process. This chapter provides guidance for the health assessor in each of these areas.

- Section 4.1 introduces terms used in this chapter, describes community involvement objectives, and presents the roles of various program offices and site team members.
- Section 4.2 provides information about interacting and effectively communicating with community members throughout the public health assessment process.
- Section 4.3 provides an overview of the steps involved in planning community involvement activities at your site.
- Sections 4.4 and 4.5 show how community involvement is included in the public health assessment process, including tools that can be used in the process.
- Section 4.6 explains how to respond to community health concerns in the public health assessment document.
- Section 4.7 discusses the public comment process and the release of final documents.
- Section 4.8 provides some general procedural information about disseminating information to the community.

4.1 Definitions, Goals and Objectives, and Program Roles

To effectively communicate with the public and foster opportunities for their involvement in the public health assessment process, it is important to understand (1) the basic terminology describing the process, (2) the overall goals and objectives of community involvement, and (3) the roles of the various agency programs in the community involvement process.

4.1.1 Definitions

Terms used throughout this chapter are defined as follows:

> *Community.* People who may be directly affected by site contamination because they currently live near the site or have lived near the site in the past. Community members may include, for example, residents, members of local action groups, local officials, tribal members, health professionals, and local media. The community is at the heart of all public health activities.

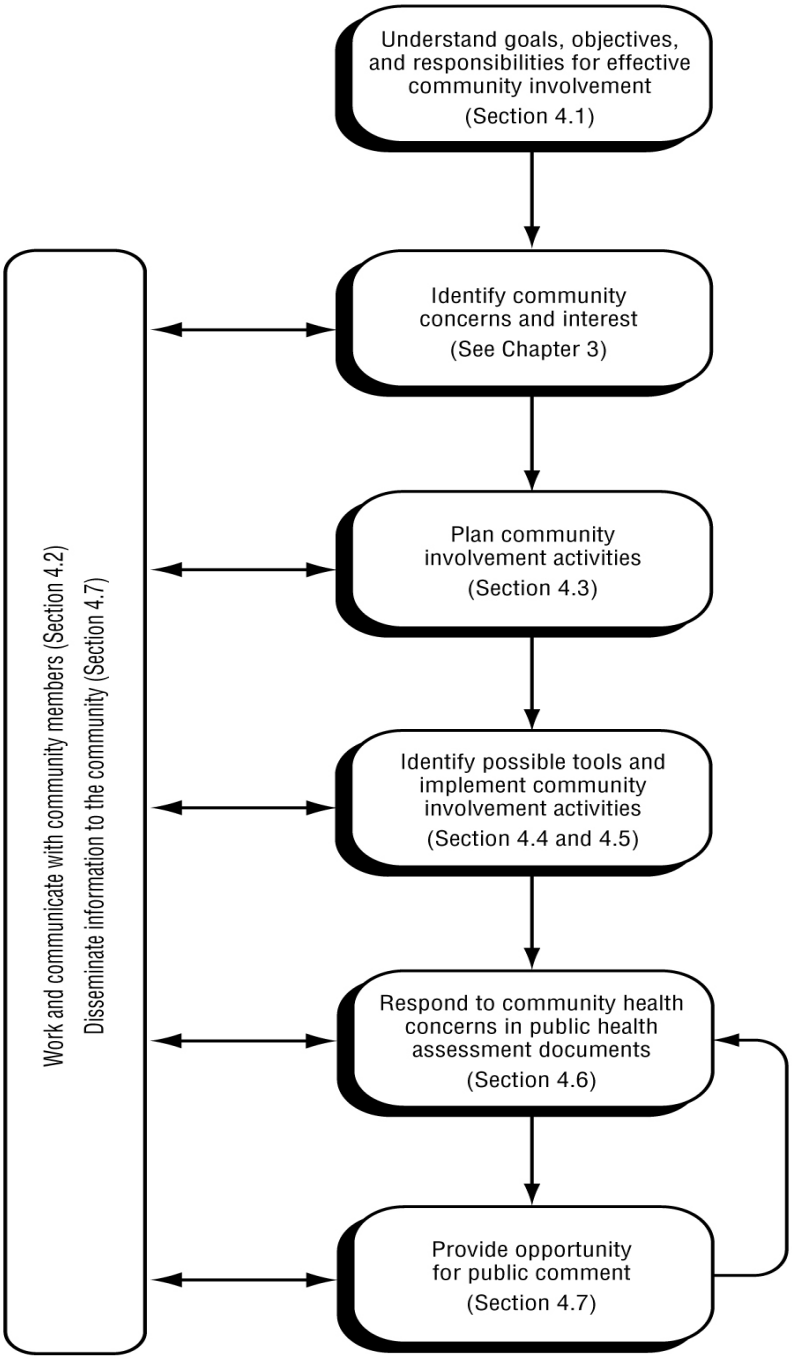


Figure 4-1. Components of Effective Community Involvement

Community involvement. Outreach from ATSDR to provide opportunities for community members to have a role in the public health assessment process. Community involvement goes beyond just the communication of information.

Health communication. The use of communication strategies and messages to best meet the needs of the community with culturally appropriate public health information and materials. Health communication may include public meetings, fact sheets, media support, translation, etc.

Health education and promotion. Any planned combination of learning experiences designed to predispose, enable, and reinforce voluntary behavior conducive to health in individuals, groups, or communities.

4.1.2 Goals and Objectives for Community Involvement

Community involvement activities should be developed and implemented with the following objectives in mind.

- Earning trust and credibility through open, compassionate, and respectful communications.
- Helping community members understand what the public health assessment process involves.
- Providing opportunities for communities to become involved in ATSDR's public health assessment activities.
- Promoting collaboration between ATSDR, communities, and other agencies.
- Informing and updating communities about ATSDR's work through managing and coordinating health communication activities with site communities.
- Helping communities understand the possible health impact of exposures to hazardous substances (or the lack thereof).

4.1.3 Program Areas Addressing Community Needs

As described in Chapter 2, the team leader is responsible for organizing a site team with the combined expertise necessary to address most or all of the needs of the community. Depending on site-specific needs, team members from various programs will participate in community involvement efforts at different levels. For some team members, such as those from ATSDR's Community Involvement Branch (CIB), community involvement is their main responsibility. Others may take more of a managerial, complementary, or supportive role. Table 4-1 outlines program areas and associated responsibilities for working with communities. Included in the table are a list of ATSDR programs/specialists, their general roles, and when you might consider including them on your team. ATSDR partners involved in the public health assessment process will call upon their local team resources to plan and implement community involvement and associated activities.

Table 4-1. ATSDR Program Areas with Responsibilities for Working with Communities

Program	Specialists	Role in the Public Health Assessment Process	Role in Community Involvement	When Included on Site Team?
Division of Health Assessment and Consultation (DHAC) (http://www.atsdr.cdc.gov/HAC/)	Health assessors, toxicologists, medical officers, other science specialties, health communication specialists.	The site team leader is almost always a health assessor who brings together a team of ATSDR staff to address the needs of the site; coordinates the site team; collaborates with other groups and agencies; evaluates environmental health data; and who is responsible for preparing public health assessment documents. Other science specialists from DHAC are often needed to address specific site issues.	The site team determines the community involvement activities that will be conducted. The team leader is usually involved in implementing community involvement activities; other DHAC scientists may be also become involved.	A DHAC health assessor is usually the team lead for all public health assessment activities and must be included on the site team. Other science specialists from DHAC are often needed to address specific site issues.
Division of Regional Operations (DRO) (http://www.atsdr.cdc.gov/oro.html)	Regional representative	Acts as a liaison with EPA; facilitates implementation of ATSDR's work in the regions; maintains current and historic knowledge of the sites and issues in the specific regions; provides and follows up on ATSDR recommendations; sometimes reviews site-specific information.	Because of proximity to communities, is often the first ATSDR staff to contact communities. Works with site team to develop and implement community involvement activities. Attends almost all ATSDR community meetings; may also attend those of other agencies. Often takes lead on political issues.	The regional representative is always included on the site team and kept informed of public health assessment activities.

Table 4-1. ATSDR Program Areas with Responsibilities for Working with Communities

Program	Specialists	Role in the Public Health Assessment Process	Role in Community Involvement	When Included on Site Team?
Community Involvement Branch (CIB)	Health communication specialists	Provides a central point of contact for community members at most sites.	Takes lead on site team in developing and implementing community involvement activities; manages and coordinates community involvement activities with site team, the community, other groups and agencies; conducts community meetings; works with media; and develops culturally-specific materials, such as fact sheets.	1) Whenever site team lead and the regional representative need additional support for community issues. 2) For petition sites not assigned to cooperative agreement partners. Note: CIB must prepare press releases for all documents released.
Office of Tribal Affairs (OTA) (http://www.atsdr.cdc.gov/tribal/)	Environmental health scientists	Provides a central, identifiable point of contact for American Indian and Alaska Native communities.	Provides tribal-cultural assistance on site-specific projects; develops needed interagency coordination to address environmental health needs of American Indian and Alaska Native populations.	OTA must be kept informed and/or included on any site team working with American Indian and Alaska Native communities.
Division of Health Education and Promotion (http://www.atsdr.cdc.gov/dhep.html)	Health education, communication, and professional educator specialists	Works with communities to understand, prevent, and/or mitigate adverse health effects associated with hazardous substances present in their communities.	Assesses health education needs including access to care; mobilizes community and institutional partnerships; builds state and local capacity; addresses health education and other community needs.	During the public health assessment process or after the evaluation is completed.

Table 4-1. ATSDR Program Areas with Responsibilities for Working with Communities

Program	Specialists	Role in the Public Health Assessment Process	Role in Community Involvement	When Included on Site Team?
Office of Communication (http://www.atsdr.cdc.gov/orgchart.html)	Public affairs specialists, writer/editors, and visual information specialists	Provides direction and essential support to the agency in the areas of policy, state capacity coordination, marketing, publications and public affairs, visual information services, and congressional inquiries.	Assists with 1) public notices and press releases; 2) visual information services; 3) public affairs as it pertains to community involvement; and 4) translating technical health risk information for the lay public.	As needed.
NCEH/ATSDR Office of the Director–Environmental Justice (http://www.atsdr.cdc.gov/orgchart.html)		Provides leadership in the areas of minority health and environmental justice.	Coordinates activities and programs for minority communities, under-served communities, and low-income communities.	As needed.
Ombudsman (http://www.atsdr.cdc.gov/COM/omweb.html)		An independent, neutral resource service for all parties (including communities) concerned with environmental health disputes involving ATSDR.	The ATSDR ombudsman can be called to impartially investigate, mediate, and assist, when all routine avenues have been exhausted. The ombudsman is an advocate for problem resolution.	As needed.
Washington, D.C. Office (http://www.atsdr.cdc.gov/legislation/)		Provides a critical information link in Washington between ATSDR and the legislative branch and the other executive branch agencies of government; improves the environmental health policy-making process by sharing ATSDR's science-based recommendations and conclusions with Congress.	Provides information to congressional members and their staffs about 1) ATSDR's site work within their legislative jurisdictions, 2) identifying environmental health resources for communities exposed to hazardous substances.	As needed.

Table 4-1. ATSDR Program Areas with Responsibilities for Working with Communities

Program	Specialists	Role in the Public Health Assessment Process	Role in Community Involvement	When Included on Site Team?
Office of the Director (http://www.atsdr.cdc.gov/orgchart.html)		Promotes programs in support of environmental health issues; supports applied research activities relevant to ATSDR's mission through the development and implementation of research plans and science policy for the agency.	Provides oversight and review for some sites.	As needed.

4.2 Working and Communicating with Community Members

A critical element to the success of any community involvement, health communication, or health education and promotion activity, is effective communication with all members of the site community. To effectively communicate your message(s) you will need to 1) earn the trust of and prove your credibility to the community; 2) assure them you are sensitive to issues of confidentiality and privacy, 3) be conscious of cultural sensitivity when interacting with community members, 4) be aware of possible environmental justice concerns that may be present at your site. This section provides you with tips and information about ATSDR's approaches to all of the above. The last subsection also includes some principles for effective communication. (Additional suggestions for effective communication and considerations when interacting with the site community may be found in Appendix D). Again, the community involvement specialist on your team can help you develop a plan and approach with any community involvement activities, but it is important for the health assessor to know what to keep in mind in his or her interactions with community members.

Appendix C provides a "community check list" developed by the Community/Tribal Subcommittee of ATSDR's Board of Scientific Counselors. This check list can be used by community members and health assessors as a guide in helping to ensure that the public health assessment process at a particular site is responsive to community health concerns and information needs.

4.2.1 Earning Trust and Credibility

ATSDR's relationship with the community is influenced by every interaction with community members. The more opportunities ATSDR creates to get to know the community better, to listen respectfully to their concerns, and to help them understand how the agency's activities will respond to their concerns, the more the community will trust ATSDR's work at the site. Trust lays the foundation for community cooperation during the public health assessment process and for the community's willingness to accept your results and conclusions and respond to your recommendations. For all these reasons, building trust is central to working with community members.

4.2.2 Confidentiality and Privacy

Personal information that ATSDR receives from the public, such as petition letters, community health concerns, and medical records may be considered confidential and may contain sensitive personal information. As discussed in Chapter 3 (Section 3.5), such data must be handled in accordance with agency guidance specific to confidentiality and privacy issues (e.g., when interacting with the public at meetings or when presenting information in written products). Potentially confidential or sensitive data include:

- Biologic/medical data
- Environmental data from private properties
- Some GIS information/data/maps

- Summaries of health information provided by community members, including names and addresses of community members

Different state and tribal policies related to confidentiality and privacy may also exist.

4.2.3 Cultural Sensitivity

In many communities, concerned or potentially impacted groups may include different ethnic or minority groups and/or members of tribal nations. To be successful, you will need to conduct your communication and involvement activities in a way that is sensitive to each group's culture and language. For example, two or more variations of outreach materials may be needed when a community contains cultural groups with significantly different profiles, concerns, behaviors, or languages.

During the initial reconnaissance of a site, the site team should identify any distinct groups within the local community (e.g., ethnic, tribal) and during telephone or subsequent in-person interviews arrange for interpreters as necessary. This initial information will help you determine whether you will need cultural contacts and interpreters during the public health assessment process. A cultural contact acts as a bridge between the cultural community and the site team and provides guidance to the site team on the most culturally appropriate, constructive, and productive ways for learning from, informing, and involving the community. The best cultural contact is someone from the community who is fluent in both English and the language of the cultural community, familiar with the community's cultural habits, and trusted by community members.

During the early stages of the public health assessment, you can work with local organizations and community leaders to identify the most appropriate cultural contacts. When tribal members are part of the site community, you will consult with ATSDR's Office of Tribal Affairs who can help you identify site-specific tribal issues and concerns. Other government agencies, such as the Indian Health Service, may also be able to provide guidance on cultural contacts. The cultural contact may or may not also act as an interpreter, depending on his or her skills and experience. As needed, your health communication specialist can help you identify skilled and reliable interpreters and translators who can provide unbiased oral and written translation between English and the community language.

4.2.4 Environmental Justice

Environmental justice refers to efforts to ensure that all populations, regardless of their economic status or political power, are treated equally with respect to the development, implementation and enforcement of environmental laws, regulations, and policies. These efforts help ensure that no population unfairly shoulders the negative human health and environmental impacts of pollution. NCEH/ATSDR's Office of the Director, Environmental Justice (EJ), has leadership responsibility for addressing environmental justice issues related to ATSDR's work in communities. The EJ program works in collaboration with other ATSDR divisions and offices to identify and address real or perceived environmental injustices in communities of concern. Environmental justice activities are initiated when there is a perceived or real concern by a minority and/or low income community that they have not been appropriately involved in

matters concerning planning, implementing or evaluating activities related to the environment or environmental health. It is important to be aware of the EJ program's role and alert for signs of any environmental justice concerns within the community at your site. If any such concerns are raised by community members at any time during the health assessment process, you should contact the EJ program to determine the next steps with regard to these concerns.

4.2.5 Principles of Effective Communication

As a health assessor, you will face two key challenges in communicating with the public during the public health assessment process:

- First, public health assessment information often is technical in nature, yet most community members are not technical specialists. Health assessors must therefore strive to present information in as clear and understandable a manner as possible without sacrificing accuracy. Clear communication is particularly important in three places in your public health assessment document: the *Summary*, *Conclusions*, and *Recommendations*. These sections are widely read by not only the community but other key stakeholders.

- Second, a number of community members often will, understandably, have strong feelings and opinions about the site. Thus communication entails not only the exchange of information, but just as importantly, listening to, understanding, respecting, and responding with compassion to the feelings and concerns of community members.

Through experience and research, public health professionals and other experts have developed basic principles and practices for communicating clearly and compassionately. Guidance on implementing these principles is provided in Appendix D. Following these guidelines from the beginning to the end of the public health assessment process will help build trust with the community—the critical foundation for a successful and credible public health assessment process. Affected community members and involved community groups should be included when possible. Remember that all community contact—particularly your initial contact—sets the tone for your continued work with the community.

As you develop communication materials, you should work with the health communication specialist on your team to ensure that your communications—particularly written materials—follow these principles. Also, where possible and appropriate, utilize technical writers, communication specialists, and the community to help ensure the quality and success of your communications. You can also refer to ATSDR's A Primer on Health Risk Communication Principles and Practices (http://www.atsdr.cdc.gov/HEC/primer.html) which provides additional information on communication guidelines, comparing risks, and responding to questions from community members.

Additional resources related to effective communication are provided at the end of this chapter.

4.3 Planning Community Involvement Activities

The extent of public communication and involvement at a particular site depends on several factors including:

- How concerned the community is about the site.
- The potential for public health hazards from the site, as determined by your data and the evaluation as it proceeds.
- The availability of resources to implement the communication and involvement activities.

This section outlines the steps involved in developing community involvement strategies and the types of activities that may be appropriate depending on your site-specific issues.

4.3.1 Overview of Community Involvement in the Public Health Assessment

Public communication and involvement during the public health assessment process can be divided into four stages:

- *Getting started*. Through your initial public health assessment activities, you will start to build a relationship with the community. You will also gather information about the site, the community, and its needs and concerns. This information will provide a foundation from which you can plan your subsequent community involvement activities. In some cases, concerns brought to ATSDR's attention may need to be referred to another agency, such as worker-related concerns. Whenever possible ATSDR should notify community members early in the public health assessment process if their concerns are beyond the scope of ATSDR's mission. It is equally important that community members be informed and understand early in the process what ATSDR can do and what the public health assessment process represents.

- *Ongoing activities as the public health assessment is conducted*. The type and nature of communication, education, and involvement activities during this stage will depend on the needs and interests expressed by the community during the previous stage, the public health issues identified at the site by the site team throughout the public health assessment process, and the resources available for communication, education, and involvement activities. While the public health assessment is underway, primary communication and involvement goals include updating the community on the status of the assessment, obtaining ongoing feedback on the process, obtaining additional information as needed or available from the community for the assessment, and recommending public health actions, if needed, about how community members can protect their health (e.g., encouraging lead testing in children, limiting backyard gardening activities).

- *Public comment on the draft public health assessment document (PHA)*. For public health assessments, the next stage begins after you prepare the draft PHA. During this stage you will be following a formal process to ensure the public has a chance to comment on the

draft document. (Note: public comment is not required but may be desirable for some public health consultations.)

- *Communication of final results and follow-up activities*. Once your public health assessment document is finalized, you will need to release the document to the public and communicate the key results, limitations, and recommendations. If ATSDR or other parties will be conducting any follow-up activities at the site (such as additional environmental sampling, exposure investigations, health education, or health studies), you may need to plan community involvement activities as appropriate in conjunction with these activities.

4.3.2 Developing Community Involvement Strategies

Team members will develop strategies for involving and interacting with the public throughout the public health assessment process. The health communication specialist on your team will define which tools are most appropriate for the particular circumstances at your site and when they should be used. In addition to site-specific issues, the team must also consider whether ATSDR has sufficient resources to implement the strategies. Other agencies and groups (e.g., federal, and state health and environmental agencies, tribal governments, local health departments, citizens' advisory groups, and medical advisory groups) may already be working with and providing information to community members at a site. As appropriate, the team should collaborate with these groups to enhance the efficiency, effectiveness, and credibility of public communication and involvement activities. Also, the team may need to change strategies as the public health assessment process progresses.

Community involvement strategies will be based on factors such as:

- The community's level of concern, interest in the site, and other community issues
- Environmental public health factors
- Political and congressional issues
- Other site-specific considerations, such as how many people are on the site team and how many other agencies are collaborating with ATSDR on the site

Table 4-2 lists some of the issues that the team should consider when developing community involvement strategies. Focus on community concerns related to public health issues.

Table 4-2. Issues to be Considered When Developing Community Involvement Strategies.

Type	Issues to be Considered When Developing Community Involvement Strategies
Community	Community's Health Concerns: • How many community members are concerned about site? • What is the level of the community's concern? • Is the level of community concern higher (or lower) than would be expected based on the environmental health risk alone at the site? • Are community concerns known? Demographics: • How many community members live near site? • Are there any potentially sensitive populations that could be exposed? • Does socio-demographic information suggest a need for additional community involvement resources, such as translation, interpreter services, or cultural brokers? • How do the community members get information? From newspaper, radio, television, Internet, word-of-mouth? Community's interest in the public health assessment process: • How involved in the public health assessment process would the community like to be? • How would the community like to be kept updated and informed about ATSDR's activities and work? Community meetings? Fact sheets? Specific types of media? • Would some community members or community groups prefer e-mailed newsletters and updates? • How many community and/or activist groups are involved? How active are they? • Will ATSDR be working with a specific community group already formed or should the agency consider forming a new one? Media Support: • What has the community already heard from the media? Are there misconceptions that need to be dispelled? • Will media support require more community involvement resources than usual? Should the Office of Communication be directly involved? ATSDR's support of the community: • Are there American Indian or Alaskan Native communities at the site? Should the Office of Tribal Affairs (OTA) be involved at the site? • Are there particular issues of concern (e.g., environmental justice, child health, Brownsfield) at the site? Will the Environmental Justice program be involved? • What past experiences has the community had with government agencies? • Does the site have a higher level of need for community involvement resources, such as the need to keep the community informed more regularly than usual? • How active will the regional representative be in community involvement efforts? The Division of Health Education and Promotion (DHEP)?

Table 4-2. Issues to be Considered When Developing Community Involvement Strategies.

Type	Issues to be Considered When Developing Community Involvement Strategies
Environmental Public Health	• Is the site a public health hazard? Is the hazard acute or chronic? • Are environmental health risks unknown? • Does DHAC/ATSDR management consider the site a high priority? • Does site work involve a health study or exposure investigation? • Are there any health outcome data or biologic data relevant to the site? • Does it seem plausible that a health connection could be established between contaminant exposures and community health concerns? • Would a physician enhance outreach at the community meetings? • Are data available for review now or must DHAC wait for it? • If site is a Superfund site, where is it in the remedial process? • Has ATSDR only recently become involved in this site? Or has ATSDR almost completed its work at this site? • Do the community members need information/outreach/health education now or can this wait until a report (e.g., PHA, PHC) is generated?
Political/Congressional	• Is the ATSDR Washington Office already involved? Informed? • What other agencies are involved and must be kept updated? • Is coordination with other agencies especially difficult? • How often will congressional briefings be required? • How many agencies, congressional staffers, and other political entities, will need to be notified in a certain order, with a certain protocol? How resource-intensive will this be? • Will the regional representative be taking the lead on political issues?
Other	• How many people are on the site team? How many divisions/offices are involved? • What is the time frame for report (e.g., PHA, PHC, fact sheet) development and communication? • What type of clearance will be required? At what levels? • Will the Visual Information Center (VIC) be involved in preparing outreach materials?

4.3.3 Types of Community Involvement Activities

Various options for involving the community are available. Determining the activities most appropriate for a site typically involves discussions among the site team as well as with the community. Community involvement activities can occur throughout the public health assessment process, from information gathering stages through implementation of recommendations or public health actions, such as during a health study or an exposure investigation.

Opportunities for site communities to become involved in the public health assessment may include the following. The specific tools for implementing these activities are discussed in the remainder of this chapter.

- Individual one-on-one sessions to enable community members to inform the site team about their health concerns and other information.

- Meetings, conference calls, and informational mailings to keep the community updated about the status of public health assessment activities.
- Formal or informal community groups to discuss issues and formulate questions.
- Public comment periods to enable community input on draft public health assessment documents (e.g., PHAs).
- Access to experts at ATSDR that enable community members and other stakeholders to:
  - Obtain site-related public health information and any explanations that may be needed.
  - Add names to the site mailing list.
  - Provide health concerns or other information about the site.
  - Express their desire to influence site activities.
  - Provide feedback about ATSDR's public health assessment activities at a site.

4.4 Community Involvement Tools

The following information will familiarize you with frequently used community involvement tools or activities. Not all of these tools will be used at every site. Section 4.4 outlines how the level of community involvement activities may vary from site to site depending on the phase of the public health assessment process, the level of community interest, and the degree of hazard a site poses.

4.4.1 Tools for Initial Data Gathering

A first step in the public health assessment process is gathering information about the site and the characteristics of the site community. The team will initially review information readily available about the site. This may include information documenting site conditions (e.g., site investigation reports) or community health concerns (e.g., a petition letter). As you collect information, the site team can begin to determine how much community interest and concern there is about the site, identify some of the community leaders, and decide what shorter- and longer-term activities might be warranted. See also Chapter 2, which highlights the important first steps in the public health assessment process, and Chapter 3, which provides detailed guidance on collecting site information, including information specific to the site community.

Geographical information system (GIS) and various Internet tools can be helpful early in the process to obtain information about the general characteristics of the site community, especially before the site team visits the community. For example, introductory GIS maps generated based on U.S. Census data can assist in identifying populations near the site and populations that might be more susceptible to site contamination. In some cases, social characterization maps can be generated to help anticipate various characteristics of the population and to prompt the team to ask appropriate questions during the site visit. During the site visit and subsequent

communications with the community, you will learn first-hand more about specific characteristics of the community and how they may influence community involvement activities (see Table 4-2). The Internet is also a good source of demographic and other types of information. Claritas, Inc., for example, has a Web site that summarizes lifestyle groups for 5-digit zip code areas (www.claritas.com/index.html). See Chapter 3 for additional Internet resources.

4.4.2 Community Meetings

Community meetings can be held throughout the public health assessment process and in several formats depending on the type of interaction that the community has requested and what is needed to address the community's site-specific health issues.

Different meeting formats will be suitable depending on the purpose of the meeting and the information needs and preferences of the site community. These include:

- *Interviews*. One-on-one meetings with local community members who represent different groups and perspectives within the local community. Interviews can be conducted in person or by telephone. For petitioned public health assessments, interviews with the petitioners are the highest priority.

- *Public availability session.* An informal meeting where community members can talk confidentially one-on-one with ATSDR about their health- and site-related concerns. ATSDR uses the community health concerns gathered at this session to help direct the public health assessment process.

- *Poster sessions.* Gatherings where ATSDR meets with community members in small groups to discuss information displayed on posters on a wall or table top. A poster session could have a theme, for example, ATSDR and the public health assessment process. Agency staff are available at these sessions to give informal presentations, answer questions, and discuss concerns with interested members of the public. Representatives from other agencies may also display information and discuss their agencies' work at the site. Attendees have the opportunity to ask questions and share their concerns in smaller group settings than would be possible in public meetings.

- *Public meetings.* ATSDR and (possibly) representatives from other agencies meet with community members to discuss the public health assessment process and the findings of its site-specific evaluations. A specific agenda is developed prior to the meeting by the site team, with community member input, when possible. Agency representatives and experts discuss the public health activities and community involvement conducted at the site—past, current, and planned future activities. ATSDR often includes a question and answer period during the meeting.

- *Public availability meeting and poster session combination.* Community members can learn about ongoing public health assessment activities at the poster session as they wait to discuss their health concerns individually with an ATSDR representative.

- *Public meetings and poster session combination.* An initial public meeting is held to provide general information to the community and to respond to their questions; afterwards the larger group divides to learn more about specific aspects of the site through a poster session.

- *Other meetings.* Other types of meetings can be held in response to specific community needs or environmental issues. These may include meetings of community groups, local officials, workgroups formed to address a particular issue, or workshops conducted to provide technical or educational information to communities.

4.4.3 Community Groups and Committees

ATSDR has had the opportunity to work with various types of informal community or neighborhood groups. These groups are made up of people who have decided to work together to address one or more issues related to environmental contamination in their neighborhood and its possible effect on the health of the community. Sometimes neighborhood groups grow in numbers and in impact such that their membership expands to include not only current residents, but also former residents; local environmental activists; national environmental activists; local and national officials; local, state, tribal, and federal agency representatives; and others. As the group becomes more formalized with specific procedures and policies, it may be described as a coalition, alliance, or forum.

Community members at some sites prefer more direct participation in the public health assessment process. ATSDR works with community groups to determine the best way for the agency to meet their needs and, at the same time, obtain the information needed for the public health assessment process. ATSDR's role can range from being a participant to having some responsibilities for conducting group meetings.

At a specific site, there might be several different community groups, each with a specific mission and goals. ATSDR staff strive to ensure that the agency interacts with all segments of a community, not just organized community groups, but also individuals who may even be unaware of the environmental concerns. When segments of a community are strongly divided over the public health issues and activities at a site, ATSDR may recommend establishing a formal community participation group.

4.4.3.1 Community Groups Established by ATSDR

Community members can become involved in planning, implementing, and decision-making through a community group established by ATSDR. With this mechanism, ATSDR can engage interested community members in data collection and evaluation, joint problem-solving, the preparation and distribution of the PHA document, and the development of intervention and prevention strategies. Two types of formal community participation groups that ATSDR has established are Community Assistance Panels (CAPs) and Federal Advisory Committee Act (FACA) committees with subcommittees. Contact CIB if more information is needed than the summaries below provide.

4.4.3.2 Community Assistance Panels (CAPs)

A CAP is a group of people, both community members and ATSDR staff, who meet regularly to (1) share environmental and health information about a specific site that may be environmentally contaminated and (2) assist ATSDR in making public health decisions that could affect the lives of community members. Factors that influence whether ATSDR decides to form a CAP at a particular site include: the degree of community interest, whether varying viewpoints exist regarding the health issues, and a willingness on the part of the public to actively participate in the process. CAPs have been established by ATSDR at seven sites during the last decade. For more information about CAPs, see http://www.atsdr.cdc.gov/HAC/caps.html.

4.4.3.3 Federal Advisory Committee Act (FACA) Committees

Under the Federal Advisory Committee Act (FACA), federal government agencies can convene committees to provide consensus advice and recommendations. FACA committees must meet the requirements of the Federal Advisory Committee Act. They are much more resource-intensive than CAPs and they require a much greater time commitment on the part of community members than CAPs. ATSDR has used FACA committees only in rare situations where sufficient resources are available and community members have indicated a very strong interest in providing consensus advice to the agency. A health communication specialist on your team, or at CIB, can provide more information on FACA committees.

4.4.4 Fact Sheets and Other Materials

Health assessors need to share newly learned information with the community in a timely manner. As such, you may disseminate information to the community in the form of fact sheets and other materials throughout the public health assessment process. Materials may need to be translated into another language for some of the community members. In some cases, you may choose to establish a Web site to disseminate and even collect site information. This method should only be considered if recommended by the community and in settings where access to or use of computers is known to be prevalent.

Fact sheets and flyers are probably the most frequently used materials. Sometimes letters are prepared to individual community members when a more personal format is needed, such as when requesting community members to participate in an exposure investigation or providing results of sampling on their property. Articles may also be prepared for newsletters published by community groups or other government agencies.

4.4.4.1 General Fact Sheets

Several general (not site-specific) fact sheets are available that can assist you in introducing the community, the media, and other stakeholders to ATSDR and its mission and work. The fact sheets can be distributed as is, or pertinent information can be excerpted to place in site-specific fact sheets as needed. The fact sheets can be mailed out to familiarize the recipients with the information prior to a meeting or they can be given out at the meeting. Only the fact sheets that are pertinent to the specific site should be distributed.

The following fact sheets can be obtained through CIB, ATSDR's Visual Information Center, or over the Internet. When requesting fact sheets, it is important to allow enough time so that copies can be printed if necessary.

- *About ATSDR*—provides general information about ATSDR and an overview of some of its programs and its work with communities; tribes, and local, state, and federal agencies.(http://www.atsdr.cdc.gov/COM/about.htm)

- *What you can expect from ATSDR*—explains ATSDR's mission and describes what ATSDR can and cannot do based on its legal authority. (http://www.atsdr.cdc.gov/COM/whatyou.htm)

- *Get information from and about ATSDR*—explains information available from ATSDR and how to contact ATSDR by web site, phone, fax, email, or writing. Additional information is available at ATSDR's Information Center.

- *Agency overview*—describes the various activities conducted by ATSDR, including public health assessments, health studies, toxicological profiles, health education, and several more.

- *Community assistance panels*—describes why and how a community assistance panel is established when community members prefer more direct participation in ATSDR's work in their neighborhood—beyond the usual community involvement activities.(http://www.atsdr.cdc.gov/HAC/caps.html)

Additional fact sheets are available that describe ATSDR activities that may be occurring in the site community. For example:

- *Public health assessment*—describes what this evaluation considers, the types of information that it evaluates, and how the evaluation is used. It also includes information about how the community can get involved in the process. (http://www.atsdr.cdc.gov/HAC/pha.html)

- *Health consultation*—describes what this type of evaluation considers, the types of information that it evaluates, and how the evaluation's recommendations are used. (http://www.atsdr.cdc.gov/HAC/consult.html)

- *Petitioned public health assessment*—describes how community members can ask ("petition") ATSDR to evaluate an environmental site. (http://www.atsdr.cdc.gov/HAC/petition.html)

- *Exposure investigations*—describes how an exposure investigation is one approach ATSDR uses to develop better characterization of past, current, and possible future human exposures to hazardous substances in the environment and to evaluate existing and possible health effects related to those exposures more thoroughly. (http://www.atsdr.cdc.gov/HAC/expinfaq.html)

- *Public health advisories*—describes how ATSDR evaluates and responds to a hazardous substance release into the environment that poses an immediate and significant danger to people's health. (http://www.atsdr.cdc.gov/HAC/healthad.html)

4.4.4.2 Site-Specific Fact Sheets (Newsletters)

Fact sheets are one of the ways ATSDR site teams provide communities with site-specific information.[1] Usually, fact sheets briefly introduce the reader to ATSDR, summarize the information that ATSDR currently knows about the site, and describe ATSDR's current and future plans for the public health assessment process, including plans to meet with the community. They can also be used to inform the community about the availability of a report (PHA, PHC) and how to obtain a copy. Fact sheets can be mailed out to familiarize the recipients with information prior to a meeting or they can be given out at a meeting. They can also be used to update communities between community meetings.

Fact sheets can be prepared in a variety of ways, often dependent upon how much preparation time is available. Generally the quality of the product is higher if sufficient time is available for the preparation. Work with the health communication specialist on your team when planning for and developing fact sheets.

4.4.4.3 Site-Specific Flyers (Meeting Announcements)

Flyers are one page (or one card) meeting announcements that are distributed to community members and other stakeholders. The agency has found that, for most sites, this is the most effective way to notify the community about a meeting. Sometimes community members or other stakeholders assist in the distribution, either via door-to-door distribution or by leaving the flyers in public locations, such as libraries, post offices, or grocery stores. The flyers contain information about the type of meeting and the agenda, the meeting location, and any background information that might be helpful and serve to encourage the recipient to attend. The health communication specialist and lead health assessor are often listed as contacts via ATSDR's toll-free number.

4.4.5 Media Support

The media, including local newspapers and radio and television stations, are an important communication resource for the site team. ATSDR's need for timely, cost-effective distribution of information to the public often complements the media's need for interesting material to publish or broadcast. ATSDR's site teams often provide information to the media by issuing press releases, by holding media sessions, or by providing or requesting interviews. However, the site team cannot be sure if and when the information will be disseminated or what the media will specifically report. The team may also submit a public service announcement, but cannot always be sure if and when the information will be disseminated. Occasionally ATSDR may pay for advertising. When using this approach, the site team is able to control what information is disseminated to the public and when.

[1] All site-specific fact sheets must be included in the site file.

ATSDR is required to submit press releases to the media whenever a public meeting is held or when a public comment or final report (e.g., PHA, PHC) is released. Other types of information are provided to the media as needed on a site-by-site basis.

4.4.6 Establishing Information Repositories

During the initial stages of the public health assessment process, ATSDR establishes information repositories at convenient locations (e.g., public libraries) within the community. These repositories will be used to house copies of important site-related documents, including PHAs. At many sites, the repository is co-located with EPA's, the tribe's, or the state's information repository. The distribution channels described above can be used to publicize the existence and location of the information repositories.

4.4.7 Access to Experts and Toll-Free Hotline

Community members and others reading public health assessment documents may need to talk to specialists to help clarify specific issues and decisions. You should establish a main point-of-contact within ATSDR who can refer residents to appropriate staff or other experts to answer their questions. Residents should be made aware of ATSDR's toll-free hotline (1-888-42-ATSDR) and should be provided with other contact information to facilitate two-way communication. Other vehicles for communities to access information include ATSDR's Web site (http://www.atsdr.cdc.gov) and its community involvement email address (atsdrcib@cdc.gov).

4.5 Including Community Involvement Activities in the Public Health Assessment Process

Community involvement and health communication activities, based on the strategies developed by the site team, are an important component of the public health assessment process, but will vary from site to site. Table 4-3 shows the types of community involvement activities that could be implemented at a site during various stages of the public health assessment process depending on site-specific issues.

ATSDR's involvement is different (low, medium, or high involvement) for the three site examples in the table. The levels shown are *only* examples of community involvement activities that may be conducted at sites. Activities for a specific site may vary in type and in when they are conducted during the public health assessment process.

4.6 Community Health Concerns in Public Health Assessment Documents

During the evaluation phase of the PHA process, the site team investigates whether the site may be contributing to actual or potential health concerns of the community based upon careful examination of exposure and health data. When the PHA or health consultation is prepared, a section is included that responds to the community health concerns that the site team has gathered.

Community health concerns are typically introduced in the *Purpose and Health Issues* section of public health assessment documents. More detailed information is then presented in either a

Community Health Concerns section or as a subsection of the *Discussion* section, whichever seems most appropriate for the overall flow of the document. The following information should be provided:

- What health concerns, including suspected exposures and health effects, the community has expressed.
- The nature and extent of efforts to learn about community health.
- How the health concerns may or may not relate to site-specific contaminants and exposures pathways.

Conclusions and public health recommendations about the community health concerns should be repeated in the *Conclusions and Recommendations* section of the document.

4.6.1 How to Respond to Community Health Concerns

Every site is unique in terms of the nature and intensity of community health concerns and the availability of data to respond to these concerns. Here are some factors to consider in responding to these concerns:

- The amount of detail appropriate for your response section will vary depending on the complexity of the issues involved and the public health implications. If there are numerous community health concerns, it is not necessary to answer each specific concern individually, but responses can be provided to common topics or issues. (An appendix that lists each comment organized by type of concern can also be included.) If there is little community interest in a site, it can be stated that few community concerns were found, and then information organized by exposure pathway can be presented. In general, the level of detail provided should be that which will best meet the needs or interests of the community.

  Some health concerns may not be related to contaminants at the site. Generally, a response to a health-related concern should be provided even if the contaminant in question was not detected at the site or was present but not found to pose a health hazard. If the health concern relates to a potential source *off site*, the response can simply note that the contaminant relates to an off-site rather than on-site source. When possible, residents should be referred to other agencies that may be able to provide information or assistance in addressing their concern. At sites where there is a high level of community concern about off-site sources, it may be appropriate to provide a more detailed response to these concerns.

Table 4-3. Activities That Might Be Conducted at Three Different Levels of Community Involvement and Participation

Phase of Public Health Assessment Process	Community Involvement Activities and Information		
	Low Involvement Site	**Medium Involvement Site**	**High Involvement Site**
Initial data gathering about community from petitioner(s) (if a petitioned site); community leaders; local, state, tribal, and federal agencies; local media (See Chapter 3)	Results of data gathering: 1) Few, if any, community members are interested, or 2) Collection of community health concerns has been coordinated with other agencies. Establish repositories.	Results of data gathering: Some community interest seems to exist. Establish repositories.	Results of data gathering: High level of community interest, political interest, and/or high likelihood of exposure identified. Establish repositories.
Initial interaction/meeting(s)[2] with community	No meeting is held. Additional information may be gathered to ensure there is no community interest, even in small segments of population.	Usually at least one meeting[2] held (usually a public availability session) to gather community health concerns and other information. Preparation of mailing list. Notification of meeting via flyers, press release.	Multiple community meetings[2] held in coordination with local, state, tribal, and federal agencies. Local, state, tribal and/or congressional briefings. Media sessions and interviews. Preparation of mailing list(s). Notification of meetings via flyers, press releases, advertisements, etc.

[2] Community meetings can refer to any of the various types of meetings ATSDR might conduct with the public (e.g., public availability sessions [individual community member interviews], poster sessions, public meetings, community group meetings).

Table 4-3. Activities That Might Be Conducted at Three Different Levels of Community Involvement and Participation

Phase of Public Health Assessment Process	Community Involvement Activities and Information		
	Low Involvement Site	**Medium Involvement Site**	**High Involvement Site**
Compiling and determining how to address community health concerns	If no community health concerns are identified, note the community involvement efforts taken to determine the concerns. This information will be included in the PHA.	Compile the community's concerns into at least three categories: 1) health concerns, 2) environmental concerns, and 3) other concerns. Plan how ATSDR will address each concern. Some concerns may need to be referred to another agency, such as work-related concerns. Whenever possible, notify community members at this time, if their concerns are beyond the scope of ATSDR's mission.	Compile the community's concerns into at least three categories: 1) health concerns, 2) environmental concerns, and 3) other concerns. Plan how ATSDR will address each concern. Some concerns may need to be referred to another agency, such as work-related concerns. Whenever possible, notify community members at this time, if their concerns are beyond the scope of ATSDR's mission.
Planning evaluation methodology to determine effectiveness of public health assessment activities	Minimal evaluation efforts: 1) Professional judgement. 2) Reader's survey that is included with documents.	In addition to low level: 3) Community feedback on logistics of meetings (does not require Office of Management and Budget [OMB] clearance). 4) Evaluation of indices of community participation (e.g., attendance at meetings, calls to ATSDR, requests for information).	In addition to low and medium levels: 5) Additional surveys that measure a) increased level of community participation and community satisfaction; b) improved responsiveness and relationships with community members/groups; and c) short- and long-term impact of ATSDR's work on community's health and quality of life. Note: Any surveys conducted via mailing or telephone will need OMB clearance.

Table 4-3. Activities That Might Be Conducted at Three Different Levels of Community Involvement and Participation

Phase of Public Health Assessment Process	Community Involvement Activities and Information		
	Low Involvement Site	**Medium Involvement Site**	**High Involvement Site**
Participation of community in the public health assessment process (Note: ATSDR determines the level at which the community would like to participate via interviews with community members and others, actual participation rates, etc. The level of interest may change over time.)	Ways the community might participate: 1) Contact ATSDR as notified in press releases. 2) Provide comments on ATSDR's reports (e.g., PHAs, PHCs).	In addition to low level participation, the community might: 3) Attend meetings and provide health concerns. 4) Contact ATSDR to get on mailing list. 5) Encourage other community members to attend meetings and provide health concerns.	In addition to low and medium levels of participation, the community might: 6) Indicate that they would like more direct participation. 7) Discuss best ways to enhance community participation with ATSDR. 8) Consider forming a community group or ask ATSDR to work with one already established by community. Each site community has specific needs and interacts differently. ATSDR responds to all reasonable requests, continually reminds the community what they can expect from ATSDR, and prioritizes community involvement activities at the site based on available resources.

Table 4-3. Activities That Might Be Conducted at Three Different Levels of Community Involvement and Participation

Phase of Public Health Assessment Process	Community Involvement Activities and Information		
	Low Involvement Site	**Medium Involvement Site**	**High Involvement Site**
Community involvement activities conducted during evaluation of environmental and health data and other information.	None	Update community one or two times via distribution of fact sheet.	Provide more frequent updates (e.g., quarterly via community meetings, through distribution of fact sheets, through newsletters). Conduct various public health activities during evaluation, such as health education, community workshop, an exposure investigation, the release of a public health advisory
Community involvement information/assistance included in document (PHA and other documents as needed) For all sites, include the following: 1) Document community involvement activities. 2) Respond to community health concerns in a clear and concise way. 3) Work with health communication specialists, as necessary, to ensure language in the *Summary*, *Conclusion*, and *Recommendation* sections is suitable for the site-specific audience (see also Section 4.2.5 and Appendix C).	In addition to 1–3 include: 4) Efforts to find community members concerned about site. 5) How community health concerns were obtained. 6) Location of information repositories.	In addition to low level include: 7) Community involvement activities conducted to involve community members and their participation. 8) How community was informed of meeting(s) and other community involvement activities, including the use of electronic media. 9) Any pertinent coordination efforts with community groups, other organizations, the media, and other government agencies.	In addition to low and medium level, include: 10) Community involvement activities conducted to enhance participation by community members and their response. 11) How ATSDR interacted with community groups, either those already formed or newly established with ATSDR's help. 12) How community members participated in planning, assessment, and intervention activities. 13) Indications of mutually beneficial partnership with community, organizations, and other government agencies.

Table 4-3. Activities That Might Be Conducted at Three Different Levels of Community Involvement and Participation

Phase of Public Health Assessment Process	Community Involvement Activities and Information		
	Low Involvement Site	**Medium Involvement Site**	**High Involvement Site**
Community involvement activities conducted during distribution of document (e.g., PHA, PHC, Exposure Investigation) for public comment, if applicable, and then later as final document.	Press release. Copy of document placed in repositories.	Press release. Notification of distribution via flyers or a fact sheet explaining location of document in repositories and also how to obtain a copy of the document from ATSDR. A community meeting if there is enough community interest. Copy of document and accompanying summary fact sheets (if prepared) placed in repositories.	Press release. Notification of document distribution via flyers and/or fact sheets/newsletters, press releases, advertisements, etc. Coordination with local, state, tribal, and federal agencies. Local, state, tribal, and/or congressional briefings. Media sessions and interviews. Community meeting(s). Notification of meeting(s) via flyers, press releases, advertisements, etc. Copy of document and accompanying summary fact sheets placed in repositories.
Community involvement activities conducted during implementation of recommendations in PHA or PHC, such as additional assessments, a health study, or an exposure investigation.	Dependent on the type of recommendations, the site, and the expressed needs of community members.	Dependent on the type of recommendations, the site, and the expressed needs of community members.	Dependent on the type of recommendations, the site, and the expressed needs of community members.

- Since public health assessment documents focus on health issues, you might not want to respond to non-health issues such as certain environmental, property, or liability concerns unless they are in some way related to public health. At a minimum, acknowledge that such concerns were voiced, but that they are beyond the scope of the public health assessment. The site team may direct the concern or inquiry to an appropriate local, state, or federal agency.

4.6.2 How to Present Responses to Community Concerns in the PHA

When developing the section on community concerns and ATSDR responses, you should follow the principles of effective communication described in Section 4.2.5 and Appendix D—that is, you should present the information with clarity, accuracy, respect, and sensitivity.

Respect includes presenting community concerns as they were expressed by the community, without evaluating the concerns. To protect privacy, you should not name the individuals who expressed concerns, although you can name community groups that have raised concerns.

To make the concerns and your responses easier to understand, you might want to present the community concerns as questions posed by the community to ATSDR. For example: "Is the well water in Grant Acres neighborhood safe to drink?" or "Can breathing air from the site cause skin rashes?" Your responses can summarize the evaluation results that answer the question and then can refer the reader back to information discussed previously in the document (e.g., discussions on exposure pathways, toxicologic information). You can briefly summarize the information from other sections if this will help clarify the point you are trying to make, but you should not repeat other sections of the report in their entirety.

4.7 Public Comment Process and Release of Final Public Health Assessment Documents

Once you have assembled a draft document, you may wish to distribute it for review by other public agencies and stakeholders to make sure the data are accurate, current, and complete, and that your conclusions and recommendations are clearly presented and well documented. For PHAs, this is often referred to as the "initial release" or "data validation" PHA. The next step for PHAs is a formal public comment process, described below. (Note: For public health consultations, public comment is not required but can be useful, particularly at sites with a high level of interest or concern. Also, excluding interested community members can potentially foster mistrust.)

4.7.1 Public Comment Process

The public comment process gives the public—particularly the community near the site—an opportunity to review the results of the public health assessment and the agency's conclusions and recommendations, and to provide additional information and comments. In their review of the document, members of the community may provide input on such issues as: Is the document clear and understandable? Has ATSDR taken into account all relevant site information known to the community? Has the agency identified and responded to the community concerns? See also Appendix C (Community Check List).

If ATSDR receives public comments, you will need to consider making revisions to address those comments. You will also need to prepare an appendix for inclusion in the final PHA that presents formal agency responses to all public comments received. After reviewing the comments and making revisions as needed, ATSDR will release the document as a final PHA. The public comment process proceeds through three distinct stages, as described below.

4.7.1.1 Releasing the Draft PHA

The first step in the public comment process is the release of the draft document to the public. To help encourage community members to read and comment on the document, you can develop a simple concise summary (e.g., a fact sheet) describing the PHA's main findings and distribute this summary together with the draft PHA. The summary should capture key findings and recommendations, including public health actions. Communication experts have suggested to ATSDR that the writing should be simple and at a sixth-grade reading level. Health communication strategies developed during the PHA process should influence how you prepare your document. Appendix D provides an example of this type of PHA summary fact sheet.

Proper distribution and publicity are critical to an effective release. You should use a number of mechanisms to get the draft document and summary into the hands of interested community members and to let them know the deadline for receipt of comments and where they should send their comments. Depending on resources and appropriateness, release and publicity mechanisms may include the following:

- Place copies of the draft document and extra summaries for people to take home in all local ATSDR and EPA information repositories.

- Provide a copy of the public health assessment to EPA, the state health agency, and any other agencies that have an interest or have been involved with the site.

- Use your mailing lists and community contacts to send the draft document and summary to all interested parties, including local health departments and community organizations and leaders. If mailing lists are large, you can send a notice, or a fact sheet summarizing the findings, to everyone on the list and ask anyone interested in obtaining a copy of the draft document to request one.

- Announce the availability of the document in a press release to local media.

- Hold a public meeting a few weeks before the document is released, or during the comment period, to further publicize the availability of the document and to encourage community members to review and provide their comments.

- Send letters or flyers about the document to key community contacts and to school, faith, or civic organizations, as appropriate.

- Consider using e-mail as a distribution vehicle in communities where many people have Internet access. Be sure to also make hard copies available to people without Internet access through the mechanisms described above.

4.7.1.2 Receipt of Public Comments

The deadline for receiving comments is usually printed on the cover of the draft PHA. Typically the public is given at least 30 calendar days from the official release date of the document to comment. However, you may decide to extend the public comment period as appropriate to ensure that all interested parties have a reasonable opportunity to comment.

4.7.1.3 Responding to Public Comments

Once the public comment period has ended, you should meet with the other site team members to determine how the agency will respond to each comment. In responding, the team may decide to make a change to the document or—with appropriate rationale—not to make a change. Changes in factual information, such as measurements of contaminant levels, should be supported by valid data. As in any review of scientific documents, when a reviewer identifies what they believe to be factual errors in the draft document, the authors may request valid data or information from the reviewer before making corrections in the document.

As described in Chapter 2, the agency's responses to comments must be summarized in an appendix in the final PHA. The structure of the appendix depends on the number and nature of the comments received. Consider the following factors when compiling and responding to public comments:

- Do not identify the commenter(s) (e.g., individual names or private organizations) when presenting the comments. Provide a brief introduction to the appendix describing the number of comments received from various entities. For example: "ATSDR received a total of 60 comments from a number of parties, including the U.S. Environmental Protection Agency, state health and environmental agencies, community groups, and individual community members."

- Package comments and responses in a way that will maximize readability and best meet the information needs of your audience. For example, a tabular format can work well when presenting a large number of comments: it is sometimes easier to read a table that presents each comment and response side by side.

- Group similar comments together by topic or theme. This will produce a more streamlined presentation of comments and help to lay out the logic behind ATSDR responses. Also, where possible, summarize comments expressing the same question or concern.

- If the comment is succinct and clear, present it verbatim. This will minimize the chance of miscommunicating or misinterpreting the comment. But use some judgment in discerning the need to edit comments for content, length, or both (e.g., separate out distinct points, condense to eliminate redundancy). In all cases, accurately mine the essence of the issue and present it clearly.

- When responding to comments, focus on addressing technical issues related to the public health assessment process or to the PHA's conclusions. Because response to public

comments can be time- and resource-intensive, maintain your focus on public health issues. Acknowledge comments that are not specific to site-related public health issues, but explain that the comment is beyond the scope of the public health assessment. In some cases, you may refer the reader to another agency or group for additional answers.

When considering whether and how to respond to public comments—especially those comments that contain arguably inflammatory statements—remember that in addition to the public comment section of the appendices, a log of all comments received is kept with the official site file as part of the site administrative record. The administrative record is available for public inspection upon written request.

4.7.2 Release of Final PHA or PHC

Once the PHA or PHC is final, you should place a copy of the document (and the document summary if you have developed one) in all ATSDR and EPA information repositories. You can also disseminate the main findings to the community via press releases, newsletters, and/or e-mail.

You should also meet with the other site team members to determine whether a public meeting is needed to announce the results of the PHA. If a public meeting is to be held, be prepared to discuss your responses to public comments, future activities, and other issues associated with the PHA. Criteria for determining whether a public meeting is needed at this point in the process include:

- The number of comments received (an estimate of community interest).
- The advice of community members who have been active in the process.
- Input from key community contacts and the larger community, as indicated in meetings or by telephone.
- The amount and type of media coverage.
- History of community interest (estimated by the number of community-based environmental groups, the number of people visiting the information repository, or calls to ATSDR staff from the community).
- The number of people who have attended past meetings.

4.8 Disseminating Information to the Community

Throughout the public health assessment process you will be readying information for release to the public. Several procedures related to the dissemination of information are required or strongly recommended to ensure consistent products are disseminated and in a timely and efficient manner.

ATSDR has found that direct mail is usually the most effective distribution channel to publicize and disseminate information to specific site communities. Advertisements via local newspaper

and media outlets have also been used effectively, except they are usually much more expensive than direct mail distribution. Other distribution channels can include newsletters or e-mail lists of local organizations or community associations, and bulletin boards (e.g., at stores and supermarkets). The media can also be an important means for disseminating information to the community (see Section 4.4.5).

4.8.1 Developing Mailing Lists

To conduct mailings through direct mail, you must first have a mailing list to use. Different sources of mailing lists may include:

- Mailing list from another government agency that has been working at the site.
- List of addresses created by GIS—a list of addresses can be determined based on an geographic area at or near the site (e.g., within a ½ mile or 1 mile radius of the site).
- List of addresses from U.S. Postal Service.
- Names and addresses of attendees at community meetings from sign-in sheets.
- Other local sources including: local utilities, county tax maps, community group membership lists, and mailing lists created by community members through neighborhood surveys.

Because some of the community members that ATSDR works with may not have access to or be able to use a computer, e-mail mailing lists have seldom been used.

4.8.2 Clearance Procedures

To ensure the quality of ATSDR's external communication, the agency requires that all public information products be cleared for policy, scientific and technical accuracy, propriety, necessity, appearance, format, and editorial quality before release. This mandatory clearance process ensures that all persons associated with and responsible for the material agree with its content and format. All outreach materials, as well as the PHCs and PHAs, *must* be cleared by the director of the originating division or office (or by their designee). In addition, clearance by other offices may also be necessary. For example, clearance by the Office of Communication is typically required for all media-related materials (e.g., press releases, interviews, letters to editors, editorial boards, public service announcements, Web news postings, media sessions, and advertisements).

When the material is ready for release, the author must obtain clearance for each item by filling out ATSDR's clearance form CDC 0.576. Reviewers initialize the form to document their review and clearance. ATSDR's mandatory clearance policy is described in detail in *Policy Guideline: Clearance of Informational Material* (ATSDR 2000).

References

ATSDR. 2000. Policy guideline: clearance of informational material. Atlanta: US Department of Health and Human Services.

ATSDR. n.d. A primer on health risk communication principles and practices. http://www.atsdr.cdc.gov/HEC/primer.html.

Other Resources

ATSDR. n.d. A primer on health risk communication principles and practices. Agency for Toxic Substances and Disease Registry. http://www.atsdr.cdc.gov/HEC/primer.html. Provides a framework for the communication of health risk information to diverse audiences. Discusses issues and guiding principles for communicating health risk and provides specific suggestions for presenting information to the public and interacting effectively with the media.

ATSDR. 1997. An evaluation primer on health risk communication programs and outcomes. Agency for Toxic Substances and Disease Registry. http://www.atsdr.cdc.gov/HEC/evalprmr.html. Can be used to facilitate planning evaluations for risk communication programs. The primer informs decision-makers about what should be communicated, in what form, to whom, and with what expected outcome; identifies performance indicators; and provides guidance on how to use target audience ideas and opinions effectively to shape the risk communication message.

Chess C, Hance BJ, Sandman, PM. 1991. Improving dialogue with communities: a risk communication manual for government. Summarizes practical lessons for communicating about environmental issues. Available from the Center for Environmental Communication (CEC) http://aesop.rutgers.edu/~cec/ at Rutgers University.

EPA. 1991. Air pollution and the public: a risk communication guide for state and local agencies. Air Risk Information Support Center. Research Triangle Park, North Carolina. EPA 450/3-90-025. Provides examples of effective methods in presenting public health risk information to the public.

ATSDR and the National Association of County and City Health Officials (NACCHO). Assessment to Action: A Tool for Improving the Health of Communities Affected by Hazardous Waste. Provides steps and methods to assess community needs and concerns related to hazardous waste sites. Copies are available from NACCHO,1100 17th Street, Second Floor Washington, DC 20036 (202) 783-5550, or at www.naccho.org.

National Association of County and City Health Officials (NACCHO). Don't hazard a guess: addressing community health concerns at hazardous waste sites. A practical hands-on guide. Copies are available from NACCHO,1100 17th Street, Second Floor Washington, DC 20036 (202) 783-5550, or at www.naccho.org.

National Research Council. 1989. Improving risk communication. Washington, DC: National Academy Press; 1989. Provides guidance about the process of risk communication, the content of risk messages, and ways to improve risk communication.

Pereira G, Patterson MB, Lybarger J. 2000. Use of citizen panels to enhance community involvement in environmental public health actions at ATSDR. Environ Epidemiol Toxicol (2000)2(2-3):74-8. Provides information about effective interaction with community assistance panels.

Williams, R.C., M. Lichtveld, S. O. Williams-Fleetwood, and J.A. Lybarger. 2000. Communities at the center: in response to community concerns at hazardous waste sites. Environ Epidemiol and Toxicol (2000)2:56-66. Highlights ATSDR's philosophy pertaining to effective community involvement.

Online Resources

American Industrial Hygiene Association (AIHA) Founded in 1939, AIHA is an organization of more than 13,000 professional members dedicated to the anticipation, recognition, evaluation, and control of environmental factors arising in or from the workplace that may result in injury, illness, impairment, or affect the well-being of workers and members of the community. As part of a continuing education program, AIHA offers an Effective Risk Communication Training Series. http://www.aiha.org/.

California State University at Northridge (CSUN) The Risk Communication Forum provides links to key sources of environmental health risk information and to fellow professionals in the environmental health community. http://www.csun.edu/~vchsc006/tom.html#Introduction.

The Center for Environmental Communication (CEC) at Rutgers brings together university investigators to provide a social science perspective on environmental problem-solving. CEC (formerly the Environmental Communication Research Program) has gained international recognition for responding to environmental communication dilemmas with research, training, and public service. http://aesop.rutgers.edu/~cec/.

The Center for Environmental Information (CEI) is a private, nonprofit educational organization founded in Rochester, New York, in 1974. CEI's Environmental Risk Communication Program offers training, resources and skills to enable all parties involved in an environmentally risky situation to work together toward a mutually acceptable outcome. http://www.rochesterenvironment.org.

University of Cincinnati Center for Environmental Communication Studies The mission of the Center is to enhance the understanding and quality of communication processes and practices among citizen, industry, and government participants who form and use environmental and health policies. http://www.uc.edu/cecs/cecs.html.

The University of Tennessee College of Communication and Information offers seminars on risk communication. http://excellent.com.utk.edu/.

The National Partnership for Reinventing Government has developed a guidance document, *Writing User-Friendly Documents*, to help writers avoid producing complicated, jargon-filled documents. http://www.plainlanguage.gov.

Hotline

Risk Communication Hotline. Responds to questions on risk communication issues and literature, provides information on EPA's Risk Communication Program, and makes referrals to other related agency sources of information. 202-260-5606, Monday through Friday, 8:30 a.m. to 5:00 p.m., E.S.T.

Chapter 5
Exposure Evaluation: Evaluating Environmental Contamination

An important component of the *exposure assessment* process is the evaluation of environmental contamination using available environmental sampling data and, in some cases, modeling studies. You must understand environmental contamination to conduct exposure pathway analyses (see Chapter 6) and determine appropriate exposure point concentrations for health effects evaluations (see Chapters 7 and 8).[1] The following two questions are critical when evaluating environmental contamination data:

- Are the available site data—whether measured or modeled—of sufficient quality and quantity to evaluate the exposure pathways?
- If *critical* data gaps are identified, how should they be filled?

By considering the above questions, you can determine whether the available data for a site accurately and sufficiently reflect exposure conditions, and you can avoid basing important public health decisions on unreliable data or asking for additional data that do not fill critical data gaps.

This chapter will help you answer the questions listed above. Specifically, Section 5.1 describes how you can evaluate the usability of environmental sampling data; Section 5.2 provides guidelines for interpreting modeled data; Section 5.3 indicates how you should consider "background" levels of contamination in your assessment; Section 5.4 lists several approaches for identifying and filling data gaps; and Section 5.5 suggests how you can compile and summarize environmental data in public health assessment documents. Refer to Chapters 6, 7, and 8 for how health assessors should interpret environmental contamination data in drawing public health conclusions and recommending actions to protect public health.

For reference, the text box on the following page describes how the environmental data evaluation fits into the larger public health assessment process.

5.1 Evaluating Environmental Sampling Data

Environmental sampling data indicate the levels of contaminants in water, soil, air, and food chain (biota). ATSDR strongly prefers to base public health conclusions on environmental sampling data rather than modeled data, since they often are direct measurements of exposure point concentrations. Because they are essential inputs to the public health assessment process, you need to understand how to evaluate sampling data. Unfortunately, no single formula or prescribed approach exists for data evaluation, and the level and extent of data review needed often varies from site to site. However, some fundamental concepts apply to most data evaluation exercises.

[1] In limited cases, biological monitoring data may be available to serve as an additional source of information related to possible site-related exposure (see Chapter 6, Section 6.7). In all cases, however, environmental sampling data are critical to the public health assessment and the evaluation of possible exposures.

Environmental Contamination Data:
How do data evaluations fit into the public health assessment process?

Environmental data help characterize possible exposures and are therefore one of the four primary data inputs for the public health assessment process, along with exposure data, health effects data, and community concerns. Health assessors should evaluate the quality and usability of all environmental data, whether measured or modeled, before using them in the public health assessment process. This chapter provides guidance on how to evaluate environmental contamination, but remember that these evaluations are conducted to support other parts of the health assessment process, including the following:

Analysis of exposure pathways: An important task in the public health assessment process is determining whether people are exposed to contamination, because public health hazards (other than physical hazards) cannot exist if exposure does not occur. Environmental data indicate when and where contamination has been detected—insights that are useful for evaluating exposure pathways. Chapter 6 describes the elements of exposure pathways in great detail.

Health effects evaluation: Many different factors determine whether public health hazards will result from exposure. Critical questions to ask are: to what contaminants were people exposed? At what levels? And for how long? Environmental contamination data assist in addressing these questions, and Chapters 6, 7, and 8 describe how to identify substances and pathways of potential concern and how to interpret the environmental contamination data in a public health context.

Though the individual sections that follow present important considerations for evaluating environmental sampling data, you should remember that your ultimate goal in these evaluations is to determine what data you can and cannot use for a public health assessment. This should be something that you consider in all steps of your data evaluations.

5.1.1 Background Information on Environmental Sampling

Before evaluating the validity and representativeness of environmental sampling data, you should first become familiar with the scope and goals of a site's environmental sampling projects. Because different parties collect environmental samples for different reasons, the quality of environmental data for a given site can vary widely from one sampling project to the next. Therefore, having some general background information about the type of sampling conducted is an important first step in evaluating data.

Sampling studies used to support public health assessments can vary widely in scope and purpose, and therefore have varied data quality objectives (DQOs). In many cases, you will use whatever data are available, event hose that were collected in programs not designed for public health evaluations. Regardless of the scope of the individual sampling programs, you should realize that sampling techniques generally fall into one of the following four categories, which have significant bearing on how data are interpreted:

- **Field Screening Techniques.** Sampling teams usually rely on field screening techniques to obtain real-time indications of levels of contamination. This is typically done during

the preliminary site investigations of hazardous waste sites. Examples of field screening techniques include chemical test kits, organic vapor analyzers, Drager tubes, ion-specific probes, and other portable monitoring equipment. These techniques help field personnel quickly identify the presence of certain contaminants and may even areas of relatively high and relatively low contamination. Their outputs, however, often are of limited quality and reliability in terms of precise quantitation and specificity, as the following examples show: Certain surveying devices report measured concentrations as ranges (e.g., "between 50 and 100 [parts per billion]"), rather than reporting actual concentration; other devices report concentrations of groups of substances, rather than for individual compounds (e.g., "all VOCs in air at 2.0 ppm [parts per million]"); and other techniques have relatively high detection limits (see text box below), which often limits their utility in environmental public health evaluations.

Though such observations may be useful for planning more refined sampling programs, they generally are not useful for generating rigorous measures of chemical-specific environmental contamination. Therefore, you should rely on data generated by field screening techniques only when data from more advanced sampling approaches (see below) are not available. In such cases, recommending additional sampling may be appropriate, as described in Section 5.4.

Detection Limits:
What Are They? Why Are They Important?

By definition, the detection limit is the lowest level of contaminant that analytical equipment can discern from the "noise" inherent to scientific measurements. When laboratories report that a contaminant was not detected in a sample, that does not mean that the contaminant was not present. Rather, it means the contaminant was not present at levels that can be reliably measured by the analytical method, and the only conclusion that you can draw is that the actual concentration is somewhere between zero and the reported detection limit. In statistical analyses of environmental sampling data, therefore, a common practice is to replace nondetect observations with surrogate concentrations of one-half the detection limit.

Health assessors need to be wary of how detection limits compare to appropriate health-based comparison values, which Section 7.1 describes in greater detail. If an analytical method has detection limits for a contaminant higher than the corresponding comparison values, the method is not sensitive enough to measure concentrations of potential concern. In such a case, a "nondetect" result will not tell you if concentrations are above or below a comparison value, and further sampling using more sensitive methods might be necessary to evaluate the levels of contamination at the range of interest.

- **Field Laboratory Techniques.** Sampling teams typically use field laboratory techniques when data quality objectives demand quick reporting of reliable data that cannot be generated by available field screening techniques. Quick turnaround of sampling results may be necessary in many circumstances, such as to evaluate whether an acute health hazard exists during site remediation. Field laboratory techniques include a broad suite of

applications, but most rely on collecting samples at a site and immediately analyzing them in an on-site mobile laboratory. An example of a commonly used technique is a mobile gas chromatography and mass spectrometry (GC/MS) unit, which can generate highly precise and accurate data at concentrations lower than many field screening techniques can.

Field laboratory techniques can produce data that meet data quality objectives if proper quality control procedures are used (EPA 1992a). In some cases, however, environmental regulators may request that site investigators have a subset of samples analyzed by both the field laboratory and a stationary laboratory—a step that can help gauge the accuracy of the measurements made in the field. You should carefully review quality control procedures of these sampling techniques (see Section 5.1.2) before using data from field laboratories in a public health assessment.

- **Stationary Laboratory Techniques.** For sampling projects designed to generate data of a known and high quality, site investigators usually collect samples in the field and then ship them to stationary laboratories for analysis (i.e., laboratories in fixed building and not mobile units). These laboratories are generally capable of analyzing samples for many more substances than can be identified by other techniques. Moreover, by following detailed quality assurance/quality control (QA/QC) protocols, these laboratories can produce data that EPA deems to be "legally defensible" and usable for its site-specific human health risk assessments (EPA 1992a).

  For Superfund site investigations, site investigators are typically required to generate data using stationary laboratories in EPA's Contract Laboratory Program (CLP). This subset of stationary laboratories must adhere to specific data quality criteria, such that the data produced under this program are of known analytical quality. Where possible, you should seek out CLP-quality or equivalent data; only use CLP or equivalent data in public health assessments after conducting a brief review of the QA/QC information (see Section 5.1.2.).

- **Unspecified Techniques.** It is not uncommon for health assessors to uncover environmental sampling records that do not indicate exactly how samples were collected and analyzed. For instance, you may find a page of groundwater concentrations in an EPA site file but not supporting information on the depth of the well or the specific analytical methods used to measure concentrations. Or you may access data collected in the early 1970s, prior to when many laboratories routinely used and documented all aspects of quality control. In these instances, you can present and discuss such data in a public health assessment, but you should acknowledge the limitations of the data—primarily that the data may be inaccurate and are of questionable quality.

In summary, stationary laboratory techniques tend to generate data of a higher quality than field laboratory techniques, which tend to generate data of a higher quality than field screening techniques. Though generally true, this rule has many exceptions. For instance, when stationary laboratories use improper analytical procedures, the data they generate may be no more accurate than those generated by field laboratory techniques. Further, some field measurements are clearly

more representative of true environmental conditions than laboratory results (e.g., because the pH of a water sample can change with time, direct field measurements of water pH are usually more representative of actual environmental conditions than laboratory measurements of pH made days later). Due to these and other exceptions, you must take steps to review the validity and representativeness of environmental sampling data. These topics are addressed in Sections 5.1.2 and 5.1.3, respectively.

5.1.2 Validity of Environmental Sampling Data

Environmental sampling is not a perfect science, and many factors can bias sampling results. For instance, surface water samples can have "false positive" results of sampling vials were not cleaned properly before a site investigation, and air samples can have "false negative" results if the sampling canisters leak when being transported between the field and the laboratory or an inappropriate analytical method is used. Given these and a wide rage of other potential problems, you should not assume that all environmental sampling data are accurate. Ask yourself: How confident am I that the reported concentrations truly indicate the levels of contamination in the environmental media? Or, more simply: Are the sampling data valid?

Answering this question is not as easy as it may seem. With extensive sampling projects, for example, an exhaustive data validation exercise can take weeks. However, ATSDR's health assessors generally do not conduct such exhaustive evaluations, except possibly in cases where you have reason to believe environmental sampling data are not valid. In general, you should take the basic steps outlined below to have a certain degree of confidence in sampling results before using them in a public health assessment. Should you decide to conduct a more thorough data validation exercise, there are several references that offer detailed guidance on how this should be done.

The resource list at the end of this chapter provides more detailed information about what you may want to know about sampling and analytical methods. EPA's Guidance for Data Usability in Risk Assessment (Part A) (EPA 1992a), for example, presents an extensive discussion of possible sampling strategies, sampling methods, and analytical methods. The discussion of analytical methods includes a listing of available methods for identifying a number of substances commonly found in water, soil, and air. These methods have been approved by EPA for conducting human health risk assessments at Superfund sites.

Conducting a detailed review of sampling practices and data quality (referred to as a data validation) requires specialized training and a detailed understanding of data quality concerns. Health assessors generally are not expected to conduct in-depth data validations. You should, however, be familiar with the terms and general methods used to validate data, and you should consult with other team members (e.g., analytical chemists), site investigators, or the laboratory that generated the data to clarify questions you may have related to methods used or data validation documentation.

Three general tips are presented below for how you can gauge the validity of environmental sampling data without conducting a detailed review of data quality. These tips are mere

suggestions for helping you assess the validity of the data that you review. For some sites, you may want to examine the validity of data in far greater detail than suggested below.

- **Check the sampling and analytical methods.** The methods that site investigators use to collect samples and analyze them for concentrations of contaminants have a significant bearing on the validity of sampling data. Specifically, the selected sampling and analytical method usually determines what contaminants can be measured and in what range of concentrations. You should identify the methods used in every site investigation and ensure that they are appropriate for the contaminants reported. If you do not know how to evaluate this type of method, you should ask another member of your team to help you.

  Now that EPA has published most of its sampling and analytical methods on its Web site (http://www.epa.gov), this type of evaluation is easier to conduct. Examples of the clearinghouses of sampling and analytical methods follow:

  - EPA's Office of Air and Radiation has posted numerous documents on ambient air sampling methods on its "Technology Transfer Network" Web site (http://www.epa.gove/ttn). This site houses EPA's compendium of methods for measuring concentrations of organic compounds, its compendium of methods for measuring concentrations of inorganic compounds, and its sampling methods for six priority pollutants.

  - EPA's Office of Solid Waste has published an extensive list of methods for measuring various types of contamination in water, wastes, and soils. This list of methods—"Test Methods for Evaluating Solid Waste," also known as SW-846—is also available on-line (http://www.epa.gov/osw).

  - EPA has published guidance for sampling levels of contamination in fish and shellfish, and this guidance also is posted on the Agency's Web site.

  When consulting these sources, you should ensure that the methods used to collect samples have been designed to measure concentrations of those contaminants of particular concern at a site (e.g., those associated with contaminant sources). Also determine whether the detection limits for the methods used are low enough to enable an evaluation of health hazards. That is, detection limits generally need to be lower than ATSDR's comparison values (see Chapter 7). Because some comparison values—such as those for hexavalent chromium—are lower than typical background levels or even levels that can be measured with widely used sampling and analytical methods, you will need to determine whether the methods used for those cases are sufficient to evaluate public health hazards.

- **Review data validation documentation.** The availability of QA/QC documentation varies form sampling project to sampling project. Samples that community members might collect and submit for analysis often do not have extensive supporting documentation, while those collected for remedial investigations in the Superfund

program often are supported by multiple volumes of QA/QC information, known as Quality Assurance Program Plans and Data Validation Reports. In general, data quality documentation addresses field practices, laboratory practices, QA/QC procedures, and data quality indicators. Regardless of the volume of information available, you should consider certain data quality indicators when reviewing the documentation:

- *Completeness* refers to the fraction of attempted sampling events that have valid results and is often expressed as a percentage (e.g., 92% of the samples collected were valid). The completeness of a sampling program is a rough measure of how successfully it was implemented. A sampling program with low completeness might result from field or laboratory personnel having routine problems resulting in a significant number of samples being invalidated. Such scenarios might cast doubt on the overall validity of a sampling program.

- *Precision* in environmental sampling is a measurement of random errors inherent to the process of collecting samples and analyzing them in a laboratory. It is usually quantified by collecting duplicate samples or analyzing samples in replicate. Ideally, concentrations of contaminants in duplicate samples should be equal. In reality, random errors in sampling and analysis almost always cause concentrations in duplicate samples to be different. Highly precise sampling data have relatively low differences in concentrations between duplicate samples; imprecise data, on the other hand, have relatively large differences.

  Precision is usually reported as a relative percent difference (RPD), and most sampling and analytical methods (see Section 5.1.1) specify acceptable ranges of RPDs for environmental sampling. Comparing the reported RPD to these ranges or to a program's data quality objectives should give you insight as to how precise the sampling data are. In some cases, precision may not meet QA/QC criteria, but the data may still be usable for public health assessment purposes. For example, if RPDs in duplicate samples are very different but both measurements are at concentrations considerably lower than ATSDR's comparison values for that substance, obtaining more "precise" data would not be necessary. You may want to consult an analytical chemist, however, when making such judgments.

- *Accuracy* indicates the extent to which measurements represent their corresponding "true" or "actual" value. Site investigators can characterize accuracy in many ways. In some cases, they collect and analyze certified audit samples (i.e., samples with known levels of contamination) and compare them against the measured levels of contamination reported by the analytical laboratory. In other cases, they collect and analyze "blank" samples. When contaminants are detected in the blanks, the sampling results might suffer from a systematic bias introduced by equipment contamination.

  Regardless of the approaches used, site investigators typically characterize the accuracy of their sampling in data qualifiers reported with the sampling results, and you should review qualifiers carefully and understand what they signify. EPA

has published references that describe standard data validation qualifiers in greater detail (EPA 1992a). Where possible, laboratory-specific descriptions of qualifiers should be reviewed because some laboratories might not follow EPA's conventions for reporting qualifiers. The text box on the following page presents important information on data qualifiers and what the most commonly observed ones mean. Consulting with an analytical chemist can help determine whether using a particular set of qualified data is appropriate for your site.

In some cases, you may encounter data that are invalidated (or rejected). These results should be discarded, unless you can justify their use in a scientifically defensible manner. For instance, a laboratory might reject a series of measurements of toluene in soil due to blank contamination. You might find, however, that the measured concentrations—even with the blank contamination—are lower than corresponding health-based comparison values (see Chapter 7). In such a case, you could safely conclude that the amount of toluene in the soil samples is not higher than the health based comparison value.

- **Consult with site investigators, regulators, and technical experts.** Many times, the best source of information for assessing the validity of environmental sampling data is the people responsible for collecting and reviewing the data. These individuals often can give insights on the successes and failures of environmental sampling projects. Contacting site investigators and regulators is particularly important in cases where little or no data validation documentation is available.

The above three steps again are suggestions for how you can assess the validity of environmental sampling data. After conducting your data validation review, you may determine that environmental sampling data indeed suit your needs for understanding levels of contamination at distinct locations. The next step in your evaluation is to examine the representativeness of the environmental sampling data, as described below.

5.1.3 Representativeness of Environmental Sampling Data

You will never review a site that has sampling data that characterize all possible exposures. Typically, the data available for a site characterize levels of contamination at very specific locations and for very specific time frames. A challenge you will face is determining how representative those measured levels of contamination are of other locations and other time frames. Health assessors routinely use their professional judgment to make this determination, erring on the side of caution, and this section provides guidance on how you can do so. In certain cases, however, models are used to estimate levels of contamination at locations that have not been sampled (see Section 5.2) or additional sampling might be recommended (see Section 5.4).

Data Qualifiers:
What are they? What do they mean?

Laboratories that analyze environmental sample and data validation experts who review laboratory measurements assign qualifiers to certain observations. The qualifiers are essentially footnotes to the reported concentration and provide some insights on the actual measurement. Following are definitions for some of the most commonly used qualifiers:

B For organic compounds, a contaminant with a B-qualified concentration was detected not only in the environmental sample, but also in one or more blank samples. In these cases, environmental scientists typically compare the magnitude of the B-qualified concentration to the levels of blank contamination to determine if the data are usable. EPA has guidance on this matter (EPA 1989).

J J-qualified data generally indicate that the reported concentration is an estimated value. This qualifier actually has more subtle meanings depending on the contaminant. In some cases, it means the contaminant was "tentatively identified" and the concentration is an estimate. In other cases, it means that a contaminant was positively identified, but the measured concentration was lower than the quantitation limit. You should review the ampling report carefully to determine what this qualifier actually means. Whether J-qualified data should be used in public health assessments should be reviewed on a case-by-case basis.

Health assessors should be extremely cautious when using J-qualified data, particularly in dose calculations. However, in certain screening applications, these data can be used in a defensible manner. For instance, if the highest measured air concentration is a J-qualified result, but is orders of magnitude lower than a comparison value, one can be reasonably confident that the highest concentration does not exceed the comparison value even though the reported concentration is an estimated value.

R R-qualified data are results that have been rejected for data quality reasons, and the compound of interest may or may not have been present in the original sample. These data should not be used in public health assessments, with very few exceptions.

U U-qualified data indicate that a sample was analyzed for a contaminant, but the contaminant was not detected. The concentration reported with the qualifier is the quantitation limit. Nondetect observations are valid results.

Laboratory analytical staff and data validation reviewers use many more qualifiers than listed above. Health assessors should review sampling reports and other references (e.g., EPA 1989; EPA 1992a) to understand what data qualifiers mean.

Assessing the representativeness of data is typically a subjective task, which draws from your technical understanding of the fate and transport of environmental contaminants—a topic covered in greater detail in Section 6.3. The following questions, and associated examples, should help guide you in determining whether environmental sampling data (from specific locations and times) can be assumed to be representative of exposure point concentrations (which may be at other locations and other times). These questions should not be viewed as a complete guide for evaluating data representativeness, but rather as examples of the thought process you should go through when interpreting environmental sampling data:

- Were enough samples taken to understand the spatial extent of potential exposure?

  Example: At sites with groundwater contamination, you should ask yourself whether the number and placement of monitoring wells are sufficient for characterizing the spatial extent of contamination to which people are most likely exposed and whether an adequate number of residential and municipal water supply wells have been tested.

- How are contaminants distributed? Are there "hot spots"?

  Example: When discharged to rivers, hydrophobic contaminants (e.g., PCBs) tend to accumulate primarily in depositional areas, often resulting in "hot spots." For such sites, you should ask yourself whether sampling locations were selected specifically to identify such areas of elevated contamination.

- Were samples taken in areas most likely impacted by site contamination?

  Example: The nearest ambient air monitoring station to a large municipal landfill is approximately 1 mile downwind. You should ask yourself if this proximity is close enough to capture the highest ground-level (or breathing zone) impacts of the landfill's emissions. Knowing that passive releases from landfills tend to have their highest impacts closer to the source would help in such evaluations.

- Were samples collected over time to understand the temporal extent of contamination?

  Example: For an industrial site that has discharged wastewater to a river for 20 years, with surface water monitoring data available only for the last 5 years, you should ask yourself if the recent data are representative of past levels of pollution. Changes in the facility's production levels and wastewater treatment practices over the years would be important to consider.

- Are the sampling data grab samples or long-term sampling efforts?

  Example: At some sites, the only environmental data you might find are from a single sampling event, say one air sample collected downwind from a smelter. You should evaluate how representative this one sample is of air quality over the

longer term. It is important to remember that lone grab samples only give you a "snapshot" of the overall trends in environmental contamination.

- Is the frequency of sampling adequate to characterize the public health threat?

  Example: Methane is often measured in on-site gas monitoring wells at operating landfills on a weekly basis. However, landfill gas concentrations increase or decrease greatly in just a few hours as a result of climate changes. If people live adjacent to the landfill, weekly sampling might not be sufficient to characterize potentially hazardous acute exposures or physical hazards due to explosion.

- What are the measured concentrations at the point of contact?

  Example: Sampling from a single municipal water supply well shows elevated levels of chlorinated solvents, but water from this and many other municipal supply wells feeds into a complex distribution system before ever reaching homes. For such scenarios, you should ask yourself how much the water is likely to be diluted before reaching a resident's tap. If concerned about water quality at the tap, you may recommend sampling at that location.

- In what forms were contaminants sampled and analyzed?

  Example: When working on a site with extensive electroplating operations, the site owner proposes collecting air samples and analyzing them for chromium. You should ensure that the samples are analyzed for the types of chromium of interest. In this case, analytical methods that can distinguish hexavalent chromium from trivalent chromium should be used. You may also research the electroplating process to determine if any specific metal compounds (rather than the elements themselves) should be identified.

- Based on your knowledge of the site, does the pattern of contamination make sense?

  Example: At a site with air releases of tetrachloroethylene (PCE) from a soil excavation project, you would expect the highest concentrations of PCE to occur in the immediate vicinity of the excavation site and to decay with downwind distance. If concentrations increase with downwind distance, however, you should conduct additional research to understand why. In this case, knowing whether dry cleaners and other sources of PCE are located in the area would help in your evaluation.

In addition to the above general concerns, there are numerous media-specific concerns for evaluating the representativeness of sampling data. This is because samples collected in some media might be representative of contamination over very small areas, while other media-specific samples might be representative of contamination over broad ranges. As an example, when evaluating air releases of contaminants from a ground-level source, you would expect to see the highest concentrations of the contaminant in close proximity to the source, with

concentrations decreasing considerably with downwind distance. Some air pollutants, on the other hand, are known to have minimal spatial variations over broad ranges: ozone, for instance, forms in the air as a product of photochemical reactions, and its concentrations typically have minimal variations over entire cities.

ATSDR's guidance entitled *Environmental Data Needed for Public Health Assessments* (ATSDR 1994) identifies media-specific concerns that you need to evaluate when assessing data representativeness. In all cases, you should question how adequately sampling locations represent exposure conditions at points of known or suspected exposure. Key issues, by medium, are highlighted below.

Groundwater

- Were groundwater samples collected in the aquifer of concern?
- Did sampling occur both upgradient and downgradient of the site and upgradient and downgradient of any groundwater contamination plume?
- Has the temporal and spatial extent of contamination plumes been characterized?
- What is the time frame for sample collection? Had the plume either reached or passed the well location at the time of sampling?
- Were samples for metals filtered (dissolved) or unfiltered (total)? Unfiltered samples are preferred for public health assessment purposes.
- What details are provided on how the groundwater sample was collected (e.g., water collected during well construction, flushed sample, bailed sample)?
- Is field pH reported? Anomalous field pH may indicate problems with the monitoring well construction.
- Are seasonal flow or rainfall events affecting contaminant concentrations?

Soil

- Do sampling results characterize contamination in soils of areas with different land uses (e.g., restricted access areas, roadsides, gardens, farms, residential yards, parks, playgrounds)?
- At what depths were soils sampled? Soil less than 3 inches deep is considered surface soil, and soil deeper than 3 inches is considered subsurface soil. Soil samples representing other depths (e.g., EPA defines surface soil as 0–12 inches deep) are usable, but the depth should be noted.

- Is the type of soil described in the data? If not, you should assume soil includes any unconsolidated natural material or fill above bedrock and excludes human-generated materials such as slabs, pavements, asphalt, concrete, brick, rock, ash, or gravel.

- Were samples collected upwind and downwind of sources of air pollution—both on site and off site—and at "hot spots?" Were samples collected appropriately for identifying "hot spots?"

- Have any soil removal activities (e.g., excavation) occurred that may have changed contamination levels?

- Are the soil samples grab or composite samples?

Soil Gas

- Where are the soil gas sampling locations in comparison to residential populations?

- Were soil gas samples collected to characterize potential exposures or to characterize potential explosion hazards?

- What gases are monitored? Do these include those believed to be found in greatest quantities or the most toxic?

- At what depth is soil gas monitored? Is the monitoring continuous or periodic?

Air

- Over what duration were samples collected (e.g., 1-hour average, 24-hour average, or longer)? How frequently were these samples collected?

- Is particulate matter sampled as TSP (total suspended particulates), PM10 (particulate matter smaller than 10 microns), or PM2.5 (particulate matter smaller than 2.5 microns)?

- Were samples collected at locations upwind and downwind from the source?

- Was the source of concern operating at full capacity when the samples were collected?

- Are the ambient air sampling devices placed in close proximity to a source that may bias the results?

- Are stationary monitors located in areas representative of pathway exposures?

- Were the data generated by a one-time air sampling event or a long-term ambient air monitoring program? (See text box below.)

Surface Water

- Do surface water data include results for samples both upstream and downstream of the primary source of contamination?
- Is there information about the number of surface water samples taken at each sampling station, as well as the frequency, duration, and dates of sampling?
- How does the timing of surface water sampling compare to the timing of site releases?
- Were samples filtered?
- Were samples collected at locations where people have access (e.g., beaches)?

Sediment

- Was the depth of the samples specified?
- Were samples collected at regular intervals, only in depositional areas, or following some other type of scheme?
- Were sediments sampled both upstream and downstream from the site?
- Have any sediment removal activities (e.g., dredging, excavation) occurred that may have changed contamination levels?

Food Chain (Biota)

- Did biota sampling consider the species that people in the area typically eat?
- Did the sampling project consider the species that are most likely to accumulate contaminants? (Note: Vascular plants are much more likely to uptake contaminants from soil than nonvascular plants; fish at higher trophic levels are known to have greater body burdens of persistent contaminants that biomagnify than fish at lower trophic levels; and so on.)
- What age and size of the selected species were sampled? Do these correspond to the age and size of biota that people would likely capture and eat?
- For the species sampled, were levels of contamination measured in the body parts that people typically eat? (Note: In fish sampling studies, site investigators often measure levels of contamination only in fillets; some individuals consume all parts of fish. Furthermore, fish samples that are high in lipids will contain higher levels of certain contaminants such as dioxin and PCBs, and top predators will contain the highest concentrations of metals such as mercury.)

- Are concentrations reported on a wet weight or dry weight basis? (Note: Wet weight concentrations are more representative of exposure point concentrations for most forms of biota.)

Though the above list of questions outlines numerous considerations for evaluating how representative your site's environmental sampling data are of exposure point concentrations, the list is not comprehensive. Using the above questions as a guideline, you should continually question the extent to which the available environmental sampling data represent the range of likely exposure point concentrations.

Sampling Versus Monitoring:
What is the difference?

Environmental sampling for site characterization and environmental monitoring have different purposes. For instance, a state environmental agency might grab an air sample at a site that has just experienced a major process upset. Monitoring usually refers to sampling with some periodicity. As an example, a facility might be required to implement a groundwater monitoring program in which well samples must be collected quarterly. Though the definitions of sampling and monitoring are clearly different, you will often hear environmental scientists use the terms interchangeably. Be sure to use these terms correctly in your public health assessment.

5.1.4 Conclusions About Data Usability

Assessing data validity and representativeness answers two general questions: (1) What environmental sampling data are suitable for making public health decisions? and (2) What data are not suitable for this purpose? Answering these questions requires you to use professional judgment. In some cases, you might decide to use data that other agencies have left out of their analyses; in other cases, you might reject data that others have used. It is your responsibility not only to decide what data are appropriate for the public health assessment, but to justify these decisions, particularly when rejecting data.

As a general rule, you can be confident in environmental sampling data that: (1) are measured by stationary laboratory techniques or rigorously tested field methods (e.g., EPA reference methods for ozone); (2) were collected and analyzed following EPA-approved sampling and analytical methods; (3) are accompanied by thorough QA/QC documentation suggesting the data have been validated or that data quality objectives are met; and (4) adequately characterize potential exposure points. In many cases, environmental sampling data do not meet all four of these criteria. For instance, "TCLP data" (see text box below) are actually not measurements of exposure point concentrations. Such data still can be used in public health assessments, but you will need to identify the data uses and limitations. You also should acknowledge, to the extent possible, how conclusions about potential public health hazards may change if additional information were gathered.

Public health assessments must acknowledge when environmental sampling data are of limited or unknown quality (e.g., data sets are incomplete, no QA/QC procedures are documented, or

QA/QC procedures are inadequate). You should also note when sampling data—even if found to be perfectly valid—are not representative of exposure point concentrations (e.g., soil samples were collected at depth, groundwater samples were filtered prior to analysis, whole body fish samples were collected instead of fillet samples). If possible, you should indicate whether using such data may lead to overestimates or underestimates of exposure point concentrations. You also should consider how well potential exposures and community concerns will be addressed by drawing public health conclusions based on the limited data or by indicating that no conclusions can be drawn until additional sampling has been performed. Section 5.4 discusses this issue further.

The previous guidance outlines considerations for judging where environmental sampling data are valid and usable for the public health assessment process. Ultimately, health assessors do a lot more than judge the validity and utility of such data. As noted previously, environmental data are often used as indicators of exposure point concentrations. Chapter 7 provides specific guidance on how this is done (e.g., using maximum or average concentrations, selecting appropriate comparison values, and generally putting the data into a public health context).

TCLP Data:
What are they? How do they fit into public health assessments?

For many years, EPA has worked to refine its definition of hazardous waste. Currently, EPA has listed many specific types of waste that are automatically considered hazardous. The agency has also identified four characteristics of hazardous waste. These are toxicity, corrosivity, ignitability, and flammability. Wastes that exhibit any of these characteristics, as determined by specific criteria published by EPA, are considered hazardous and must be handled accordingly.

Since 1986, EPA has used the Toxicity Characteristic Leaching Procedure (or TCLP) test to determine if a waste is hazardous by virtue of its potential toxicity. In this test, the waste material is exposed to an acidic solvent that is believed to represent the leaching conditions in a municipal solid waste landfill. Eventually, the solvent is tested for contaminants that might have leached from the waste material. If concentrations of contaminants exceed regulatory thresholds, the waste material may be classified as hazardous.

In short, the results of the TCLP test characterize how mobile contaminants in a waste material might be when placed in the mixed waste stream of a municipal solid waste landfill. The measured concentrations in a TCLP test, therefore, are not direct measures of the levels of contamination in the original waste stream! For instance, a soil waste might be contaminated with lead at 500 ppm, but the TCLP test would indicate the concentration of lead in the leaching solvent (with units, perhaps, of milligrams per liter). Since TCLP test results cannot be converted to levels of environmental contamination, their utility in the public health assessment process is limited. The main conclusion that can be drawn from TCLP test results is the *presence* of certain contaminants in a given sample. The actual concentrations of the contaminant would need to be determined using appropriate environmental sampling methods.

5.2 Evaluating Modeled Data

Environmental sampling data are critical inputs to the public health assessment process, so much so that ATSDR strongly recommends the use of validated sampling data as the basis for public health decisions. Unfortunately, even validated data are often insufficient—whether spatially or temporarily—to characterize all site-specific exposure scenarios. In such cases, models or statistical tools may be used to estimate the nature and extend of contamination, typically for areas or time frames for which relevant sampling data are not available. For example, if current sampling data are available, but past exposures are a critical concern, it might be possible to extrapolate past contaminant concentrations in a particular area with a modeled estimate. Alternatively, if past sampling data are available (e.g., for contaminant concentrations from stack emissions in air before the stack was demolished), it might be useful to model the aerial concentrations so that appropriate sampling locations can be identified. In short, it may be necessary to base public health conclusions on modeling data when environmental sampling data are not available or are very limited. If you do use modeling results as the *only basis* for your conclusions, you may also consider recommending that sampling take place, where possible (see Section 5.4). Obviously, recommendations for environmental sampling generally are most appropriate for characterizing present and future exposures, and not past exposures.

An extremely broad range of models and statistical tools are available to estimate levels of environmental contamination. These include statistical tools that predict the spatial distribution of contamination by interpolating among observed values; mathematical models that hindcast and forecast the fate and transport of environmental contaminants in various media (e.g., air, groundwater, surface water, and soil) from selected input parameters; and graphical tools that help illustrate contamination trends based on statistical analyses of data. Some of the questions that models can help answer include:

- How far will groundwater contamination extend 10 years from now, based on current conditions?
- What were the ambient air concentrations of metals 20 years ago, before this facility installed air pollution controls?
- How will sediment contaminants redistribute after this dam is removed?
- When will the fish be safe to eat?
- How large of an area was affected by a spill or release?
- Where should additional sampling be conducted to assess fate and transport?

The models available to answer these questions range in complexity, from simple screening applications to refined predictive programs. The simple screening models often embody conservative assumptions such that the outputs are upper-bound estimates of the levels of contamination that would be measured in the environment. The refined models, on the other hand, tend to be more rigorous and provide more detailed representations of physical, chemical,

and biologic processes. Ideally, the model you are reviewing or using has been calibrated using site-specific data and its performance has been documented in the scientific literature.
When reviewing modeling studies, you ultimately need to determine how accurately model predictions might represent actual conditions. This determination is essentially an evaluation of model uncertainty, which is extremely difficult to quantify. It is important to note that such uncertainties exist with every model, even those that are touted as being the most realistic representations of environmental media. Though health assessors often defer to experts within or affiliated with ATSDR to conduct detailed model evaluations, you should consider certain basic issues to identify model limitations and uncertainties:

- How thorough is the documentation of the modeling? Can another modeler generate the same outputs from the documentation provided?

- Is the model designed to generate extremely conservative, upper-bound predictions? Or predictions of the actual output values? What is the likelihood that the model underestimates or overestimates results?

- What are the limitations and assumptions of the model? Is it being applied to a scenario for which it was designed?

- Has model performance been documented? Have model predictions been compared to observed values for your site, or for similar sites?

- Has the model been calibrated or have model performance evaluation studies been performed?

- What input parameters were used? How were they determined? Are they realistic? Are the model outputs extremely sensitive to the values of particular inputs?

- How consistent are modeled data and sampling results?

- How broad are the uncertainty bounds on critical model outputs?

- Are you confident that the model outputs are meaningful? Have you reviewed an appropriate use of a model? Or do you think the application is an “abuse” of the model?

> *—Remember, a model is a simplification of what might happen in the environment, based on our knowledge underlying fate and transport mechanisms. All models have assumptions and uncertainties and may not represent actual environmental conditions.*

If you decide that modeling data are appropriate to include in a public health assessment (i.e., when reliable measured data are not available and the modeling study is found to be acceptable), you must prominently distinguish the data based on models from those based on environmental sampling. The public health assessment should describe the model used, especially its uncertainties, limitations, and assumptions. You should consider recommending additional environmental sampling in cases where important public health decisions are based strictly on

modeling data. This decision also may be affected by the nature and extent of community concerns—some community members may not be satisfied knowing that decisions about their health hinge on the results of a modeling analysis.

It should be noted that many journals and books have been published addressing technical aspects of modeling fate and transport of environmental contaminants in specific media. As a result, ATSDR does not expect its health assessors to be capable of critically reviewing all types of modeling studies. If you would like to become more familiar with specific modeling applications, the text box on the following page provides several links to references with much more detailed information on the types of models that health assessors often come across. However, remember that modeling studies can be very difficult to review. If you do not have the expertise to critically review a modeling application, you should seek input from colleagues who are experienced with the model.

5.3 Considering Background Concentrations

Just because a sampling study indicates that environmental contamination exists, that generally does not tell you where the contaminants came from. Ultimately, you will need to evaluate the public health implications of exposure to measured or predicted levels of contamination, regardless of whether chemicals are naturally occurring or result from anthropogenic activities. Yet understanding the contributions from "background" concentrations is an important element of your site-specific analysis. In some cases, contaminants cannot be attributed exclusively to a particular site (e.g., "part of the arsenic in residential soil downwind from the smelter is naturally occurring"); in others, contaminants can be attributed primarily to a given source (e.g., "PCBs are not naturally occurring compounds, and the levels observed in the fish are believed to originate predominately from the capacitor manufacturing plant's discharges"), or multiple sources (e.g., "concentrations of PCE in drinking water downgradient from the commercial/industrial zone may be related to merging plumes from multiple dry cleaning facilities in the area"). It is important for public health assessments to include this perspective.

"Background" is a widely used term, but it does not have a single definition. In fact, two definitions of background are commonly used:

- Naturally occurring ambient levels of substances in the environment that have not been influenced by humans (e.g., metals that are found in soils).

- Anthropogenic levels of substances in the environment due to human-generated, non site-related sources (e.g., lead in soil along a roadway, benzene in ambient air as a result of a city's motor vehicle traffic, radiation in sediments that resulted from fallout from past use and testing or nuclear weapons).

References for Further Information on Fate and Transport Models

In February 2000, EPA established a Council on Regulatory Environmental Modeling (CREM). According to the CREM Web site (http://www.epa.gov/crem/), the CREM is ". . . the Agency's central point to address modeling issues." Though still in its inception, the CREM Web site already provides numerous links to various Web sites that address a wide range of modeling issues. Accessing this site can be a useful first step in learning more about the status and availability of many different environmental models.

Air models: EPA's Support Center for Regulatory Air Models. This Web site includes links to EPA's latest version of the *Guideline on Air Quality Models;* to user guides to many different types of models (e.g., screening and refined, simple terrain and complex terrain, and mobile sources and stationary sources); and to meteorological data sets for locations across the country. The Web site can be accessed at: http://www.epa.gov/ttn/scram.

Subsurface models (soil and groundwater): EPA's Center for Subsurface Modeling Support (CSMoS) is an excellent reference for information on fate and transport models that apply to vadose zone soils and to groundwater. According to the CSMoS Web site, ". . . the primary aims of CSMoS are to provide direct technical support to EPA and State decision makers in subsurface model applications and to manage and support the ground-water models . . ." The CSMoS Web site can be accessed at: http://www.epa.gov/ada/csmos.html.

Surface water and bioaccumulation models: EPA does not have a clearinghouse developed specifically for surface water and bioaccumulation models. However, the Agency's Center for Environmental Assessment Modeling (CEAM) specializes in this field. According to CEAM's mission statement, the center ". . . distributes environmental simulation models and data bases for urban and rural nonpoint sources, conventional and toxic pollution of streams, lakes and estuaries, tidal hydrodynamics, geochemical equilibrium, and aquatic food chain bioaccumulation." The CEAM Web site can be accessed at: http://www.epa.gov/ceampubl/.

Multimedia models: The Analytical Contaminant Transport Analysis System (ACTS) is a software application that environmental scientists can use to evaluate fate and transport in various media, including air, surface water, and groundwater. ACTS uses both deterministic and stochastic techniques. More information on ACTS, which was developed under ATSDR's direction, can be found at: http://groups.ce.gatech.edu/research/MESL/software/acts/acts.htm.

NOTE: This list should not be viewed as an exhaustive account of the available fate and transport models. EPA, consulting companies, researchers, and many other scientists have developed models for environmental applications. Conducting detailed Web searches and literature reviews can help identify these models.

When reading or hearing references to "background" contamination, you should be sure to understand exactly what that means in the context of your site. There are general rules for how to interpret environmental sampling data in light of background concentrations.

- When levels of contamination are higher than background, you can generally conclude that some source—either the site you are evaluating or some other source—has contaminated the media of concern. (Providing you with perspective on your sampling data, not on pinpointing a particular source.)

- When valid and representative sampling data are consistent with background concentrations, you typically conclude that local sources have not significantly impacted the media of concern.

- Finally, when sampling data indicate that levels of contamination are lower than background, there might be a problem. By definition, "background" is supposed to be the naturally occurring or ambient levels of substances in the environment or the levels of contamination that result from anthropogenic sources. If environmental samples consistently show concentrations lower than background, then it is possible that the samples are biased low or that the background levels you have selected are biased high.

This last scenario emphasizes the need for identifying reliable, representative background data. In general, site-specific background data are preferred for use in public health assessments. If not available, background data for the region, state, or nation may be applied. When identifying appropriate background data, you should select high-quality data that are most representative of the site. For instance, when identifying background data for metals in soils you should use soils that have similar physical and geological characteristics as site soils, such as sandy or loamy. Some sources of background data include site investigation reports, data from nearby sites, state and local environmental agencies, or other state and local organizations. Refer to the text box on the following page for tips on where to access background data for certain media.

5.4 Identifying and Filling Critical Data Gaps

After reviewing environmental and modeled data, you still may be missing some information that will help you understand to what substances and at what concentrations people could be exposed. What you will need to decide is whether the missing information is critical and therefore should be highlighted as a data gap or whether the missing information is not essential for reaching public health conclusions. This distinction is important and is best gained through experience, but some examples might help illustrate the difference:

- **Critical data gaps.** In some cases, the available site documentation truly is insufficient for drawing public health conclusions on certain issues. Perhaps surface soil at a site of an unplanned release where the public has access was never sampled, or a drinking water well downgradient from a leaking underground storage tank was never sampled, or the well was sampled but not for the substance you have identified as a concern. These cases are examples of data gaps that must be filled if you are to reach a defensible conclusion. In cases where sampling data are available, you still might decide that the spatial and temporal extent of the sampling—or the quality of the sampling—do not form an

Background Concentrations:
Where are representative background data documented?

There is no single reference that documents background concentrations for all contaminants in all media. The following documents, however, might include reasonable estimates of background concentrations for your site: (also consider accessing similar state sources)

- ATSDR's Toxicological Profiles: In each profile, the chapter titled "Potential for Human Exposure" contains a section named "Levels Monitored or Estimated in the Environment." This is a useful reference for concentrations of contaminants that have been reported in the literature. When accessing these references, note that the chapter often times cites both levels of environmental contamination measured near sources of significant releases and levels that are believed to represent background.

- For soils, the U.S. Geological Survey (http://www.usgs.gov/), the U.S. Department of Agriculture Natural Resources Conservation Service (http://www.soils.usda.gov), U.S. Department of Energy's Office of Environmental Management (http://rais.ornl.gov/homepage/back_com.shtml) and the State Geological Surveys are all potential sources of county, state, and national soil data. In the absence of other more recent or geographically similar information, a 1984 technical paper, released by USGS, provides national background concentrations for metals in soil (Shacklette and Boerngen 1984).

- For sediments, the U.S. Army Corps of Engineers and EPA have worked together to assess the nature and quality of sediments in Federal Navigation Channels, and the sediment sampling data are available from most EPA regional offices. EPA's Council on Regulatory Environmental Modeling (CREM) has a Web site that has sediment data archived for many watersheds. (http://www.epa.gov/osp/crem)

- For surface water and groundwater, background levels will vary from one watershed to the next and from one aquifer to the next, respectively. Health assessors should access background data that applies specifically to the watershed or aquifer of interest. Such data might be documented in site reports or might be accessible from literature searches. EPA and the U.S. Geological Survey often report background data for specific watersheds and aquifers.

- For air, background concentrations can vary widely depending on when they were measured and where. A good reference for levels of organic contaminants commonly measured in air is EPA's Urban Air Toxics Monitoring Program (UATMP). Summary reports from this program are available at: http://www.epa.gov/ttn/amtic/ cpreldoc.html. Be sure, however, to understand how, where, and when the air concentrations were measured before using any UATMP data in your public health assessments.

adequate basis for drawing public health conclusions. You can address these critical data gaps by recommending future sampling efforts; you may also recommend additional sampling to confirm results from modeling studies that predict current and future levels of contamination. If the data gap pertains to past exposure, which obviously cannot be characterized by sampling, modeling studies or exposure investigations may be warranted.

- **Data gaps that do not necessarily need to be filled.** In other cases, however, you might recognize that your site has gaps in sampling data, but these gaps do not necessarily preclude you from reaching a defensible public health conclusion. An example of this is for sites with eliminated exposure pathways. If a site has an unplanned release to soil, but no one has access to the area where the spill took place, then sampling of the contaminated soils is unnecessary to answer public health questions. As another example, you might be able to make judgments about levels of contamination in one medium based on other information you have available for your site. For instance, a site with metal-contaminated sediments might have fish tissue sampling data for species at higher trophic levels (i.e., at the top of the "food chain"), but not for species at lower trophic levels. Knowing that mercury biomagnifies in the food chain, you can evaluate exposures assuming that mercury concentration in the fish at lower trophic levels likely does not exceed that at higher trophic levels. Such an approach not only is scientifically defensible as a first approximation in most ecosystems, but would help ensure that the available resources are not spent collecting information that probably will not change your public health conclusions.

  (Note: Any approach to assuming contaminant concentrations obviously varies among sites and with the contaminant(s) in question. For example, for organic compounds like PCBs or dioxins, species-specific lipid content typically influences the concentrations in fish more than trophic level hierarchies. It is always critically important to consider the specific characteristics of your contaminants of interest.)

Typically, when you conclude that data gaps need to be filled, ATSDR will recommend that other agencies or organizations, such as EPA, tribal groups, state agencies, or site owners, conduct sampling. In a few cases, ATSDR will conduct additional sampling itself. (State-of-the-art modeling tools may also be appropriate in cases where ATSDR has sufficient reason to believe these tools will help define past exposures or help determine where sampling should be conducted). Regardless of who conducts the sampling, you should be familiar with the components of designing and implementing environmental sampling programs, because health assessors often are asked to review sampling plans or help develop them.

Understanding the goals of the sampling program is essential to designing and implementing a sampling program that will meet public health assessment needs. Asking why sampling is being conducted is critical. For instance, at a site with soil contamination and pending remediation projects, do you want to gather samples to confirm that reported soil excavation was completed? Or do you need information about the substance concentrations at exposure points? If the former, a quick and efficient field screening sampling program may be all that is necessary to meet your goals. If the latter, a detailed field sampling program meeting the more stringent CLP methods

and QA/QC requirements may be necessary. Other considerations for establishing goals of sampling programs include:

- What public health value will be added by completing the sampling program?
- How will sampling characterize the spatial extent of contamination?
- How will sampling characterize the temporal extent of contamination?
- Will follow-up sampling be necessary?

After establishing the sampling goals, sampling and analysis plans are developed to ensure that the sampling effort meets these goals. As part of preparing a plan, background information about the site is collected to understand site conditions that can impact the implementation of a sampling program. Conditions to consider include presence of other sources of contaminants, access restrictions, physical hazards, and location of existing sampling stations. These factors will influence where samples can be collected and the logistical considerations that need to be addressed as part of program implementation. The sampling and analysis plan should act as a guide for the agency or organization conducting the sampling program. Components of a plan include:

- Environmental media to be sampled.
- Analytes to be measured within these media.
- Sampling and analytical methods.
- Proposed sampling locations.
- Sampling schedule (frequency and duration).
- Data quality objectives, which consider precision, accuracy, completeness, and representativeness.
- QA/QC measures (e.g., use of duplicate samples and replicate analyses to characterize measurement precision; use of audit samples to assess measurement accuracy; analysis of field blanks to determine whether sampling equipment are contaminated; specification of sample handling procedures, such as holding times and chain-of-custody requirements; types of equipment calibration).
- Health and safety considerations for field personnel.

Other agencies, particularly EPA, have published far more extensive guidance on this topic. Some references for conducting sampling are included at the end of this chapter, but environmental agencies are an excellent source for this type of information.

5.5 Summarizing and Presenting Environmental Data in the Public Health Assessment Document

After evaluating a site's environmental sampling data, you will begin to evaluate the public health significance of the measured or estimated levels of contamination (see Chapters 6, 7, and 8). As you proceed with these evaluations, you eventually will need to summarize and document the data in the public health assessment document. Though seemingly straightforward, this task is often quite challenging, especially for sites with large volumes of sampling data available. Because the amount and types of sampling data vary greatly from one site to the next, there is no single protocol to follow for how to summarize and present data. This section does, however, provide several guidelines that can be followed when summarizing and presenting data.

Above all else, summaries of environmental sampling data should focus on the most important aspects of the site or issue being evaluated (see text box below). For example, a site might have years of quarterly monitoring data of contaminated groundwater. If no residents have ever been exposed to this groundwater, however, the public health assessment probably does not need pages of summary statistics of the sampling data. Detailed summaries are most appropriate for potential and completed exposure pathways (see Chapter 6) and exposure point concentrations (see Chapter 7).

The text of the PHA or PHC (usually the *Discussion* section) should provide a brief narrative summarizing the available environmental sampling data. The text may include a discussion of trends in the data. The discussion of trends can include descriptions of spatial distribution, "hot spots," concentration changes in time, and substance differences between media. The text should also describe the limitations, quality, and usefulness of the data. Ultimately, you will have to use your judgment in deciding how to present and summarize data. Following are some questions that health assessors typically ask regarding data presentation, along with some guidance on typical presentation approaches:

- **What format should be used to display the information?** You have many different options when deciding how to present site data. The data and information can be described in text, tables, charts, maps, and other formats. The most appropriate selection depends on the data that are available and the concepts you are communicating. For instance, to illustrate the spatial extent of a contaminant plume, maps are especially helpful (see Figure 5-1); to show how the number of days with potentially unhealthy ozone concentration has changed each year during the past 25 years, a chart is a useful tool (see Figure 5-2); and to list sampling summary statistics for many different substances that have been measured at a surface water monitoring station, a table is an appropriate display (see Table 5-1). Regardless of the display used, the text should also describe the contents of the summary.

  Further, all displays developed should be standalone. As shown in the examples, always include the source of the displayed data, acronym definitions, and specific notations that might be needed to support interpretation of the display.

Presenting Environmental Data in PHAs:
Should health assessors summarize every sampling event? What can be left out?

Public health assessments should provide meaningful summaries of environmental contamination data. Listing every data point for every contaminant in every medium is absolutely not necessary. The public health assessment should communicate the information that is most important to the readers, without overwhelming them with unnecessary details.

Health assessors generally do not know what contamination data are essential to communicate until *after* they have completed their health effects evaluations (see Chapters 7 and 8). Thus, even though tips on summarizing and presenting environmental data are discussed here, the final decision on what data are most important to convey is usually made much later in the public health assessment process. As a general rule, data summaries should be most detailed for the contaminants of greatest concern in the exposure pathways of greatest concern, and brief summaries need be prepared for other contaminants.

- **How extensive do data summaries need to be?** Once again, the answer to this question depends on the type and amount of data available for a site. For example, at a site where the only sampling data available are roughly a dozen tap water "grab" samples collected by a concerned resident, it makes sense simply to list the result of every single sample. At a larger site with multi-media contamination, however, presenting every sampling result would likely cause the public health assessment to be incredibly long. In these cases, it makes sense to condense large volumes of sampling data into summary tables (see the next bulleted item for more details on this). For other applications, it might be possible to summarize an extremely large volume of sampling data in just one sentence. For example, "the state has sampled the air for sulfur dioxide for 20 years but has never found a concentration higher than EPA's health-based air quality standards."

  When deciding how extensive data summaries should be, you should ultimately consider the information needs of the audience. For instance, at sites with widespread contamination, residents often want to know how levels of contamination vary across neighborhoods, or even from one house to the next. Your data presentations should be sensitive to these needs, to the extent possible.

- **What pieces of information need to go into data summaries?** You may find presenting substance concentrations in the text useful when only a few substances are discussed, but overwhelming when many substances are discussed. Regardless of how much information you present in the text, you should include summary tables that provide more detailed information about the substances found at the site. Where possible, summary tables should list:

  - Contaminants detected.
  - Range of concentrations
  - Locations and date of the maximum concentration

- Central tendency value (e.g. mean concentration or 95 percent upper confidence limit for the mean)
- Frequency of detection (overall)
- Appropriate health-based comparison values or screening values (see Chapter 7)
- Frequency of detection (above comparison values)
- Uncertainty (measures of error)

For a better feel for how sampling data are reported in public health assessments in practice, you may wish to consult with your experienced colleagues and browse through a selection of ATSDR's public health assessments, many of which are available on the agency's Web site (http://www.atsdr.cdc.gov/HAC/PHA/). You should remember, however, that every site presents unique data summary challenges, and a data summary format used for a given site might not be appropriate for your site.

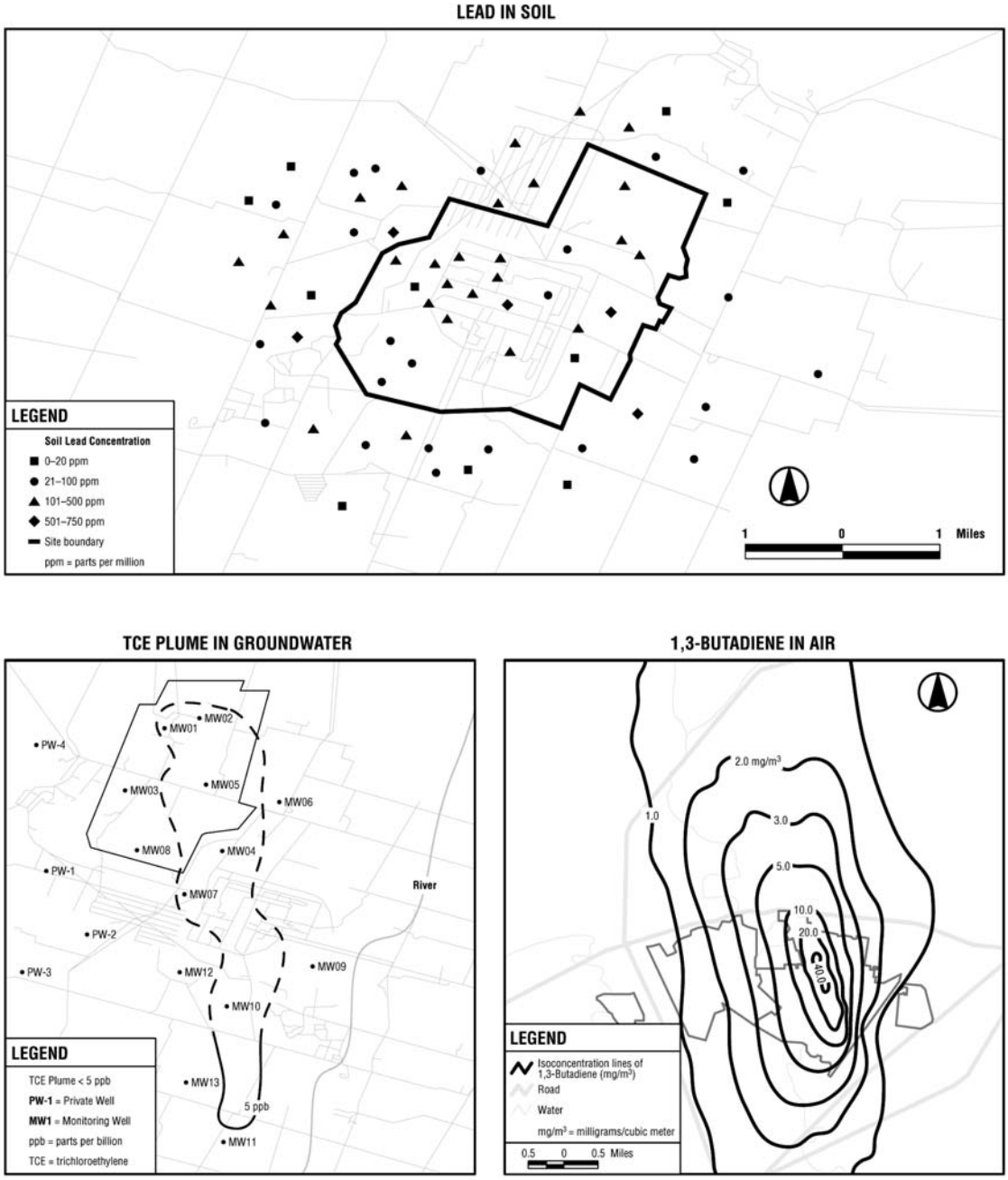
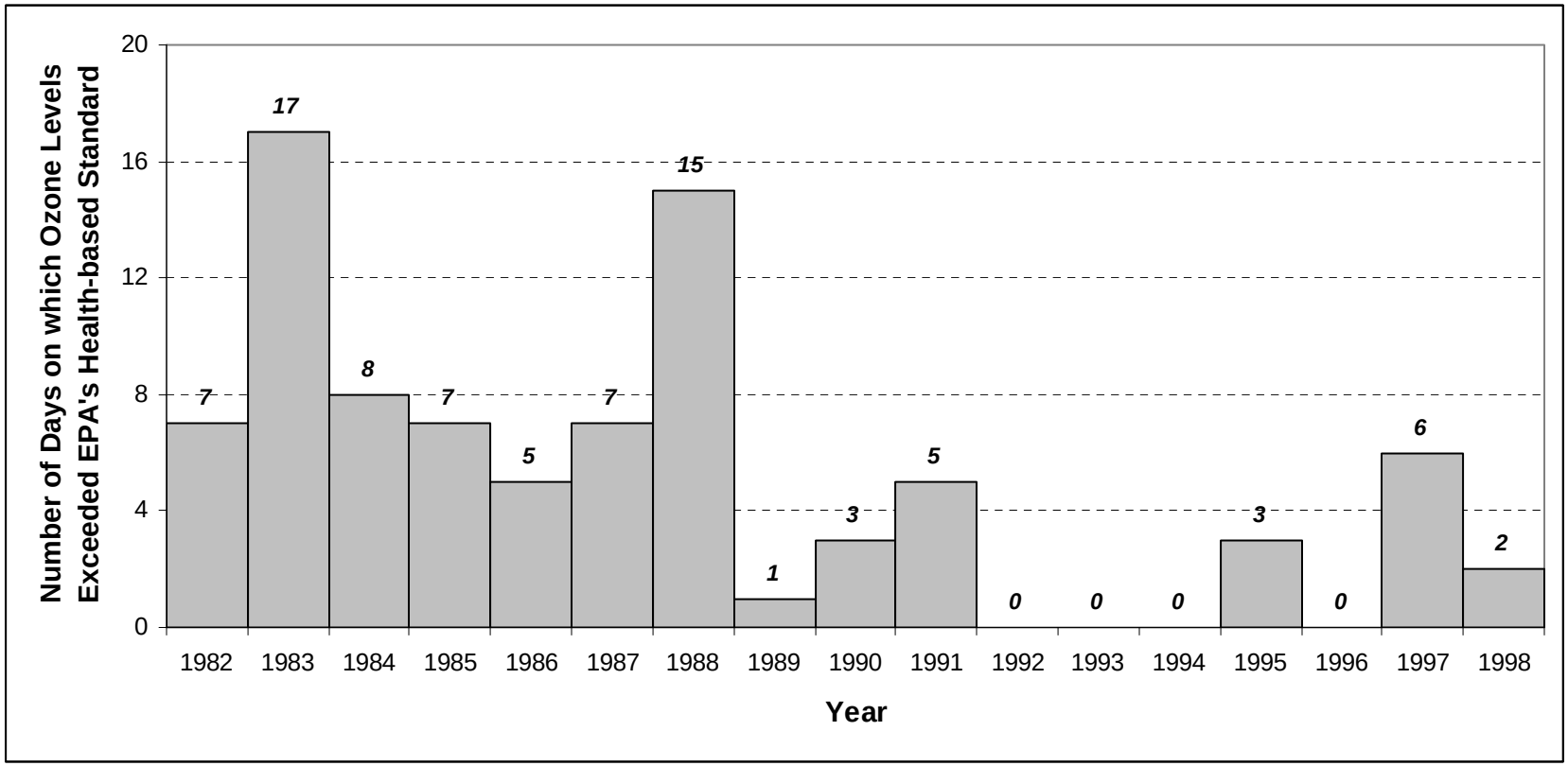


Figure 5-1. Examples of Maps Used To Display Environmental Data



Source: Data in figure are based on ozone monitoring data collected at Site X and reported to EPA's Aerometric Information Retrieval System.

Figure 5-2. Example Use of a Chart to Display Data:
Number of Exceedances of EPA's Health-based Ozone Standard at Site X since 1982

Table 5-1. Example Use of a Table to Display Data:
Surface Water Sampling Data for Selected Metals Along the XXX River

Contaminant	Number of Samples	Number of Detections	Range of Concentrations Measured at Levels Greater Than the CV (ppb)	Health-Based Comparison Value (CV) (ppb)	Type of CV	Number of Detections Greater Than CV
Aluminum	100	99	21,200–123,000	20,000	EMEG-ci	6
Barium	100	99	839–3,280	700	RMEG-c	7
Beryllium	106	28	9.1	4	MCL	1
Chromium	102	83	34.7–151	30	RMEG-c	4
Copper	100	99	2,810	1,300	MCLG	1
Manganese	99	99	576–84,900	500	RMEG-c	98
Mercury	100	97	2.2–43.9	2	MCL	53
Nickel	102	65	219	100	LTHA	1
Silver	105	80	50.2–308	50	RMEG-c	6
Thallium	103	17	0.51–54	0.5	LTHA	9
Vanadium	103	58	31.4–172	30	EMEG-ci	10

Notes: Source of data: (REFERENCE).
Concentrations listed are *total metals* in surface water; detailed data for antimony, arsenic, cadmium, lead, and zinc are shown in a separate table.
All samples were collected after field personnel vigorously disturbed sediments at the sampling locations.
For contaminants with multiple health-based comparison values, the lowest comparison value was selected for this presentation.
Abbreviations used (see Chapter 7 for definitions of these values):

EMEG-ci	Environmental Media Evaluation Guide for children's intermediate exposure (ATSDR)
LTHA	Lifetime Health Advisory for drinking water (EPA)
MCL	Maximum Contaminant Level for drinking water (EPA)
MCLG	Maximum Contaminant Level Goal for drinking water (EPA)
ppb	parts per billion
RMEG-c	Reference Dose Media Evaluation Guide for children's exposure (ATSDR)

References

ATSDR. 1994. Environmental data needed for public health assessments: a guidance manual. Atlanta: US Department of Health and Human Services. March 1994.

EPA. 1989. Risk assessment guidance for superfund. Volume 1. Human health evaluation manual. US Government Printing Office. Publication No.: EPA/540/1-89/002.

EPA. 1992a. Guidance for data useability in risk assessment (part A). Publication No.: 9285.7-09A. PB92-963356. http://www.epa.gov/superfund/programs/risk/datause/parta.htm.

Shacklette H, Boerngen J. 1984. Element concentrations in soils and other surficial materials of the conterminous United States. Washington: US Government Printing Office. US Geological Survey Professional Paper 1270. http://pubs.er.usgs.gov/pubs/pp/pp1270.

Other Resources

Note: The first two of these resources are written specifically for remedial investigations at Superfund sites, but the information they contain is broadly applicable.

EPA. 1992b. Guidance for data useability in risk assessment (part B). Publication No.: 9285.7-09A. PB92-963356. http://www.epa.gov/superfund/programs/risk/datause/partb.htm.

EPA. 1998. Test methods for evaluating solid waste, physical/chemical methods, revision 5. http://www.epa.gov/epaoswer/hazwaste/test/main.htm. April 1998.

EPA. 1999a. Data validation standard operating procedures for Contract Laboratory Program routine analytical services. Version 2.1. U.S. EPA Region 4 Science and Ecosystem Support Division. Office of Quality Assurance. http://www.epa.gov/region4/sesd/oqa/rassop.html.

EPA. 1999b. Compendium of methods for the determination of toxic organic compounds in ambient air—second edition. Publication No.: EPA/625/R-96/010b. http://www.epa.gov/ttn/amtic/airtox.html.

EPA. 1999c. Compendium of methods for the determination of inorganic compounds in ambient air. Publication No.: EPA/625/R-96/010a. http://www.epa.gov/ttn/amtic/inorg.html.

EPA. 2004. List of designated reference and equivalent methods (For measuring ambient air concentrations of criteria pollutants). http://epa.gov/ttn/amtic/files/ambient/criteria/ref804.pdf.

EPA. 2000a. Data quality objectives process for hazardous waste site investigations. Publication No.: EPA/600/R-00/007. http://www.epa.gov/quality/qs-docs/g4hw-final.pdf.

EPA. 2000b. Guidance for assessing chemical contaminant data for use in fish advisories volume 1: fish sampling and analysis. Third Edition. http://www.epa.gov/waterscience/fishadvice/volume1.

Chapter 6
Exposure Evaluation: Evaluating Exposure Pathways

A critical early step in the public health assessment process is evaluating exposure pathways. The goal of exposure pathway evaluations is to identify likely site-specific exposure situations and answer the questions: Is anyone at a given site exposed to environmental contamination? Under what conditions does this exposure occur?

This chapter describes how to clearly define and explain exposure pathways:

- Section 6.1 defines exposure pathways and identifies the five elements of a pathway.
- Sections 6.2 through 6.5 outline considerations for evaluating these five elements.
- Section 6.6 offers guidance on how to make an overall judgment on a given exposure pathway: Is a pathway completed or potential? Can it be eliminated from analysis altogether?
- Section 6.7 discusses exposure investigations and when they might be appropriate for filling critical information gaps.
- Section 6.8 describes how to document information on exposure pathways in public health assessment documents.

Figure 6-1 illustrates the overall process of evaluating exposure pathways. As the figure shows, health assessors typically evaluate exposure pathways *before* they conduct health effects evaluations (see Chapters 7 and 8). This order is logical because extensive health effects evaluations are not necessary if people are not coming into contact with environmental contamination. When reading this chapter, however, keep in mind that exposure pathway evaluations eventually inform the health effects evaluations, if they need to be performed. Specifically, thorough exposure pathway evaluations should define the points of exposure, concentrations of environmental contamination at these points, and the populations that are potentially exposed.

6.1 Exposure Pathway Evaluation

Every site presents unique challenges and exposure scenarios. The health assessor considers site-specific factors that might enhance, prevent, or modify exposures to environmental contamination. Environmental health professionals use “exposure pathways” to evaluate the specific ways in which people might come into contact with environmental contamination.

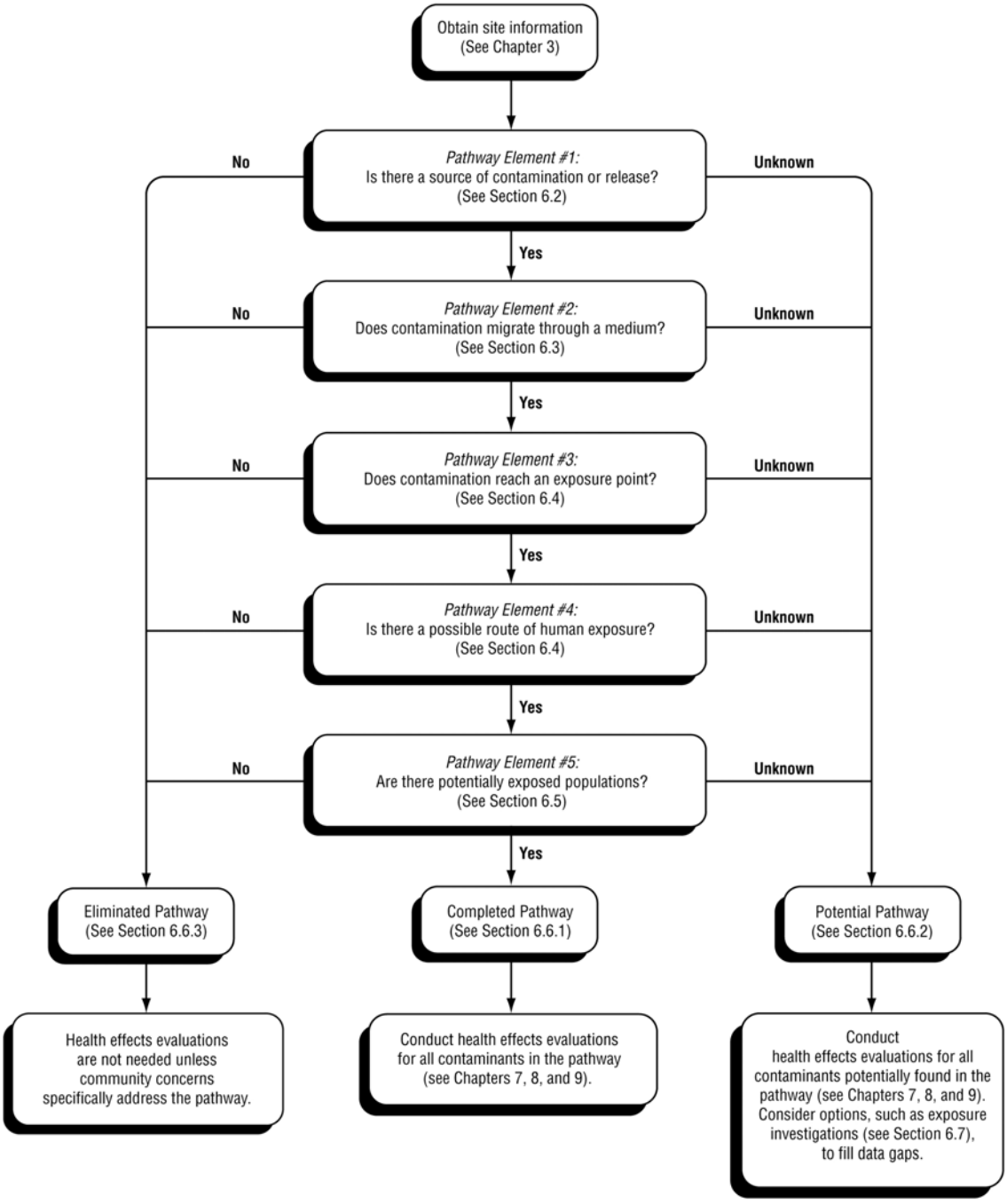
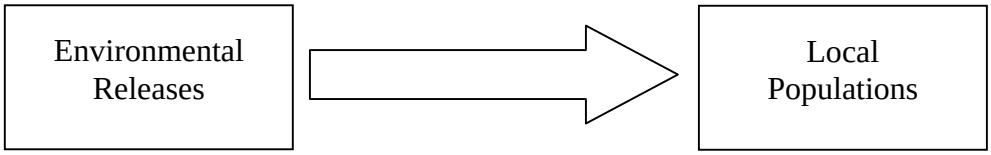


Figure 6-1. Evaluating Exposure Pathways

As the schematic below shows, an exposure pathway is the link between environmental releases and local populations that might come into contact with, or be exposed to, environmental contaminants. An exposure pathway evaluation, therefore, determines if site contaminants have been, are, or will be in contact with local populations. In other words, it answers the key question: Could people be exposed to site-related contaminants? Past, current, and future exposure conditions need to be considered because the elements of an exposure pathway typically change with time.

Exposure Pathway



6.1.1 The Five Elements of an Exposure Pathway

ATSDR environmental health scientists study exposures in the context of the following five exposure elements:

Element 1: The contaminant source or release. Sources may include drums, landfills, and many others which may release contaminants into various media. Refer to Section 6.2 for further information.

Element 2: Environmental fate and transport. Once released to the environment, contaminants move through and across different media and some degrade altogether. Section 6.3 describes these processes in detail.

Element 3: Exposure point or area. As Section 6.4 reviews, this is the specific location(s) where people might come into contact with a contaminated medium.

Element 4: Exposure route. The route is the means by which people physically contact environmental contamination at the exposure point (e.g., by inhalation, ingestion, or dermal contact). Section 6.4 also addresses this issue.

Element 5: Potentially exposed populations. Section 6.5 offers guidance on how to identify and characterize populations that may come or may have come in contact with contaminants.

These five elements largely determine to what extent exposures may have occurred, may be occurring, or may occur in the future at and around a site. Though you may find that some elements require more detailed evaluations than others, reviewing these elements will help you identify exposure situations that require further investigation for a public health assessment. *All five elements* of an exposure pathway must be present to consider that pathway "complete," as Section 6.6.1 describes. Note, however, that a complete exposure pathway does not necessarily

mean that a public health hazard exists, a finding that should be communicated early. Rather, specific exposure conditions, such as the route of exposure and the magnitude, frequency, and duration of exposures need to be examined more closely to evaluate possible health implications of the exposures (see Health Effects Evaluation in Chapters 7 and 8).

Section 6.6 provides additional guidance on the three different categories of exposure pathway information commonly used in public health assessments—completed, potential, and eliminated—and how health assessors should evaluate them.

6.1.2 Developing a Site Conceptual Model

Different people have different ways of evaluating exposure pathways at their sites, but a common approach involves developing a site conceptual model, which helps you envision how people might come into contact with environmental contamination. Regardless of the site-specific nuances, developing a site conceptual model will ultimately help you visualize how contaminants move in the environment at your site and how people might come into contact with these contaminants.

Figure 6-2 is an example of a schematic that may form the basis of a site conceptual model for a site with a pile of waste drums. The schematic indicates the various ways in which contaminants can move from the source through media to points of exposure. Naturally, the model for your site will depend entirely on site-specific conditions. For instance, if the pile of waste drums shown in Figure 6-2 were located in a lined landfill with leachate controls, contaminants likely would not enter the groundwater and move off site.

The information presented in Figure 6-3 is another way of presenting a site conceptual model for the pile of drums. This type of diagram more explicitly outlines examples of some factors you should consider when analyzing the exposure pathways at your site: What media are affected? What media transport contaminants from the source to exposure points? Where are the exposure points? What are the potentially exposed populations? Sections 6.2 through 6.5 outline the thought process for evaluating the five elements of exposure pathways, but having a detailed site conceptual model will help in these evaluations.

Developing a site conceptual model early in the public health assessment process ultimately will help you prioritize pathways evaluations. For example, consider a closed landfill site with homes immediately adjacent to the landfill. Such sites usually produce some level of both groundwater and soil gas contaminants. If information collected early in the process indicates that the municipal water supply for homes is from a reservoir located many miles away, then researching the groundwater contamination pathway is clearly not a priority. If, on the other hand, on-site soil gas measurements indicate methane levels many times above the explosive limit, the migration of flammable gases into homes would require immediate investigation. Therefore, by developing a site conceptual model early in the process, and by periodically revisiting this model, you can ensure that you address the most critical public health issues in a timely manner.

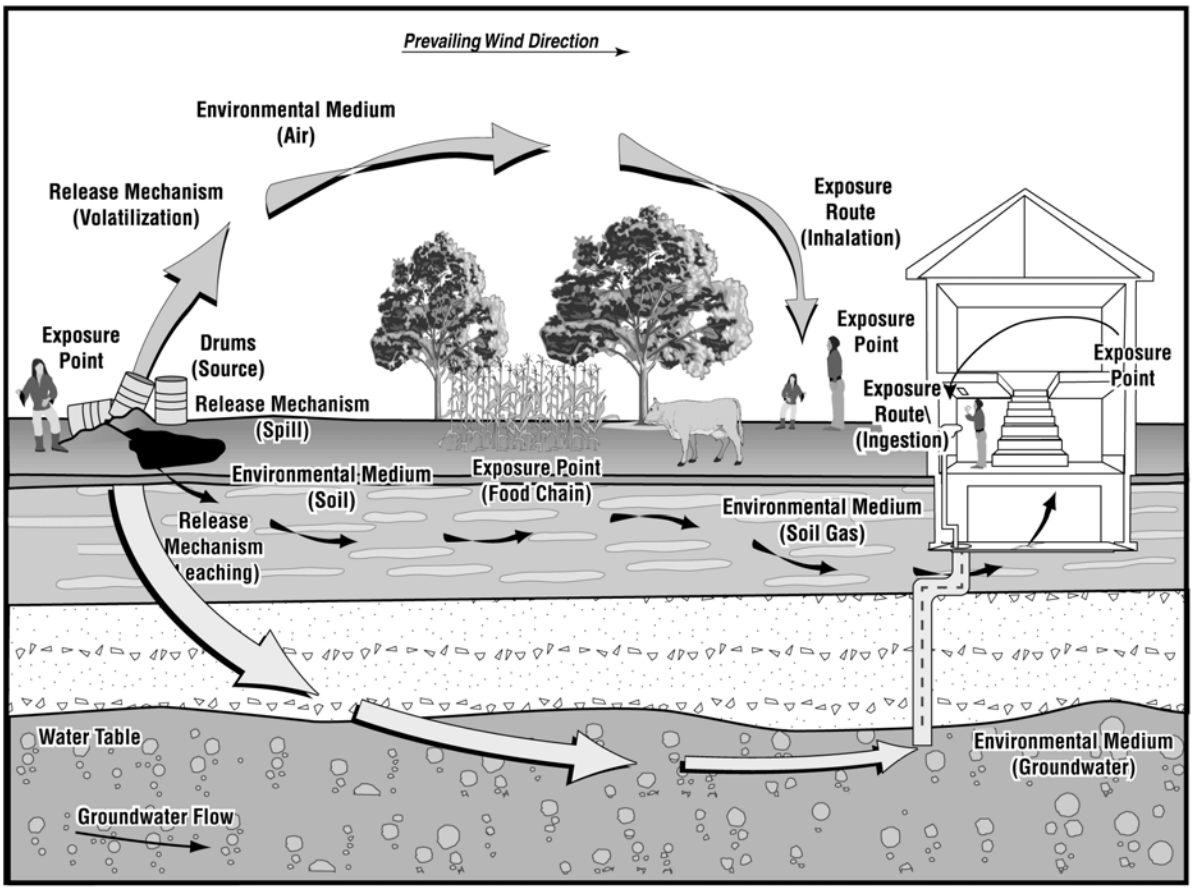


Figure 6-2. Site Conceptual Model—Exposure Pathway Schematic

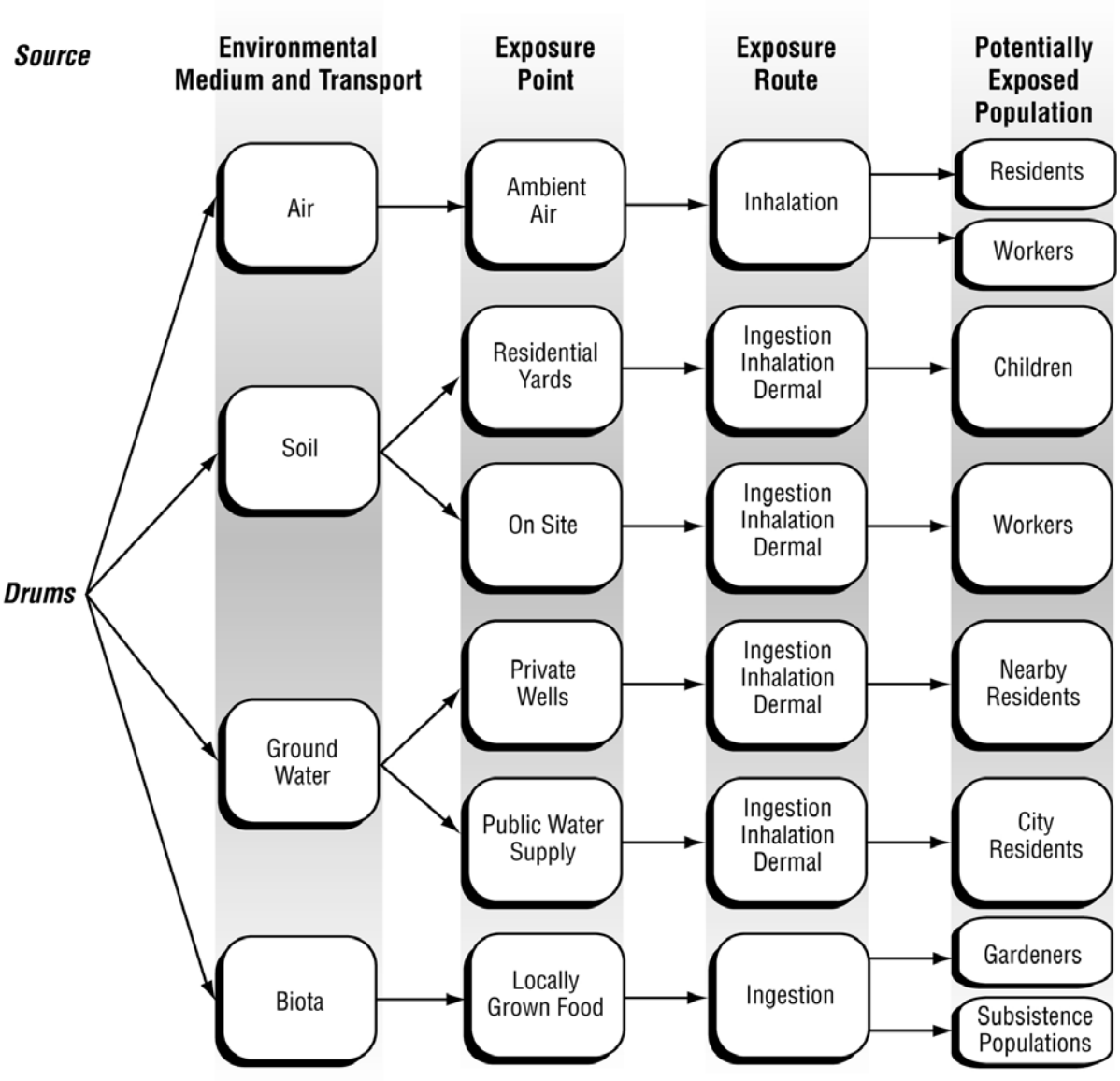


Figure 6-3. Site Conceptual Model—Exposure Pathway Evaluation

6.2 Contamination Source(s) and Releases

Exposure pathways start with a source of contamination. Section 6.2.1 defines this term and offers guidance on how to identify sources. Section 6.2.2 describes how to characterize the environmental media that sources of contamination may affect. Public health assessments need to consider both the sources of chemical public health hazards and physical public health hazards. Section 6.2.3 presents considerations for addressing physical hazards.

6.2.1 Identifying Contamination Sources

A contamination source is, as the term implies, the origin of environmental contamination. Identifying possible contamination sources helps determine what environmental media may be affected and how hazardous substances might reach populations at or near a site. Examples of contamination sources include, but are not limited to, the following:

- Drums
- Tanks
- Buried waste
- Emission stacks and vents
- Landfills
- Lagoons
- Impoundments
- Open burning areas
- Detonation areas
- Airfield and fire training areas
- Waste piles
- Spills
- Disposal pits or trenches
- Pipes/culverts

Some sites have just one contamination source, but many sites have numerous sources. Each source represents a location—a point or area—where a release of contaminants may be occurring or may have occurred. Knowledge of a site's sources is critical because it enables you to determine whether all possible receiving media have been adequately studied. For example, if the source of contamination is a leaking underground storage tank, reviewing levels of contamination in soil, soil gas, and groundwater will be necessary to accurately determine if people are being exposed.

Sometimes, you may identify elevated contaminant levels, but may not be able to identify the original source of contamination. For example, elevated levels of lead (compared to background) may be detected in site soils but the source of the lead might not be identified. In such cases, you might conclude that a source of contamination existed at some point in the site's history, though the details of the original release might not be known. In other cases, the source of detected contamination may be upgradient of your site.

To identify possible contamination sources, health assessors review site descriptions and data from site investigation reports (e.g., RI/FS and other environmental reports) (see Chapter 3). In most cases, information on sources of contamination is well-documented in existing reports, largely because environmental investigations often are designed to conduct sampling at known or suspected source areas and in potentially affected media. Studying site plans and maps can provide additional perspective on the exact locations and possible exposure implications of contamination sources.

It is important to have information on how sources of contamination change over the years. Such insights can be gleaned from the following considerations:

- *History of the site*. By interviewing site contacts and local residents, reading reports, and reviewing files on past and current site activities, you can find out whether contaminants have been intentionally or unintentionally disposed of or released at a particular location. More importantly, you can find out exactly when those releases occurred and how long they persisted.

- *Operating period.* Simply knowing the window of time a site operated can tell you the time period during which certain sources may have existed—a crucial insight for determining lengths of possible exposures.

- *Source controls or remedial actions.* By identifying when specific control measures or remedial actions were implemented at a site, you can gain insights on how environmental releases have been mitigated. Examples of such controls include landfill liners, leachate collection systems, scrubbers, wastewater treatment systems, and baghouses. Knowing whether any cleanup actions have taken place will also inform your evaluations of sources.

- *Other contributing sources.* Evaluating the potential for other sources or releases in nearby areas also provides useful perspective, particularly for air contamination. For instance, an emissions test might find that landfill vents release 10 pounds of benzene to the air in a year. If the site is in an urban area, further research would likely reveal that this emission rate is dwarfed by benzene emissions from motor vehicles, gasoline stations, and other sources.

Ultimately, you will use information on contamination sources for perspective on the types and durations of possible exposures. Keep in mind that, when identifying contamination sources, you will need to clearly indicate what is known about the type and extent of contamination at the source and at the receiving media. In addition, you should clearly state whether contamination sources have been adequately characterized, whether source areas have been remediated, and how the available information affects the ability to characterize exposures.

6.2.2 Identifying Affected Media

After identifying the contamination source, you should identify all environmental media that may serve to transport contaminants from the source(s) to possible points of human exposure. Affected media may include:

- Groundwater
- Surface and subsurface soils
- Sediment
- Surface water
- Air
- Soil gas
- Food chain (biota)
- Sludge, leachate, waste materials

Identifying contaminated media and gaining an understanding of the nature and extent of contamination will be accomplished in various steps. You will probably start to characterize the media by studying available sampling data, reviewing detected concentrations, evaluating sampling data quality and adequacy, and making comparisons between site-related data and background data (see Section 5.3). You may also begin to gain a sense of the relative degree of contamination by comparing detected substance concentrations to media-specific comparison values (see Chapter 7).

Sampling data can be extremely useful in evaluating the media that are known to be contaminated. Sampling data collected over time can tell you how long media have been contaminated and the extent to which remediation projects have been successful at reducing levels of contamination. When media have not been adequately sampled, however, you will still need to determine whether the media have been, are currently, or may in the future become contaminated (see Section 6.3). The extent to which substances may persist in, or migrate to and through, these media depends on a number of substance- and site-specific factors. In some cases, you will find that mathematical models have been used to estimate environmental conditions at locations and times when sampling has not been conducted. Chapter 5.2 provides guidance on the usefulness of modeling in the public health assessment process.

6.2.3 Identifying Physical/Safety Hazards

Though most of this manual focuses on evaluating the public health implications of exposure to environmental contaminants, ATSDR, as a public health agency, also considers physical or safety hazards of the sites (or sources) under evaluation. In doing so, the agency helps to ensure that the health *and safety* of the public are protected. Various physical and safety hazards may exist at hazardous waste sites, such as: unsafe structures, dangerous or abandoned equipment, debris, accumulation of explosive and asphyxiating gases, open pits and mine shafts, confined spaces, unexploded ordnance (see text box), lagoons, and unsafe terrain. All physical threats should be considered, including threats of fire or explosion.

When evaluating a site, you need to identify any safety hazards that have the potential to cause harm to people working or living on or near the site. Review of site documents (including the CERCLA required site safety plan), contacts with site officials, and observations during site visits will help identify such hazards (see Chapter 3). As is true when studying any site-related hazard, you should evaluate the likelihood, if any, that people have access to unsafe areas before determining the extent to which a safety hazard exists. For example, an abandoned building may be in serious disrepair but it may pose no public safety threat if it is located inside a securely fenced, inaccessible area where no signs of trespassing (e.g., foot prints or garbage) have been observed.

ATSDR's mandate does not include the health of workers—this issue is mainly the responsibility of the Occupational Safety and Health Administration (OSHA) and the Centers for Disease Control and Prevention (CDC)/National Institute for Occupational Safety and Health (NIOSH). Exposures directly related to worker activities fall under the purview of these agencies. If workers request information on potential occupational hazards, whether chemical or physical, you should generally refer them to these agencies. However, ATSDR has limited authority to

Unexploded Ordnance (UXO):
What is it? How should it be evaluated?

By definition, unexploded ordnance (UXO) is explosive ordnance in the environment that has not been detonated. Concerns about UXO are generally limited to Department of Defense sites, but UXO may also be found at industrial sites that handle military items. UXO is often defined as ordnance that meet the following three criteria:

- It has been armed or prepared for action.
- It has been fired, dropped, launched, buried, or placed in a manner that can cause hazard.
- It remains unexploded, either by design or by malfunction.

In simple terms, UXO accidents will only occur when ordnance is present, the public has access to the area where ordnance is present, and a person's actions detonate the ordnance. Numerous factors, however, determine the extent of the potential hazards related to UXO. These include the amount of UXO at a given location, the depth at which UXO is buried, land use, site accessibility, topography, climate, UXO fuse type and sensitivity, and soil type. Some references at the end of this chapter provide more detailed information on the potential physical hazards associated with UXO.

examine health issues of workers who perform remedial tasks, and the public health assessment process does consider exposures related to the environmental releases under study (e.g., worker exposure to contaminated groundwater via the drinking water supply).

6.3 Evaluating Fate and Transport of Contaminants

Fate and transport refers to how contaminants move through, and are transformed in, the environment. Evaluating fate and transport of contaminants within environmental media is the step in the exposure pathway evaluation that helps you determine if and how contaminants might move from a source area to an exposure point. The fate and transport evaluation is generally a qualitative exercise and often does not require quantitative evaluations (i.e., modeling studies) of environmental fate and transport.

You might use different types of information when evaluating fate and transport, the second element of an exposure pathway. The following categories of information may be useful for some site-specific evaluations:

- Possible *transport processes* that may carry a substance away from its source (see Section 6.3.1).
- *Physical, chemical, and biologic factors* that influence the persistence and movement of a substance within and across environmental media, which can be important in determining whether opportunities for human exposure may exist (see Section 6.3.2).
- *Site-specific environmental conditions* such as climate and topography that determine how contaminants move through the environment at a given location (see Section 6.3.3).

The extent to which you will need to examine fate and transport issues depends on many factors, such as the availability of site-specific environmental data sets, the complexity of site issues, and community health concerns. If you have determined that the nature and extent of contamination in all relevant media have been adequately characterized after reviewing pertinent studies, little or no fate and transport evaluation may be necessary. If the fate and transport issues are difficult to determine, you should use the worst-case scenario. In other cases, a fate and transport evaluation may be required to answer questions such as: What is the likelihood of contamination migrating from a surficial aquifer to a deeper aquifer that serves as a drinking water source? What is the direction and path of a particular groundwater plume? What is the potential for soil or sediment contaminants to accumulate in plants, animals, or fish? What is the likelihood of a groundwater contaminant volatilizing and migrating via soil gas into indoor air? What is the likelihood that degradation of volatile organic compounds is producing measured contaminants?

You can often obtain pertinent fate and transport information in site investigation reports. All Superfund remedial investigation reports, for example, include chemical- and media-specific fate and transport information. When evaluating and interpreting various fate and transport information, you may need to consult technical experts (e.g., hydrogeologists, air modelers), especially when more quantitative analyses are needed to characterize affected media.

Ultimately, fate and transport evaluations should help you determine how likely it is that contaminants have moved or will move beyond the source area and how likely it is that contamination and exposure may occur beyond the sampled areas.

Fate and Transport and Exposure Pathways:
What exactly needs to be done?

This section presents information on factors that you might consider when evaluating fate and transport of environmental contaminants, the second element of an exposure pathway. Remember that this detailed information is provided as guidance for the issues that you *might* need to consider on *some* sites. This section is not meant to imply that every site requires a comprehensive, quantitative fate and transport analysis to classify exposure pathways. Health assessors often use their judgment when evaluating this element of an exposure pathway.

Some examples might help illustrate this point. Assume your site is that of a massive PCB release to a river, where sampling studies have found elevated levels of PCBs in fish tissues. Based on your understanding of how PCBs bioaccumulate, you can safely assume that part of the PCBs detected in the fish probably originated from the spill and that this second element of the exposure pathway is present. For this example, you do not have to run a hydrology and bioaccumulation model to prove that fate and transport exists, nor do you have to step through every chemical and physical property of PCBs to evaluate their fate and transport.

6.3.1 Fate and Transport Processes

Fate and transport are interdependent processes. *Transport* involves the movement of gases, liquids, and particulate solids within a given medium and across interfaces between water, soil, sediment, air, plants, and animals. *Fate* refers to what eventually happens to contaminants released to the environment—some fraction of the contaminants might simply move from one location to the next; other fractions might be physically, biologically, or chemically transformed; and others still might accumulate in one or more media.

When evaluating sites, you need an overall appreciation of the primary fate and transport release processes, intermedia transfer mechanisms, and transport pathways that might influence the ultimate fate of site-related contamination. Depending on site issues, understanding these basic fate and transport mechanisms may help you understand the implications for possible past and future exposures. The following questions are useful considerations for understanding how fate and transport mechanisms might influence the likelihood of exposures:

- *How fast are contaminants moving?*
  Groundwater flow rates, for example, determine when a groundwater contamination plume may have reached downgradient private wells or may migrate to other downgradient wells in the future.

- *How fast are contaminants dispersing along the flow path?*
  In some cases, residents living far from sources of contamination express concern about potential exposures. Insights from fate and transport models can provide context for these concerns. For instance, air models (see Chapter 5) can estimate how ambient air concentrations of pollutants are expected to decrease with downwind distance from a particular emissions source. The rate of this decrease ultimately will depend on the type of source (e.g., stack or area), its release parameters (e.g., height, exit velocity), and other factors (e.g., terrain).

- *Where are contaminants moving in a particular medium?*
  Grasping the anticipated spatial variations in contamination will help you determine whether exposure points might be impacted. For instance, when evaluating a site with contaminated groundwater, you should consider the likelihood that contaminants might migrate laterally (perhaps to drinking water supply wells) or vertically (into different aquifers which may or may not be used for drinking water supply).

- *To what extent might natural attenuation be occurring?*
  Natural attenuation refers to any natural process that is known to degrade or dissipate environmental contamination. Natural attenuation processes, therefore, include biologic degradation, volatilization, and adsorption. As a site-specific example, for chemicals found at elevated concentrations in soil, you might decide that migration to exposure points is unlikely for those chemicals both with a high propensity for adsorbing to soil and with a relatively short half-life for biologic degradation. Note that some biodegration products can be equally or more toxic than their parent compounds (e.g., vinyl chloride as a byproduct of trichloroethylene).

- *Are contaminants entering the food chain?*
  Even though contaminants are essentially never released directly to fish, animals, or plants, fate and transport processes sometimes can make food chain contamination the most important public health issue for your site. For instance, though the source of contamination at a facility might be limited to its wastewater discharge of PCBs to surface water, these contaminants can biomagnify resulting in relatively high concentrations in fish at the highest level of the food chain.

Appendix E presents an overview, by environmental medium, of the various factors that can affect the fate and transport of a substance within and across environmental media.

6.3.2 Physical and Chemical-Specific Factors That Influence Environmental Fate and Transport

Sometimes your understanding of a contaminant's physical and chemical properties is sufficient to characterize fate and transport for the exposure pathway evaluations. This section briefly describes chemical and physical properties that can influence a contaminant's fate in the environment. Knowledge of these properties will enable you to understand a contaminant's behavior in the environment and can help, when necessary, to focus the assessment on transport mechanisms of possible significance. For example, chemical-specific factors can help determine whether particular pesticides detected in lake sediment are likely to accumulate in fish.

The chemical and physical properties described below, however, are the results of laboratory studies in highly controlled conditions and may not reflect accurate behavior of chemicals in uncontrolled environmental conditions. Laboratory studies usually do not reflect the multiple variables and influences found in the environment such as chemical mixtures and varying geochemical conditions of soils and geologic materials. *Health assessors should not rely too heavily upon theoretical and laboratory studies to predict the fate and transport of site-specific contaminants. Site-specific environmental measurements that reveal how much and where contamination exists are always preferred.*

The list below reviews some commonly cited chemical and physical properties that might help with your pathways evaluations. Further information on these and other properties that affect environmental fate and transport in different environmental media can also be found in ATSDR's Toxicological Profiles and the National Library of Medicine's TOXNET Hazardous Substances Data Bank, in addition to many other sources.

- *Water solubility* refers to the maximum concentration of a chemical that dissolves in a given amount of pure water. Environmental conditions, such as temperature and pH, can influence a chemical's solubility, which, in turn, also affects a contaminant's volatilization from water. Solubility provides an important indication of a contaminant's ability to migrate in the environment: highly soluble compounds will tend to move with groundwater, while insoluble compounds do not.

- *Density of liquid* refers to a liquid's mass per volume. For liquids that are insoluble in water (or immiscible with water), liquid density plays a critical role. In groundwater,

liquids with a higher density than water (called dense non-aqueous phase liquids or DNAPL) may penetrate and preferentially settle to the base of an aquifer, while less dense liquids (called light non-aqueous phase liquids or LNAPL) will float.

- *Vapor pressure* is a measure of the volatility of a chemical in its pure state. Thus, the vapor pressure largely determines how quickly contaminants will evaporate from surface soils or water bodies into the air. Contaminants with higher vapor pressures will evaporate more readily.

- *Henry's Law Constant* is a measure of the tendency for a chemical to pass from an aqueous solution to the vapor phase. It is a function of molecular weight, solubility, and vapor pressure. A high Henry's Law Constant corresponds to a greater tendency for a chemical to volatilize to air.

- *The organic carbon partition coefficient (K_{oc})* describes the sorption affinity a chemical has for organic carbon and consequently the tendency for compounds to be adsorbed to soil and sediment (based on the organic carbon content of the soil or sediment). This coefficient is often referred to as the adsorption coefficient. A high K_{oc} indicates that organic chemicals bond tightly to organic matter in the soil so less of the chemical is available to move into groundwater or surface water.

- *The octanol/water partition coefficient (K_{ow})* indicates a chemical's potential to accumulate in animal fat by representing how a chemical is distributed at equilibrium between octanol and water. Contaminants with higher K_{ow}s are more likely to bioaccumulate.

- *The bioconcentration factor (BCF)* is a measure of the extent of chemical partitioning at equilibrium between a biologic medium, such as fish or plant tissue, and an external medium, such as water. This factor can be qualitatively used to evaluate the potential for exposure via the food chain. A high BCF represents an increased likelihood for accumulation in living tissue.

- *Transformation and degradation rates* take into account physical, chemical, and biologic changes in a contaminant over time.

  Chemical transformation is influenced by hydrolysis, oxidation, photolysis, and biodegradation. A key transformation process for organic pollutants is aqueous photolysis (i.e., the alteration of a chemical species due to the absorption of light), often in the form of photochemical reactions (i.e., reactions in the air driven by the sunlight). The transformation rates for chemical reaction are expressed in different rates, including reaction rate constants and half-lives.

  Biodegradation, the breakdown of organic compounds by microorganisms, is a significant environmental process in soil. Precise estimations of chemical-specific transformation and degradation rates are difficult to calculate and to apply because they are subject to site-specific physical and biologic variables.

Media-specific half-life provides a relative measure of the how persistent a substance might be in a particular environmental medium.

6.3.3 Site-Specific Factors That Influence Environmental Fate and Transport

Many climatic and physical factors can affect—speed up, slow down, or even stop—how contaminants transport through the environment and ultimately affect whether human exposures may occur. Obtaining this information can help you determine whether and how quickly contaminants are likely to reach points of possible exposure. For example, precipitation, topography, hydrology, hydrogeology, and soil type indicate how quickly water-soluble contaminants will enter groundwater, while temperature and other factors affect whether and how quickly contaminants will volatilize into the air.

An overview of potentially important site-specific factors is presented below. Some of the pertinent information is usually documented in site investigation reports already conducted by EPA or other regulatory agencies. See Chapter 3 for other possible sources.

6.3.3.1 Climatic Factors

Factors related to climate can be important when trying to understand the likelihood of contaminant movement in a particular setting. The following factors are a partial list of those which affect environmental fate and transport:

- *Annual precipitation and evaporation rates* are useful in determining the amount of surface-water runoff, groundwater recharge rates, and soil moisture content influencing contaminant migration at a given site. The topography of the land and local surface water flow patterns will, of course, affect the materialization of these properties. In addition, precipitation promotes the removal of particulates and soluble vapors from the atmosphere.

- *Temperature conditions* affect the volatilization rate of contaminants: chemicals are more likely to evaporate in warmer environments. In addition, ground temperature can affect the movement of contaminants as frozen ground cover can increase runoff and inhibit groundwater recharge. Also, frozen soils can increase the lateral spread of soil gas.

- *Wind speed and direction* clearly influence the dispersion and volatilization of airborne contaminants, as well as the generation rates of fugitive dust. Knowing the prevailing wind patterns for a site can help provide a qualitative understanding of where "downwind" locations are, increasing your ability to more accurately evaluate potential air exposures. However, you should not rely solely on the prevailing wind direction when identifying potentially exposed populations. For example, prevailing wind directions may suggest areas of long-term pollutant impact from a particular emissions source, but winds may also periodically blow from other compass directions during certain times of the year. Therefore, emissions may have short-term air quality impacts in all compass directions around a site, with the extent of these impacts determined by how often a location was downwind from the facility.

- *Seasonal conditions* could be a major factor affecting rates of contaminant migration where precipitation temperatures vary greatly according to the season. For example, the extent and distance of contaminant migration will be dramatically different if during a period of heavy rain versus a heavy snow.

6.3.3.2 Geologic and Hydrogeologic Conditions

Understanding site-specific conditions that affect the subsurface movement of contaminants is important in many public health assessments, largely because of concern about drinking water obtained from groundwater wells. Geologic and hydrogeologic conditions will influence how fast and in what direction contaminants in soil and groundwater might move, and ultimately if and how contaminants might reach people. These conditions should also be considered when deciding whether available sampling data are sufficient to characterize exposure points. Some key considerations are highlighted below:

- *Groundwater hydrology and geologic composition* affect the direction and extent of contaminant transport in groundwater. To understand a site's groundwater flow patterns, you should review site reports or U.S. Geological Survey or state geological survey data to identify groundwater flow direction, hydraulic conductivity (water-transmitting characteristic), gradient, water table contours, and possible discharge points (e.g., seeps, springs, surface water).

- The *physical characteristics of aquifers* beneath or near a site, especially the porosity and permeability of their geologic materials, will greatly influence the vertical and lateral movement of groundwater and contaminants. Note the presence and continuity of aquitards (i.e., geologic layers that restrict the flow of groundwater) and rapid recharge areas, such as sinkholes and solution channels. Be aware that discontinuities in the aquitard, overpumping the lower aquifer, poorly installed or maintained wells piercing the aquitard, etc., can all lead to contaminant migration from an upper aquifer down to a "protected" lower aquifer.

- *Depth to groundwater*—or the depth of the water table—can be important in your analyses. For instance, this depth is a key consideration when evaluating whether volatile contaminants from groundwater might evaporate and migrate into indoor air. Shallow aquifers, particularly water tables at or just below building foundations, would clearly pose more of a threat for such a scenario than water tables at greater depths below ground surface.

- *Wells installed within aquifers* can affect groundwater flow and direction. Pumping rates of high-capacity municipal, industrial, or agricultural wells can influence localized groundwater flow patterns, and may affect contaminant transport in the aquifer in the area surrounding the well, sometimes referred to as the "capture" zone.

- *Soil characteristics*, such as configuration, composition, porosity, permeability, and cation exchange capacity of the soil ultimately influence the rates of percolation (or rainwater infiltration), groundwater recharge, contaminant release, and transport. Knowing that many contaminants tend to adsorb readily to clay materials, for example,

you might view a site with soils composed largely of clay differently from a site with soils composed largely of sand. Regardless of soil type, however, the greatest sorption will typically be to the organic material.

- *Ground cover and vegetative characteristics* of the site influence rates of soil erosion, percolation, and evaporation. Releases to a paved surfaces may be carried long distances by surface water runoff, while releases to soils might be confined to a smaller area.

- *Topography*, the relative steepness and elevation of the site, will affect the direction and rate of surface water runoff, the rate of soil erosion, and the potential for flooding.

- *Human-made objects*, such as sewers, culverts, and drainage channels, can change the movement of contaminants.

6.4 Identifying Point(s) of Exposure and Exposure Routes

As discussed in Chapter 3, the points at which people may come in contact with site contaminants can be identified by reviewing land use and natural resource data and via community interviews and concerns. Points of exposure should be identified for each environmental medium (Section 6.4.1), as should routes by which exposure could occur (Section 6.4.2). Other considerations include examining changing conditions over time (e.g., future land use) (Section 6.4.3) and conditions that might limit or eliminate contact with contaminated media (Section 6.4.4).

6.4.1 Possible Exposure Points by Environmental Medium

Possible exposure points, by environmental medium, are summarized below. Using the resources identified in Chapter 3, identify which exposure points may be relevant to a particular site. Keep in mind that possible routes of exposure can change significantly depending on the land use at a site and in its surrounding areas.

- *Groundwater*. Potential exposure points include wells and springs used for municipal, domestic, industrial, and agricultural purposes. Groundwater may also be used as a water supply source for swimming pools and other recreational water activities. In some areas, natural springs are used for both recreation and water supply.

- *Soil*. There are several different ways in which people can come into contact with contaminated soil. The matrix in the box, below, serves as a useful framework for evaluating potential soil exposure points. Of course, you should always consider how unique site-specific scenarios might differ from the general guidelines presented. For example, some cultures consume clays or earths (called geophagy), generally from depths of 18 to more than 36 inches below the surface. While the materials consumed in this instance are primarily from known and usually uncontaminated sources, identifying such site-specific scenarios is critical in accurately defining possible exposure points (ATSDR 2001a).

Possible Exposure Points for Contaminated Soil:
How do exposed populations vary by location and depth of contamination?

The following matrix is a useful tool for identifying the most likely exposure scenarios for different combinations of soil contamination:

	On-site contamination	Off-site contamination
Surface soil contamination	Exposure point for on-site workers, site visitors, and trespassers	Residents at, and visitors to, the area of contamination; exposed population determined largely by land use and zoning restrictions
Subsurface soil contamination	Exposure point primarily for on-site workers involved in excavation, digging, and other activities that turn over the soil.	Residents and visitors who dig holes for planting trees, installing swimming pools, or other uses

Note: At some sites, on-site soils and other waste materials may be used as fill at off-site locations. In such cases, contamination levels found on site might represent off-site exposure point concentrations.

- *Surface water*. Exposure points can include irrigation and public, industrial, and livestock water supplies, so, it is particularly important to identify the location of water supply intakes that might be downstream of a site. Surface water may also be used for recreational activities such as swimming, fishing, and boating. Note that recreational use of surface waters is not limited to parks and public beaches; some residents (particularly children ages 6 to 12) may wade, swim, play, and even fish in stormwater drainages, local streams, and local ponds. You can learn about these uses from observations made during site visits, from interviews with the community, and from your site contacts.

- *Sediment.* Sediment may serve as an exposure point for swimmers, workers, and others coming in contact with submerged or exposed sediment. At some sites, beaches along rivers may be important exposure points, as the sediment on the beach may have originated from upstream locations. Sand bars, overbank flood deposits, and other sandy areas along streams and in drainage ditches are often attractive unofficial play areas for young children. Additionally, sediments can be excavated and transported to other areas and used as top soils. In fact, maintenance of ditches, drainage channels, canals, and other watercourses throughout the United States commonly results in sediments being placed in a variety of areas. However, current environmental regulations require that highly contaminated sediments be handled as hazardous waste and not transported to public use areas.

- *Air.* Possible exposure points involve contaminants that are volatile or adsorbed to airborne particulates and may occur outdoors or indoors. The area downwind of a site might be an exposure point for contaminated ambient air as a result of volatilization or entrainment of contaminants in dust particles. The air inside buildings near a contaminated site may also be an exposure point for indoor airborne contaminants from migrating soil gases. Specifically, buildings on or adjacent to landfills should be evaluated for the presence of flammable (methane) and asphyxiating (carbon dioxide) conditions from migrating landfill gas.

- *Food chain.* Exposure points can be present if people consume plants, animals, or other food products that have contacted contaminated soil, sediment, waste materials, groundwater, surface water, or air. This may include fruits and vegetables grown in home gardens, orchard produce, plants used for medicinal purposes, livestock, game, and other terrestrial or aquatic organisms. In some areas, wild plants, animals, and fish may constitute a significant portion of the diet of local residents, possibly at the subsistence level.

- *Other.* Contaminated materials at commercial or industrial sites (e.g., raw materials, sludge from treatment processes, waste pilings, radiation-laden metals) may provide a direct point of contact for on-site workers, visitors, or trespassers.

Specific and clear definitions of exposure points are needed when evaluating the public health implications of exposure. For example, specify exposure points within an aquifer that have been shown to be contaminated (e.g., private wells) or locations where contaminated soil was used as fill (e.g., residential yards). In short, knowing the nature and extent of contamination at the potential exposure points is critical to conducting meaningful health effects evaluations (see Chapters 7 and 8). Also, identify what you do not know and determine whether it represents a critical data gap.

6.4.2 Exposure Routes

In general, individuals may be exposed to contaminants in environmental media in one or more of the following ways:

- *Ingestion* of contaminants in groundwater, surface water, soil, and food.

- *Inhalation* of contaminants in air (dust, vapor, gases), including those volatilized or otherwise emitted from groundwater, surface water, and soil.

- *Dermal contact* with contaminants in water, soil, air, food, and other media, such as exposed wastes or other contaminated material.

- *External exposure* to radiation. Gamma radiation is unique in comparison to chemical contaminants because it travels beyond the source. Therefore, direct contact is not necessary for exposure to occur. In fact, radiation can easily penetrate solid materials such as soils, drums, and even lead. Gamma radiation, in particular, can travel great distances before losing strength. External exposure to radiation also includes exposure to

beta particles from many radioactive materials. These, too, can easily penetrate certain materials and travel several meters prior to loss in energy.

In your exposure pathway evaluation, you will need to identify which routes are viable for each exposure point. For example, if contaminated groundwater is being supplied to a household, then the residents may be exposed via ingestion (by drinking the water), inhalation (from volatilization during a shower), and dermal contact (when taking a shower or bath). It is important to ask some critical questions in determining whether or not an exposure route is viable for a population. If residents drink bottled water and use groundwater for non-potable purposes, then they are not being exposed to the contaminated groundwater through the ingestion route. At the same time, if children are using the water for bathing or swimming in a bath, shower or pool, there may be incidental ingestion. Considering all possible populations is important.

6.4.3 Temporal and Spatial Considerations

Evaluating how contamination patterns might change over time and space is important in understanding where, how, and when people might have or might come in contact with site contaminants. A geographic information system (GIS) and various modeling tools may help in capturing important temporal and spatial trends.

6.4.3.1 Temporal Considerations

Patterns of land use may change over time. Therefore, past, current, and future points of exposure need to be considered. A site may have served a number of uses (e.g., recreational, residential, agricultural, commercial, and industrial) that resulted in a variety of exposure points, depending on the contaminated media and specific time frame being examined. Because of remedial measures or other site-related activities, no current exposure points may exist. However, recognize that past exposure points may have existed and try to identify them. Likewise, consider anticipated or planned future land uses to identify possible future exposure points.

6.4.3.2 Spatial Considerations

Many elements of an exposure pathway vary with location, including levels of environmental contamination, potential exposure points, and receptor populations. A GIS can be a valuable tool for analyzing these elements simultaneously and generating visual representations of data. For instance, GIS analysts can create maps with multiple layers that depict different types of information, such as locations of contamination sources, areas of different levels of environmental contamination (e.g., plumes), population densities and other relevant demographic characteristics, and exposure points (e.g., private wells, homes served by municipal water supplies). These data can be shown for large areas, such as counties or large cities, as well as for much smaller locations, such as census tracts or blocks. Health assessors should consult with GIS specialists to discuss whether generating maps for site-specific applications is appropriate and feasible.

GIS can also be linked with temporal data (dose reconstruction models) to evaluate possible past exposures, to define where additional sampling might be needed, or to project where exposures might occur in the future.

6.4.4 Conditions That Could Prevent Exposure

Where the presence of physical controls and barriers (e.g., permanent fences, gates, water filtration systems) or institutional controls (e.g., deed restrictions, building permits) prevents contact with the contaminated medium of potential concern, you often will assume that no exposure point exists. However, keep in mind that some of these controls are not always effective. If boundaries are not effective or well-maintained, then the pathway should be considered and your PHA should include recommendations to amend the situation. At sites with fences, you might see evidence of trespassers; at sites with fishing advisories, you might notice, or hear accounts of, residents catching fish, shellfish, frogs, or turtles. The regulatory community often discounts such barriers, but you should always critically view the impact of conditions that could prevent exposure.

6.5 Identifying Potentially Exposed Populations

As discussed in Section 6.1, identifying *specific* populations that might be exposed to contaminants and characterizing activities that will influence the extent to which exposures may be occurring is a primary component of any exposure pathway evaluation. Both the characteristics and size of the potentially exposed population need to be determined.

Populations to consider include residents, those engaged in recreational activities, workers, transients, potential “high risk” populations (defined in Section 6.5.1), and other uniquely vulnerable populations (also defined in Section 6.5.1). Potentially exposed populations should be identified as specifically and accurately as possible. A few typical examples follow:

- If the only exposure pathway is via contaminated soil in a residential area along the northern border of a site, the residents in that area and those who frequent that area are the population of concern for that particular pathway, not, for instance, all residents living within a 1-mile radius of the site.

- All users of a municipal water supply could constitute the population of concern if tap water within the system was shown to be contaminated. However, a single contaminated municipal well in a municipal water system composed of multiple wells serving different portions of the system does not result in exposure for all municipal users, only exposure for users connected to the contaminated well.

- If private wells are shown to be contaminated, then the currently exposed population would only be the users of those private wells.

Sections 6.5.1 and 6.5.2, respectively, discuss characterizing and estimating the number of people in the potentially exposed populations for a site. Section 6.5.2 also explains “exposure and demographic structure” files—brief documents that must be completed for all public health assessments and public health consultations.

6.5.1 Characterizing Potentially Exposed Populations

Each site is unique and must be considered individually to determine factors that could enhance or hinder the frequency and magnitude of human exposure. A thorough analysis identifies past, present, and potential future exposed populations and the extent of exposures via different exposure pathways. There also can be dramatic variability in exposure potential across receptor populations at a site. It is important to be as explicit as possible about the extent to which a given population may or may not come in contact with a contaminated environmental medium.

When characterizing potentially exposed populations, remember to ask:

- *Who* is exposed?
- *What* activities are occurring?
- *Where* are activities occurring?
- *When* has exposure occurred (past current, future)? For how long?
- *How* are people exposed? How is the land used? Any unique exposure situations?

A review of land and natural resource use at or near the site will provide valuable information about the activities of the surrounding population and the probability for increased human exposure. Land use will significantly affect the types and frequency of human activities, thereby affecting the degree and intensity of human contact with water, soil, air, exposed wastes, or consumable plants and animals. Site access and use (e.g., work, play, riding, recreation, hunting, fishing) need to be examined carefully. This kind of information can be obtained during the site visit, in site documentation, and through communications with community members and state, local, and tribal officials (see Chapter 3).

Summarized below are key considerations for identifying potentially exposed populations, their activity patterns, and other factors that might influence their exposure to site contaminants. Much of this information will ultimately be used in your health effects evaluation. Section 7.3.1.4 and Appendix G further discuss intake rates and consumption patterns in the context of the health effects evaluation.

6.5.1.1 Identifying Populations

- *Residential populations.* Identify houses, mobile home parks, apartment buildings, and other residential structures located on or in close proximity to the site. These residents constitute the population most likely to be exposed over time.

- *Recreational populations.* Particular attention should be given to places on or near contaminated sites where people are known to recreate. Some obvious locations include fields, parks, playgrounds, lake fronts, and beaches. Note also that children often like to play in other places, such as ditches, streams, and gullies. You may need to evaluate physical hazards for such scenarios.

- *Worker populations.* On- and off-site workers should be considered. Identify any work activities that might result in increased exposures to site-related contamination (e.g.,

excavation work in contaminated soils, utility work in areas infiltrated by contaminated soil gas). Also, consider families of workers in cases where the potential exists for carrying site-related contamination off site (e.g., on clothing, shoes). As noted previously (see Section 6.2.3), ATSDR's mandate does not generally include the health of on-site workers, except for indirect exposures that might be associated with the environmental contamination or release under study (e.g., drinking contaminated groundwater, incidental contact with contaminated soils). However, depending on the nature of the worker exposures, ATSDR may recommend public health actions or work cooperatively with the appropriate agencies to protect the health of worker populations.

- *Transient populations.* Identify populations that may visit the site area. Locations such as beaches, tourist attractions, hotels, and other establishments should be noted because transient populations will likely be exposed only during their stay in the area. Keep in mind that summer populations may include the same people year after year. Consider migrant workers in identifying transit populations, as well.

- *Potentially "high risk" populations (e.g., children, elderly, those with pre-existing health conditions).* Determine whether any schools, daycare centers, playgrounds, retirement centers, or health care facilities exist near the site. The age of the population affects the type, level, and frequency of activities at or near the site. For example, children spend more time outdoors and because of normal hand-to-mouth behaviors tend to ingest more soil than adult populations. Furthermore, some children may periodically exhibit soil pica behavior, which can result in the ingestion of even higher amounts of soil (the extent to which children engage in this behavior during long durations is not known, however) (ATSDR 2001a). Other high risk populations include those that may have differential susceptibility to toxic effects, such as an asthmatic's increased susceptibility to various air contaminants or a fetus' increased susceptibility to a developmental toxin such as methylmercury (Pope et al. 1995; Samet et al. 2000; van der Zee 1999; ATSDR 2002).

- *Uniquely vulnerable populations*. Identify populations that might be more sensitive or vulnerable due to special diets, activities, or cultural practices. Anglers, people who rely on subsistence practices, or people practicing certain religious or cultural activities might experience increased exposure to contaminants. For example, tribal populations may rely more on plant material for ceremonial or medicinal purposes (ATSDR 2001b).

Potentially Exposed Populations:
Why potentially?

Remember, the presence of a population in the vicinity of a site does not necessarily mean exposure is occurring or has occurred. It is your job to determine who, if anyone, may come in contact with contaminated media. The more specifically you can define who is or has been exposed, the better you will be able to evaluate whether harmful exposures exist and recommend appropriate public health actions.

6.5.1.2 Identifying Use Patterns

- *Groundwater use*. Determine to what extent groundwater is being used, or has been used in the past. It is critical to verify the location and use of public and private wells and springs on and near the site. Do not assume that, because municipal water is supplied to a residential area, residents are not using private wells. Identify whether private wells are actively used for all household purposes, including drinking and showering, or perhaps just for outside use (e.g., gardening). Talk to local officials, such as those in water and sanitation departments, and residents during site visits, to determine the number and use of private wells that are or could be contaminated. If needed, arrange for or request that local or state officials conduct a well survey. Contact the appropriate local or state water permit office to find out about area permits (most western states require water permits for wells and other water uses).

- *Surface water use.* Verify the use of local surface water bodies and who may have authority over them. Determine if public water supplies are drawn from area lakes or rivers or if local surface water bodies are designated for recreational use (e.g, swimming, boating). Even if certain water bodies are not designated recreational waters, local residents, particularly children, may play in them, especially small creeks and streams during warm weather. Additional use patterns to consider are local farmers who may use surface water for irrigation, livestock feeding, or aquaculture.

- *Consumption of local fish, shellfish, and game.* Contact state, local, and tribal officials, such as health departments and fish and game departments, about recreational, commercial, and subsistence fishing and hunting practices on or near the site. Local game wardens may be able to estimate the number people routinely catching fish at sites. Attempt to differentiate site-related contamination of local fish and shellfish from other sources of contamination (especially other upstream sources). Note, however, ATSDR's public health responsibility to recommend public health action as necessary regardless of whether identified exposures are site-related (e.g., recommending that local health authorities institute fish advisories).

- *Consumption and use of homegrown or locally grown foods*. The rate of consumption of plants and animals may differ considerably from the national average for certain populations. For example, families may consume homegrown vegetables as their main source of vegetables, or they may rely on locally caught fish as a major source of protein. Populations such as American Indians and Alaska Natives may use various plants for teas, medicinal practices, and other purposes. A local survey or other adequate study of regional dietary habits may be necessary to determine the amount and frequency of contaminated food intake (ATSDR 2001b).

6.5.1.3 Other Factors Potentially Influencing Exposure

- *Climatic conditions*. A review of climatic conditions provides valuable information on the general types and frequency of outdoor and recreational activities of the local population. Subfreezing and other inclement weather, frozen ground, and frozen precipitation may serve as deterrents to people spending time outside, thereby decreasing

the frequency of their contact with outdoor contaminated media, yet possibly increasing their exposure to indoor contaminated media (e.g., soil gas vapors in a basement play area).

- *Site accessibility*. People can contact on-site contamination if access to the site is not restricted or otherwise limited. The presence of a fence is not always a sufficient indication that the site is inaccessible. To determine site accessibility, check the condition of the fence and the extent of physical barriers, look for evidence of trespassers, and determine whether a security system is present. Be aware that sites with abandoned buildings, standing water, or streams may attract children looking for a place to play. Identify the locations of contaminated materials (e.g., barrels) within the site and the zones of contamination to determine how accessible specific contaminated areas may be.

- *Institutional controls*. A review of local ordinances may reveal actions that have been taken to minimize exposure, such as prohibiting the construction of private wells in areas where contaminated groundwater is present. The fact that institutional controls are on record does not necessarily assure their obedience or their effectiveness at preventing exposure. At the same time, it is also possible for such actions to have taken place without being properly communicated or recorded.

6.5.2 Estimating Numbers of People in Potentially Exposed Populations

ATSDR requires that an estimate of the number of potentially exposed people be documented in public health assessment documents for every exposure pathway. This section describes approaches that can be used to obtain and calculate such estimates.

The level of analysis you will need to undertake to generate appropriate population estimates will vary from site to site. Your efforts may range from running queries on U.S. census data in order to estimate the number of people residing within a specified distance of a site, to performing more sophisticated analyses using GIS tools. A variety of techniques are available within GIS to identify the population potentially exposed to selected contaminants. For example, ATSDR's GIS specialists can conduct spatial evaluations, integrating environmental data (e.g., groundwater plumes) and demographics (e.g., census data) to specifically identify a population residing above the plume. For most sites, generating a map depicting demographics for a specified geographic area (e.g., within a certain radius of a site) will be all that is needed.

Chapter 3 offers detailed guidance on how to obtain demographics data as does the text box on the following page.

The number of potentially exposed people can be quantified by conducting actual population counts (enumeration) or by estimating the number of people residing in or frequenting a particular area. In general, when developing any count or estimate, you must:

- Review all available environmental monitoring data to determine the extent of the geographic area for all exposure pathways.

Using GIS To Display Demographic Data

A GIS can be a valuable tool for analyzing the demographic characteristics of an area with potentially exposed populations. If specific areas of exposure can be mapped, these mapped areas can be overlain with population distribution maps to provide spatially proportional estimates of potentially exposed populations. A GIS can link digital mapping technology with population data from numerous sources to conduct graphic spatial assessments of site areas. Most demographic data from the U.S. Bureau of the Census are available electronically. Those data can be analyzed using a GIS, and the results can be shown on maps. For example, if a health assessor needs to know how many children live in a site area, the numbers for the age group he or she needs can be broken out and shown on a map. The data can be shown for large areas, such as counties or large cities, as well as for much smaller locations such as census tracts or blocks. An area of concern such as a contaminant plume can also be digitally added to a map, and estimates for the specific populations needed for that area can be attained. Geocoding can show the locations of specific addresses or households, such as those on a municipal water supply or users of private wells.

- Obtain the necessary street, topographic, and census maps onto which you should overlay the identified geographic area for each pathway.

- Evaluate exposure pathway information and review site visit information to identify areas of greatest exposure potential (e.g., a subdivision located directly downgradient of a site).

- After the completed and potential pathways have been identified, estimate the number of people exposed or potentially exposed via each pathway. For example, if groundwater has been identified as a completed pathway, identify groundwater use and determine the number of people using municipal water or the number of people using private wells that are contaminated or likely to be contaminated.

- Remember that estimating the number of people who are likely to come in contact with a contaminated medium requires consideration of distance *and* access to the contamination. For instance, the likelihood and number of people accessing an unrestricted area with soil contamination would be clearly greater if the area abuts a residential area rather than if it were separated by a four-lane highway or a heavily forested area.

Estimating Potentially Exposed Populations:
What sources of information are available?

One of the most commonly used source of data for estimating potentially exposed populations is the U.S. Census. ATSDR has GIS specialists who are highly skilled at conducting spatial evaluations of census and other types of data. However, at some sites, you may need to obtain population counts from other sources. Some of the sources you may consider follow:

- Neighborhood associations and local residents
- Representatives of municipal, county, and city agencies such as planners, managers, engineers, school officials, and health officials
- Individuals at federal, state, and tribal agencies such as park departments, departments of natural resources, geologic surveys, and health agencies
- Personnel departments
- Surveys

In some cases, you may face challenges in quantifying populations, particularly at sites with large transient populations (e.g., the homeless and seasonal travelers). See Section 3.1.1.5 for additional sources of population data.

- If an accurate population estimate cannot be generated, estimate the number of people by performing a house count—counting residences in the area of interest that represent a likely point of exposure in a completed or potential pathway. A house count can be performed with assessor maps or by performing a visual overview (or windshield survey) of the area. Each residence should then be multiplied by 2.6 people—the average number of residents per household on a nationwide basis (U.S. Census 2000). If a more accurate estimator is available (e.g., a population- specific estimate that takes ethnic or socioeconomic considerations into account) cite the source of the estimator and use that figure.

- If a very precise number is required, consider conducting a special census by enumerating the population in the area of interest using a standardized questionnaire (e.g., door-to-door interviews). A special census is usually conducted only as part of health studies or surveillance efforts at sites where more serious exposure or health concerns have been identified.

- In the public health assessment, describe the sources and methods used to estimate the population reported. You also need to prepare an Exposure Demographics and Structure File (EDS) for every site (see box, below).

See "Estimating Populations at Hazardous Waste Sites," (ATSDR 1992) for more detailed guidance on estimating populations and the resource list in this chapter for census links.

Exposure and Demographic Structure (EDS) Files

ATSDR has developed a system to help ensure consistency and reliability of the exposure information that is entered into its Hazardous Waste Database (HazDat). According to ATSDR policy (ATSDR 2000), an EDS file must be completed by the primary author of every PHA, public health advisory, and health consultation as a means for documenting critical demographic information.

The EDS file is a two page form. The first part is a cover page with site identification information, public health hazard category, and any reasons for not providing receptor population estimations. The second page contains a table for the total estimated receptor populations in on-site and off-site completed and potential pathways.

6.6 Categorizing Exposure Pathway Information

Integration of all of the information assessed in Sections 6.1 through 6.5 will enable you to determine the exposure pathways that will require further evaluation throughout the public health assessment process. Again, past, current, and future exposure situations must be considered. This section describes the criteria that you, the health assessor, should use when categorizing and documenting the type of exposure pathways.

In general, ATSDR considers three exposure categories:

- *Completed exposure pathways*. All five elements of a pathway are present.
- *Potential exposure pathways.* One or more of the elements may not be present, but information is insufficient to eliminate or exclude the element.
- *Eliminated exposure pathways*. One or more of the elements is absent.

Completed exposure pathways will require further evaluation to determine whether realistic exposures are sufficient in magnitude, duration, and frequency to result in adverse health effects (see Chapters 5, 7, and 8). The extent to which potential exposure pathways are evaluated are generally considered on a case-by-case basis and depends on the degree of uncertainty associated with the unknown pathway elements. Eliminated exposure pathways, where one or more of the elements is absent, require no further evaluation. Once evaluated, however, a clear rationale must be presented in the public health assessment as to why the pathway was eliminated.

The following subsections describe the criteria for selecting the appropriate category. The text box at the end of this section illustrates the selection of exposure categories under a site-specific exposure scenario.

6.6.1 Completed Exposure Pathways

A completed exposure pathway exists when there is direct evidence or, in the judgment of the health assessment team, a strong likelihood that people have in the past or are presently coming in contact with site-related contaminants. In other words, people have or are likely to come in contact with site-related contamination at a particular exposure point via an identified exposure route. For example, known contamination in fish from a popular fishing spot would be considered a completed exposure pathway.

When a past or current exposure pathway is identified, additional insights may be gathered on the extent of exposures through the use of *exposure investigations* (see Section 6.7). For example, in some cases, historic data may not be available or may be limited. Dose-reconstruction techniques may be considered in such cases to help characterize the extent of possible past exposures. For current exposures, collecting additional environmental data at exposure points (e.g., tap water sampling) or taking biologic samples in your "exposed" population (e.g, blood, urine) may further support your evaluation.

6.6.2 Potential Exposure Pathways

Potential exposure pathways indicate that exposure to a contaminant *could* have occurred in the past, *could* be occurring currently, or *could* occur in the future. A potential exposure exists when information about one or more of the five elements of an exposure pathway (see Section 6.1.1) is missing or uncertain. Typically, you should categorize a pathway as "potential" when the existence of human contact with or access to an environmental medium is not known. These pathways need to be clearly communicated to the community.

A future potential exposure pathway includes situations in which contamination does not currently exist at an exposure point but is speculated to occur in the future. In general, discussions of potential exposure pathways should be brief. Use professional judgment, based on site-specific conditions, to determine the extent to which possible future exposures should be evaluated. For example, a highly contaminated groundwater plume upgradient of a public water supply may warrant added attention. A future potential exposure pathway may also exist under the following types of scenarios:

- Contamination currently exists in a location that may become a point of exposure in the near future (e.g., undeveloped residential lots or vacant residential properties known to have contaminated soil).

- People in a community have continued unrestricted access to a point of exposure or may participate in activities that would expose them to contaminants (e.g., constructing a residential playground on contaminated soil).

- Institutional controls, building and zoning restrictions, or other ordinances are not in place to prevent contact with contaminants currently detected at points of existing or likely exposure (e.g., a residence or planned residence is on a lot that lies above a contaminated aquifer where municipal hook-ups are not possible and there are no restrictions to prevent drilling a well in the contaminated aquifer).

If site remediation, such as groundwater treatment or soil excavation, is planned or ongoing, future exposure is less likely. You should confirm that remedial measures include monitoring and restrictions to prevent exposure until health-based cleanup goals are achieved.

6.6.3 Eliminated Exposure Pathways

Suspected or possible exposure pathways can be ruled out if the site characteristics make past, current, and future exposures extremely unlikely. If people do not have access to contaminated areas, the pathway is eliminated from further evaluation. Also, should site monitoring reveal that media in accessible areas are not contaminated, you can eliminate that exposure pathway. It is critical, however, that no pathway be ruled out until the quality and representativeness of the data are fully evaluated and the potential for future exposures are carefully examined.

Categorizing Exposure Pathways

Consider the following scenario: A solvent transfer facility first opened in the community in 1983. Several large spills of organic solvents were documented immediately after the facility opened and a leaking underground storage tank was removed in 1986. Three residents near the facility have obtained their drinking water from private wells since the 1950s. When they first tested their wells in 1992, they found elevated levels of trichloroethylene (TCE). How would you categorize the exposure pathways for ingesting groundwater (past, current, future)?

Exposure Pathway Element	Time Frame of Exposure		
	Before 1983	1983–1992	1992–Present
Source of contamination	No	Yes	Yes
Environmental fate and transport	No	Unknown	Yes
Exposure point	Yes	Yes	Yes
Exposure route	Yes	Yes	Yes
Potentially exposed populations	Yes	Yes	Yes
CONCLUSION	Eliminated pathway	Potential pathway	Completed pathway

Private wells have been continuously used since the 1950s. As such, three of the five exposure pathway elements are present for all time frames: exposure point (the private wells), exposure route (ingestion), and potentially exposed populations (the residents). In assessing the other two elements, a source and mode of transport were not present before 1983, when the facility first opened. Exposures prior to 1983, therefore, are eliminated. Between 1983 and 1992, a source of contamination existed but it is not clear exactly when the contaminants that were released actually reached the residential wells. Because one element of the pathway is not known and cannot be confirmed, exposures between 1983 and 1992 are potential. After 1992, the pathway is completed, because contamination was verified at the exposure point and all five elements are therefore present.

6.7 Identifying the Need for Gathering Additional Exposure Data

Whenever exposure pathways evaluations reveal that additional data may be necessary to enable a more definitive assessment of human exposures and possible health effects related to those exposures, an *exposure investigation* may be considered. An exposure investigation is one approach that ATSDR uses as part of the public health assessment process to better characterize past, current, and possible future exposures to hazardous substances in the environment and to evaluate existing and possible health effects related to those exposures more thoroughly. As the health assessor, you should consult with appropriate experts on the site team (e.g., toxicologists, medical officers) to determine the need and feasibility of an exposure investigation. Exposure investigations should be a routine consideration when planning and conducting all public health assessments.

For reference, Section 6.7.1 briefly describes possible types of exposure investigations. Section 6.7.2 presents general criteria health assessors should consider when determining whether additional exposure data are needed.

6.7.1 Definition of Exposure Investigations

ATSDR defines an exposure investigation as the collection and analysis of site-specific information to determine if human populations have been exposed to hazardous substances. An exposure investigation is considered a service, not a health study. The results of the investigation are site-specific and applicable only to the participants of the investigation, and cannot be generalized to other individuals or populations[1]. No comparison populations are used. Potentially affected parties must be informed of the limitations and extent of an exposure investigation early in the process. The site-specific exposure information may include environmental sampling, exposure-dose reconstruction, biological or biomedical testing, and/or evaluation of medical information. The information gathered through an exposure investigation is included in public health assessments, public health consultations, and public health advisories. The results are ultimately used to identify appropriate follow-up public health actions for the site.

An exposure investigation can involve gathering exposure information in one or more of the following ways:

- *Environmental testing (water, soil, air, food chain [biota]).* Testing typically focuses on environmental locations where people live, spend time and play, or may otherwise come in contact with contaminants under investigation. Environmental sampling conducted by other agencies is often sufficient for exposure pathway evaluations, so this form of testing is usually not performed by ATSDR.

[1]Exposure investigations are generally exempt from the requirements of the Institutional Review Board (IRB), but exposure investigation protocols still need to be reviewed by ATSDR's Office of the Assistant Administrator (OAA). If an exposure investigation protocol is expanded to provide more than basic service, IRB clearance may be required.

- *Biologic monitoring*. In some cases, biologic samples can be collected from potentially exposed people and analyzed to confirm or rule out exposures to a contaminant under investigation. A biomarker of exposure is usually a chemical or its metabolite that is measured in a bodily fluid, such as urine or blood. Unlike environmental samples, biomarkers are an unequivocal measure of exposure, since they measure the concentration of the chemical in the body. However, such testing has limitations: testing for chemicals with short biological half-lives is limited to recent exposures; testing cannot identify the source of exposures ; and the health significance of many biomarkers is uncertain.

- *Exposure-dose reconstruction.* When measured data are not available and cannot be obtained to determine exposure point contaminant concentrations, ATSDR may consider analyzing environmental sampling information and using computer models to estimate past or potential future exposure levels. Dose reconstruction activities support exposure assessments by developing analytical methods and computational tools to quantify fate and transport of contaminants. These methods and models can then be used to predict past, current, and future levels and distributions of contaminants, and identify potentially exposed populations. Guidance for interpreting and discussing the output of such modeling efforts is discussed in more detail in Chapter 5.2.

6.7.2 When an Exposure Investigation Should Be Considered

ATSDR has established the following four criteria to consider when deciding whether an exposure investigation should be conducted:

- Is it likely that people have been exposed to a contaminant? Can the exposed population be identified?

- Does a data gap exist that affects your ability to determine if a public health hazard exists? Is more information needed regarding exposure to a contaminant?

- Would an exposure investigation provide the missing information? Can an exposure investigation address identified data gaps?

- Will an exposure investigation affect public health decisions? How would the exposure investigation impact public health decisions?

Health assessors should consider all four criteria when deciding whether an exposure investigation is appropriate for the site of concern. The ultimate question you should ask is: Will additional environmental or biologic testing or computer modeling help me make a *better* public health decision? If so, you should confer with ATSDR's Exposure Investigation and Consultation Branch or other experts available to you before embarking on an exposure investigation. This is necessary to ensure that required protocols and procedures for collecting the desired data are followed.

6.8 Presenting Exposure Pathway Information in the Public Health Assessment Document

This section describes how to integrate and present the findings of the exposure pathway evaluation into the *Discussion* section of your public health assessment documents (e.g., PHAs and PHCs). The exposure pathway discussion should clearly describe how and to what extent people are believed to come in contact with site contaminants and what populations you have evaluated.

At a minimum, the text should include:

- A description of all completed and potential exposures, and whether the pathways occurred in the past, are presently occurring, or may occur in the future.
- A brief description of any eliminated pathways. Adequately describe why certain pathways may have been eliminated (e.g., no or remote possibility of contact with contaminated media), especially for those pathways for which a community has expressed concern.
- The location and size of the potentially exposed populations.
- A brief description of the relevant activity patterns of potential exposed populations.
- The likelihood of exposures, including facts or estimates regarding the duration and frequency of exposure. This information will provide the context for the health effects evaluation and discussion.

Of utmost importance is providing a clear narrative describing how people may or may not be exposed. This will ultimately be integrated with the environmental and toxicity data and will comprise the public health "story." Discuss each exposure pathway by explaining how contaminants migrated from the source to the point of exposure. To the extent possible, describe how human exposure occurs at the point of exposure and delineate areas of potential exposure. For example, in discussing exposures associated with contaminated private well water, explain what the source of the contamination is, explain how and to what extent the contaminants have migrated off site, and explain that private well users could be exposed by drinking, bathing, and other household uses of the contaminated groundwater. Also describe the likelihood of any potential future exposures associated with the contaminated groundwater.

Clearly explain eliminated pathways. For example, groundwater is contaminated, but it is not used as a drinking water source. Or, if community members expressed concern about private wells, but they happen to be located upgradient of a site, explain why no pathway exists (i.e., contaminants have not and will not migrate in that direction). You may also want to include local water resources and contact information so the community can get more specific information on their water quality and well locations.

Discussion of environmental fate and transport should provide only the information necessary for the reader to understand how contaminants migrate. You need not include all known geologic,

topographic, hydrogeologic, climatic, and other environmental information. Likewise, discussion of physical and chemical properties of contaminants and environmental media should be limited to supporting general conclusions about the ultimate fate of site contaminants or to support a recommendation that further sampling is needed. For example, if trichloroethylene (TCE) were detected in very high concentrations (i.e., above 100 ppm) in a shallow sandy aquifer, factors affecting its potential migration to indoor air should be described: Because of the subsurface conditions, the depth to groundwater, and TCE's volatility, it is possible that TCE might migrate through foundations into indoor air.

Discussions of any quantitative transport analysis (e.g., use of models to predict indoor air concentrations) should be summarized in appendices to keep the PHA readable. However, you also need to be sure not to bury critical information or bottom line conclusions in appendices. See Section 5.2 for more specific guidance on presenting key issues pertaining to environmental monitoring and modeled data in the PHA.

Lastly, any data gaps and how they affect the assessment should be clearly described. Refer to Section 5.4 for guidance on recognizing critical data gaps and how to fill them.

In addition to text discussions, summarize the results of the exposure pathway evaluation in tabular format (such as the example provided in Table 6-1, based on the Figure 6-2 scenario) indicating the contaminated media involved, points of exposure, routes of exposure, and potentially exposed populations. Such a table can serve as a tool for documenting exposure pathway information. Some version of this table should be included in all PHAs. Estimated numbers of people exposed via each pathway should be specified as well, but this is often times done in demographic maps.

Table 6-1. Documenting Exposure Pathways

Pathway Name	Exposure Pathway Elements					Time Frame
	Source	**Environmental Medium**	**Point of Exposure**	**Potentially Exposed Population**	**Route of Exposure**	
Ambient Air	Drums	Air	Air	Local Residents	Inhalation	Past Present Future
Surface Soil	Drums	Soil	Residential Yards	Children & Local Residents	Ingestion	Past Present Future
Public Water Supply	Drums	Municipal Water	Residences & Businesses, Tap	Users of Municipal Water Supply	Ingestion	Past Present Future
Private Wells	Drums	Groundwater (Private Wells)	Residences, Tap	Residents Along County Road South of Town	Ingestion Inhalation Dermal Contact	Past Present Future
Food Chain (Biota)	Drums	Food	Food	Residents With Gardens	Ingestion	Past Present Future

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Chapter 7
Health Effects Evaluation: Screening Analysis

As you gather information for the exposure evaluation and gain an understanding of the site and community health concerns (Chapters 3 and 4), the nature and extent of contamination (Chapter 5), and exposure pathways (Chapter 6), you will begin performing the other scientific component of the public health assessment process—the health effects evaluation. The health effects evaluation consists of two pieces: a screening analysis (described in this chapter) and, at some sites, based on the results of the screening analysis and community health concerns, a more in-depth analysis to determine possible public health implications of site-specific exposures (described in Chapter 8).

During the public health assessment process, you typically need to review large volumes of environmental data and evaluate these data in the context of the site-specific exposure assessment. The *screening analysis*, described in this chapter, enables you to sort through the data in a consistent manner to identify substances within completed and potential exposure pathways that may need to be evaluated more closely. This is achieved through the use of health-based "comparison values."

As shown in Figure 7-1, the screening analysis is generally conducted in a step-wise manner:

- Step #1: The *environmental guideline comparison* involves comparing detected substance concentrations to medium-specific comparison values derived from standard exposure default values.

- Step #2: The *health guideline comparison* involves looking more closely as site-specific exposure conditions, estimating exposure doses, and comparing them to dose-based comparison values. (Some health assessors may begin with this step recognizing substance- or site-specific concerns.)

After completing a screening analysis, you will have divided substances identified at the site into two categories:

- Those not exceeding comparison values and usually requiring no further analysis.

- Those exceeding comparison values and requiring further analysis to evaluate the likelihood of possible harmful effects.

(Section 7.2) and health guideline (Section 7.3) comparisons. Other factors that you also may need to be consider during the screening analysis are discussed in Section 7.4. Lastly, guidance is provided on how to best incorporate the findings of the screening analysis into your public health assessment documents (Section 7.5).

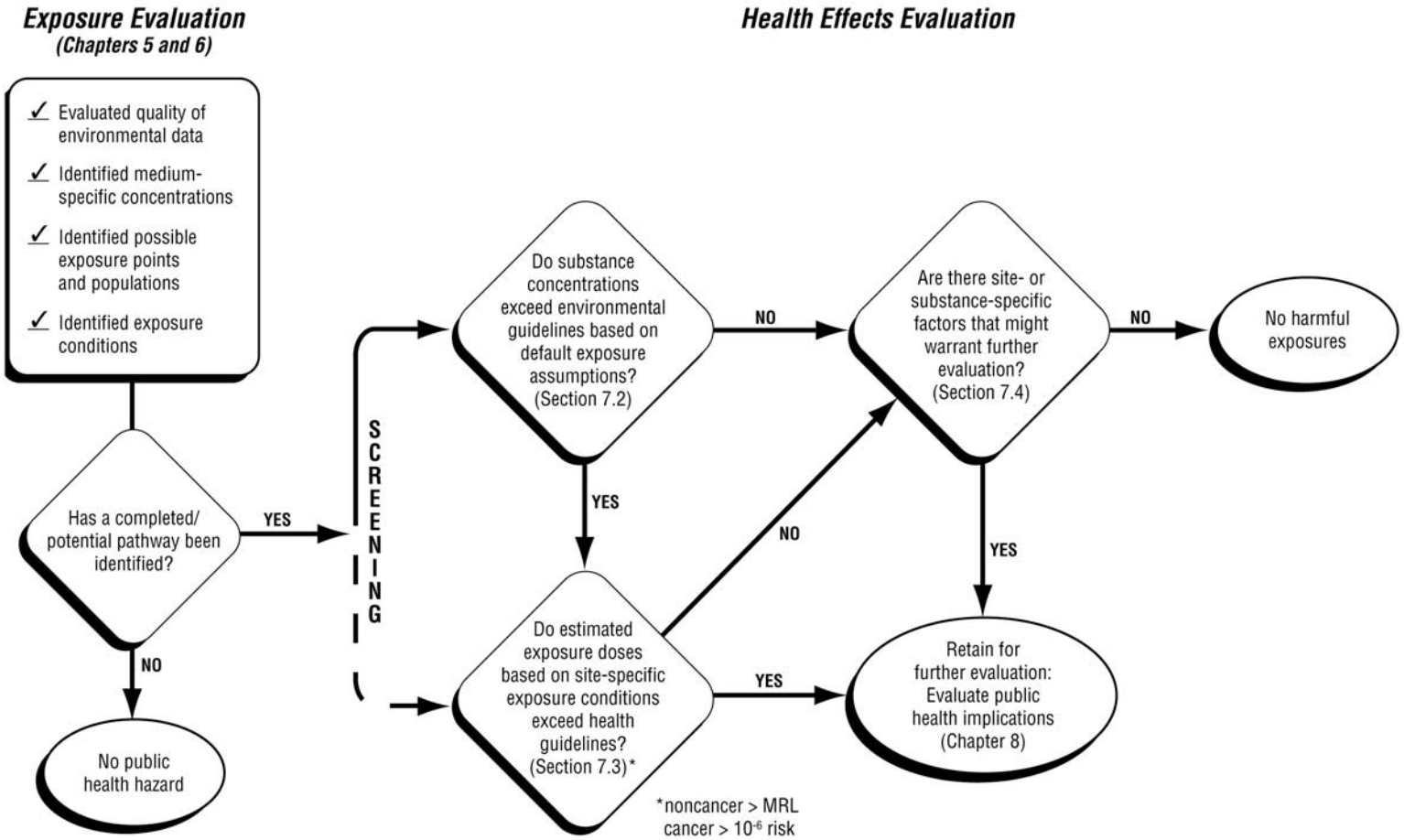


Figure 7-1. Screening Analysis Overview

This chapter first briefly describes what comparison values are and how they are used in the screening analysis (Section 7.1) and then describes when and how to conduct environmental

7.1 What Are Comparison Values?

Comparison values are doses (health guidelines) or substance concentrations (environmental guidelines) set well below levels that are known or anticipated to result in adverse health effects. ATSDR and other government agencies have developed these values to help health assessors make consistent decisions about what substance concentrations or dose levels associated with site exposures might require a closer look.

How Are Comparison Values Used?

Comparison values are used to assess voluminous data sets in an efficient and consistent manner during the screening analysis. They enable you to identify substances that are not expected to result in adverse health effects (i.e., substances detected below comparison values) and substances requiring further evaluation (i.e., substances detected above comparison values).

Comparison values are not thresholds of toxicity. Comparison values should *not* be used to predict adverse health effects. These values serve only as guidelines to provide an initial screen of human exposure to substances. Although concentrations at or below the relevant comparison value may reasonably be considered safe, it does not automatically follow that any environmental concentration that exceeds a comparison value would be expected to produce adverse health effects.

Health guidelines are derived based on data drawn from the epidemiologic and toxicologic literature with many uncertainty or safety factors applied to ensure that they are amply protective of human health. ATSDR's minimal risk level (MRL) and EPA's reference doses, reference concentrations, and cancer slope factors are the health guidelines most commonly used in the public health assessment screening process (see Section 7.3.2).

Environmental guidelines are derived from the health guidelines and represent concentrations of a substance (e.g., in water, soil, and air) to which humans may be exposed via a particular exposure route during a specified period of time without experiencing adverse health effects. ATSDR's environmental guidelines include environmental media evaluation guides (EMEGs) and cancer risk evaluation guides (CREGs). Section 7.2.1 describes available environmental guidelines in more detail.

In general, comparison values are derived for substances for which adequate toxicity data exist for the exposure route of interest. Where possible, comparison values are generally available for three specified exposure periods: acute (14 days or less), intermediate (15 to 365 days), and chronic (more than 365 days). Comparison values are also generally available for two exposure routes: ingestion and inhalation. No comparison values have been established for dermal contact exposures. Comparison values are available for many, but not all, substances you may find at a site. Appendix F details the derivation and applicability of available comparison values.

In the overall context of the public health assessment process, you need to clearly understand what comparison values represent and what they do not represent. Such an understanding will

help you use the comparison values appropriately and clearly communicate the role they play in the public health assessment. The following sections describe when and how to conduct environmental guideline (Section 7.2) and health guideline comparisons (Section 7.3), including direction on selecting the most appropriate comparison value.

Sources of Guidelines

Health assessors should ensure that they are using the most appropriate and up-to-date comparison values. ATSDR regularly updates its environmental and health guidelines. The most current values are entered into ATSDR's Hazardous Substance Database (HazDat). Detailed information about ATSDR's substance-specific health guidelines (MRLs) is provided in ATSDR's Toxicological Profiles. Information about EPA's health guidelines is reported in EPA's Information Risk Information System (IRIS) database (http://www.epa.gov/iris/). A more comprehensive listing of resources for comparison values is provided at the end of this chapter.

7.2 Conducting Environmental Guideline Comparisons

The environmental guideline comparison is a quick, easy way of choosing the contaminants that require further evaluation at your site. You will likely use environmental guidelines throughout the exposure evaluation process as you study the nature and extent of contamination at a site and begin to evaluate the potential for harmful exposures. Use of comparison values, along with background concentrations, will help you quickly gauge the relative magnitude of site contamination.

When screening against environmental guidelines, generally you begin with the list of substances found in potential or completed exposure pathways (see Chapter 6). You then need to select the most appropriate environmental guideline as well as the most appropriate substance concentration.[1] Typically, the quickest and easiest way to screen data is by selecting the maximum detected concentration in the environmental medium of interest and the lowest available comparison value. Remember that this method provides an appropriate initial screen, but does not incorporate site-specific exposure scenarios that will need to be considered during the health guideline screening.

[1]Some classes of compounds (e.g., dioxins/furans, polychlorinated biphenyls [PCBs], and polyaromatic hydrocarbons [PAHs]) contain a number of structurally-related chemicals (congeners) commonly found together and assumed to have qualitatively similar behavior in the environment but not equally potent toxic actions in organisms. In such cases, "toxicity equivalency factors" (TEFs) available in the scientific literature can be applied to individual congeners to generate a single concentration for the compound class (often referred to or reported in laboratory reports as the toxic equivalency concentration [TEQ]). To facilitate screening, the TEQ is compared against the environmental guideline for the congener considered most toxic. For detailed information on the limitations and use of the TEF approach in your screening analysis, see the resources listed at the end of this chapter.

To conduct the screening itself, just compare detected concentrations to the most appropriate comparison value. This will allow you to identify (1) substances whose concentrations are below environmental guidelines and likely pose no health hazards, and (2) substances whose concentrations are above environmental guidelines and may require further evaluation. For those substances whose concentrations are above environmental guidelines, you will proceed to the health guideline comparison. At some sites, you may find that none of the detected substances are identified as needing further evaluation. Therefore, public health conclusions are drawn based on the results of the environmental guideline comparison. However, before excluding all substances detected at concentrations below environmental guidelines from further consideration in a public health assessment, you need to consider the factors described in Section 7.4.

The following subsections describe elements to consider when selecting environmental guidelines for screening and interpreting the results, including which environmental guideline to use and what to do when no guideline is available. Be sure to clearly state all assumptions and methods used throughout the screening process in your public health assessment.

7.2.1 Selecting Environmental Guidelines

ATSDR has developed environmental guidelines for substances in drinking water, soil, and air. ATSDR's environmental guidelines include environmental media evaluation guides (EMEGs), cancer risk evaluation guides (CREGs), and reference dose media evaluation guides (RMEGs). These guidelines are derived in a uniform way using health guidelines and standard default exposure assumptions. These default exposure assumptions generally represent high estimates of exposure (greater than the mean, approaching the 90^{th} percentile), based on observed ranges of human activity patterns (e.g., water ingestion rates, residence times). Guidelines are available to evaluate both child and adult exposures. The text box below provides brief definitions of these environmental guidelines. Again, see Appendix F for a detailed description of how medium-specific environmental guidelines are derived.

When determining what environmental guideline value to use, follow ATSDR's general hierarchy, as shown in Figure 7-2. Hierarchy 1 environmental guidelines (such as CREGs and chronic EMEGs), are developed based on ATSDR analyses of substance-specific toxicity data. In the absence of these values, Hierarchy 2 intermediate EMEGs or RMEGs or lifetime health advisories (LTHAs), which are based on EPA analyses of toxicity data, may be selected. For drinking water exposures, Hierarchy 3 maximum contaminant levels (MCLs) or maximum contaminant level goals (MCLGs) may be selected for comparison in the absence of other comparison values in the hierarchy.

Definitions of ATSDR-Derived Comparison Values

Environmental Media Evaluation Guides (EMEGs)
EMEGs are estimated contaminant concentrations that are not expected to result in adverse noncarcinogenic health effects based on ATSDR evaluation. EMEGs are based on ATSDR MRLs and conservative assumptions about exposure, such as intake rate, exposure frequency and duration, and body weight.

Cancer Risk Guides (CREGs)
CREGs are estimated contaminant concentrations that would be expected to cause no more than one excess cancer in a million (10^{-6}) persons exposed during their lifetime (70 years). ATSDR's CREGs are calculated from EPA's cancer slope factors (CSFs) for oral exposures or unit risk values for inhalation exposures. These values are based on EPA evaluations and assumptions about hypothetical cancer risks at low levels of exposure.

Reference Dose Media Evaluation Guides (RMEGs)
ATSDR derives RMEGs from EPA's oral reference doses, which are developed based on EPA evaluations. RMEGs represent the concentration in water or soil at which daily human exposure is unlikely to result in adverse noncarcinogenic effects.

Minimal Risk Levels (MRLs)
A MRL is an estimate of daily human exposure to a substance (in milligrams per kilogram per day [mg/kg/day] for oral exposures and parts per billion [ppb] or micrograms per cubic meter [Fg/m^3] for inhalation exposures) that is likely to be without noncarcinogenic health effects during a specified duration of exposure based on ATSDR evaluations.

Typically, you select the lowest environmental guideline consistent with the conditions at or near the site for screening purposes. However, be sure to use judgment in selecting the environmental guideline that best applies to site conditions in terms of time frames and populations that might be exposed. Consideration of the following issues may lead you to stray from the hierarchy presented in Figure 7-2, but will help you select the most appropriate values for conducting screening:

- *Exposure duration*. Always consider exposure duration when selecting the most appropriate environmental guideline. A one-time exposure to a high contaminant concentration may result in different health effects than repeated exposure to a lower contaminant concentration. As noted, ATSDR has developed EMEGs that apply to acute (14 days or less), intermediate (15–365 days) and chronic (365 days or more) exposures. Comparison values developed by other organizations may also account for acute, intermediate, and/or chronic exposures.

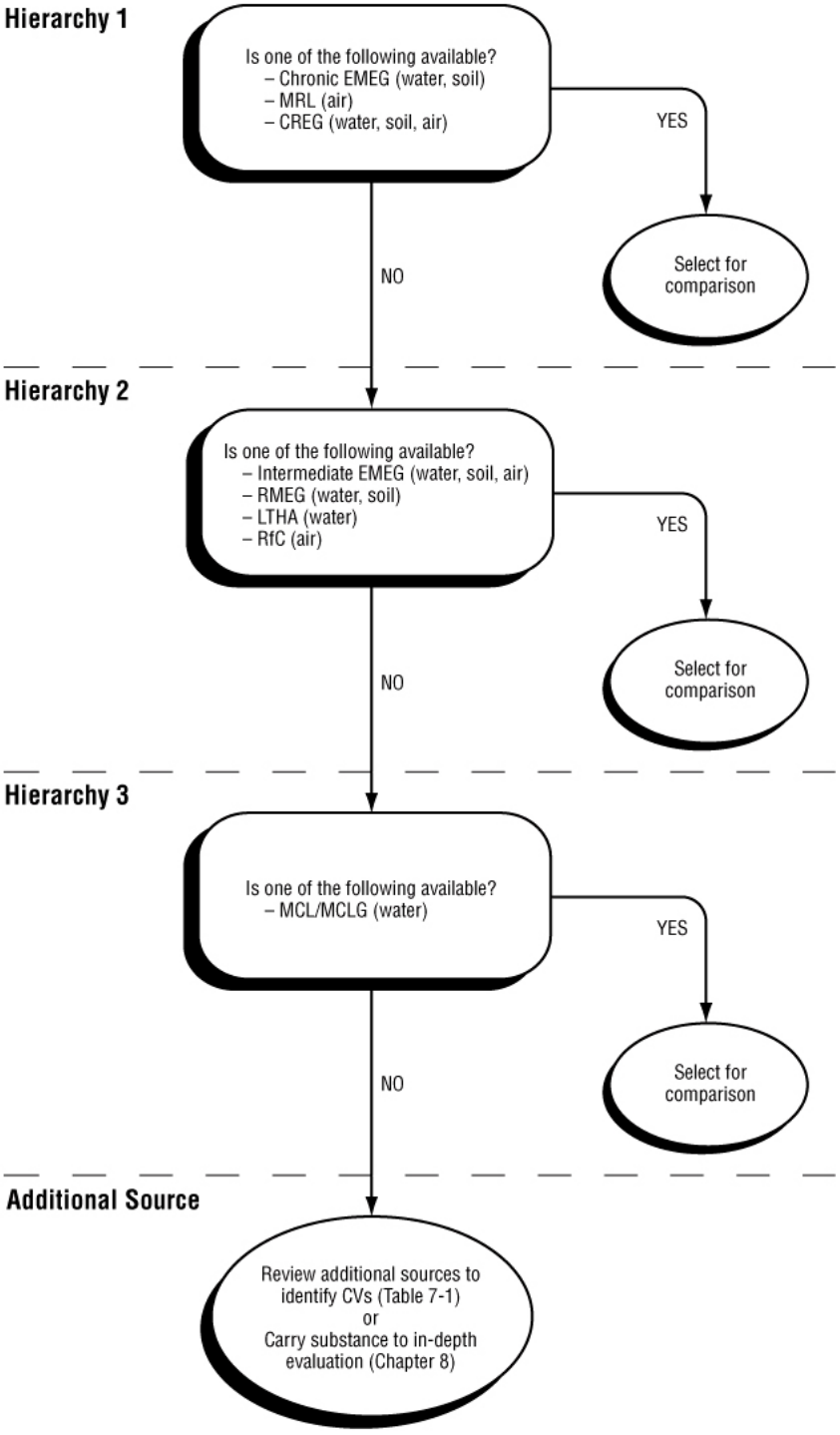


Figure 7-2. Environmental Guideline Hierarchy

- *Site-specific exposure conditions*. In some instances, the most conservative environmental guideline may not be the most appropriate value to use in screening. Of critical importance in conducting public health assessments is selecting environmental guidelines that are most appropriate and applicable to site-specific conditions. Exposures identified at the site should closely approximate the exposure assumptions used to derive the environmental guideline. For example, including a soil contaminant for further evaluation based on a comparison value for a child would be inappropriate if the contaminant is found in a restricted industrial site where children are prohibited. Be sure to keep in mind, however, past, current, and potential future exposure conditions.

When environmental guidelines listed in the ATSDR hierarchy are unavailable, those from other sources should be considered. For example, to meet their unique mandates, other government agencies, such as EPA, the Food and Drug Administration (FDA), and state and tribal environmental and health departments, have developed their own comparison values. These comparison values may address hazardous substances in water, soil, air, fish, or other biota. Possible sources of additional comparison values are listed in Table 7-1.

Before choosing another environmental guideline, be sure to understand the derivation and use of that guideline to ensure that its use in screening is adequately protective of public health. Because the mandates of different agencies may not always be strictly health-driven or consistent with the concerns of Superfund sites, fully understanding the derivation, uncertainties, and possible limitations of a comparison value is critical to determining its appropriateness for use in the public health assessment process. For example, some environmental guidelines are derived based on environmental impacts rather than human health concerns. Selecting such guidelines would not necessarily aid in evaluating public health concerns.

Table 7-1. Additional Sources of Environmental Guidelines

<	Department of Energy (DOE)
<	EPA Federal Guidance 11 (*Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion*), 12 (*External Exposure to Radionuclides in Air, Water, and Soil*), and 13 (*Cancer Risk Coefficients for Environmental Exposure to Radionuclides*)
<	EPA Region 3 Risk-based Concentrations (RBCs)
<	EPA Region 9 Preliminary Remediation Goals (PRGs)
<	EPA Soil Screening Levels (SSLs)
<	EPA National Ambient Air Quality Standards (NAAQS)
<	FDA guidelines and action levels
<	Health Physics Society, American National Standards (ANS)
<	International Commission on Radiological Protect (ICRP)
<	National Council on Radiation Protection (NCRP) Radiation guidelines
<	NCRP Soil Screening Limits
<	Nuclear Regulatory Commission (NRC)
<	Occupational standards/guidelines
<	State-derived guidelines

When evaluating possible health effects from exposures to radionuclides, you should consult a health physicist to evaluate sampling results, select appropriate environmental guidelines, and conduct further analysis of substances found above these guidelines.[2] In some circumstances, you may be able to develop a site-specific environmental guideline with assistance from a toxicologist or health physicist.

7.2.2 What If No Comparison Values Exist?

When no comparison values are available, the contaminant is generally retained for further evaluation (see Chapter 8). Exceptions exist, however. For example, essential nutrients (e.g., calcium, iron, magnesium) are typically not harmful under most environmental exposure scenarios and may not necessarily be retained for further analysis. It may be helpful to compare these and other naturally occurring elements to background concentrations when assessing the need for further examination. Section 5.3 in Chapter 5 provides some guidance on background considerations.

7.3 Conducting Health Guideline Comparisons

Understanding how site conditions may influence the extent to which people come in contact with site contaminants is central to the public health assessment process. Thus, once the simple environmental screening described in Section 7.2 has been completed, the *health guideline comparison* is designed to evaluate site-specific exposure *doses*. Exposure doses are estimated and then compared to health guideline values. In doing this, the health assessor begins to consider site-specific conditions rather than the default exposure values considered in the environmental guideline comparison. That is, you examine the likely exposure conditions (e.g., the duration, frequency, and magnitude of exposure) that may be unique to your site. Much of the information learned as part of your exposure evaluation will support this effort.

The health guideline comparison allows you to begin studying possible public health implications of site-specific conditions. Again, because health guidelines do not represent thresholds of toxicity, this process simply identifies substances in completed or potential exposure pathways that require more extensive evaluation. At some sites, however, you may find that none of the detected substances are identified as needing additional evaluation. Therefore, public health conclusions are drawn based on the results of the health guideline comparison.

After completing a health guideline screening, you will have identified (1) substances that are below conservatively derived health guidelines and likely pose no health hazards, and (2) substances that are above health guidelines and may require more in-depth analysis (Chapter 8). Do not forget that the factors described in Section 7.4 should be considered before excluding

[2] In those cases where comparison values for radioactive materials are not available (which is the rule and not the exception), a health physicist should be consulted to determine if the reported results (1) are realistic based on the methods of analysis (equipment used), (2) are plausible based on site history and description, and (3) meet standard, recognized quality control and quality assurance protocols such as minimum detectable activity and uncertainty of the measurement. (See also Chapter 5).

from further consideration those substances with site-specific exposure doses below health guidelines.

The following subsections describe how to estimate site-specific doses, including the selection of input parameters; how to select health guidelines for screening; and how to interpret the results of the comparison.

7.3.1 Estimating Site-Specific Exposure Doses

Depending on potential health concerns and site conditions, you may estimate doses for past, current, or future exposures. The ability to accurately estimate past and potential future exposure doses, however, may be limited. Information about past contaminant levels or exposures may be incomplete or unavailable. In some cases, exposures are characterized by using mathematical models, which can be used to estimate exposure concentrations. More information about selecting exposure concentrations and modeling data is provided in Chapter 6.

Estimates of exposure doses are generally determined for exposure to a single substance via a single route of exposure. However, at many sites, exposure to a substance may occur through multiple routes of exposure. When this occurs, the exposures from the various pathways can be summed to derive a total exposure dose. More information about approaches to assessing doses to multiple chemicals is presented in Chapter 8.

The procedures outlined in this section do not pertain to estimating the doses from exposure to radioactivity or radioactive materials. The terms "exposure dose" and "radiological dose" are not interchangeable as there are subtle differences in the methods of calculation. ATSDR recommends that the health assessor contact a trained health physicist or radiation specialist for assistance in evaluating radiological exposures.

Different Definitions of "Dose"

An *exposure or administered dose* is the mathematical estimation of the amount of a substance encountered in the environment per unit of body weight and time.

An *absorbed or internal dose* is the amount of the exposure dose that actually enters the body (i.e., penetrates barriers such as the skin, gastrointestinal tract, lung tissue). The route of exposure, type and form of a substance, among other factors influence how much of a substance is absorbed into the bloodstream. Levels of internal dose may be measured in some body compartments through biologic sampling (e.g., medical testing for biologic markers of exposure in blood or urine).

A *target tissue dose* is the amount of the absorbed dose reaching the cells or target sites where the adverse effect occurs.

A *biologically effective dose* is the amount of the target tissue dose needed to produce a biologic response.

Absorbed, target tissue, and biologically effective doses are considered when conducting more in-depth analyses of health effects (see Chapter 8), not when performing the health guidelines screening described in this chapter.

7.3.1.1 How Are Exposure Doses Estimated?

An exposure dose (generally expressed as milligrams of chemical per kilogram of body weight per day or "mg/kg/day") is an estimate of how much of a substance a

person may contact based on their actions and habits. Estimating an exposure dose requires identifying how much, how often, and how long a person or population may come in contact with some concentration of a substance (e.g., maximum or mean) in a specific medium.

You should strive to estimate exposure doses by using site-specific or population-specific exposure information. Doses are calculated using the following general equation:

$$\textit{Exposure Dose} = \frac{C \times IR \times AF \times EF}{BW}$$

Where:

C	=	Substance concentration (milligrams/liter, milligrams/kilogram, or parts per million)
IR	=	Intake rate (liters/day or kilograms/day)
AF	=	Bioavailability Factor (unitless) [usually considered as part of the more in-depth evaluation (see Chapter 8)]
EF	=	Exposure factor (unitless)
BW	=	Body weight (kilograms)

The exposure factor is an expression of how often and how long a person may be contacting a substance in the environment. The exposure factor is calculated using the following general equation:

$$\textit{Exposure Factor} = \frac{F \times ED}{AT}$$

Where:

F	=	Frequency of exposure (days/year)
ED	=	Exposure duration (years)
AT	=	Averaging time (ED x 365 days/year)

When estimating shorter-term or acute exposures or in situations where daily exposures are expected over time, the exposure factor term equals one.

Appendix G contains detailed information about estimating exposures from various pathways and medium-specific considerations. The appendix presents the methodology for ingestion, dermal contact, and inhalation using standardized (default) exposure assumptions, but it also provides guidance on how dose estimates can be refined to better represent site-specific exposure conditions. Although the appendix presents the method for estimating doses from dermal contact, you should recognize that ATSDR generally considers that for most exposure scenarios dermal exposure to be a minor contributor to the overall exposure dose relative to the contributions of ingestion and inhalation exposures. If dermal exposures are a particular concern at your site, substance-specific characteristics may need to be examined (e.g., absorption potential). You should consult with the team toxicologist as needed.

7.3.1.2 How Are Input Parameters Selected?

At some sites, the existing conditions may result in exposures that differ from the standard default assumptions, as described in Appendix G. For example, you may learn that the population under study does not rely exclusively on water from private wells for drinking purposes. Using the default assumption of 2 liters per day might therefore overestimate exposures. To ensure that the most reasonable, yet protective, exposure conditions are considered, select input parameters for the dose equation by carefully examining site-specific exposure conditions.

You do not need to limit dose estimates to a single point estimate. Where possible, present a range of doses. Presenting a range of realistic scenarios and doses can provide greater perspective regarding health implications. It can enable concerned community members to understand where their exposures may fit into the overall picture. For example, an exposure to a contaminant in soil may be expected to result in long-term effects to workers regularly exposed to soils. However, no adverse health effects would be expected for people contacting the same soils on an infrequent basis. EPA and others have developed tools for conducting probabilistic risk assessments that evaluate data distributions instead of point estimates (e.g., Monte Carlo analysis); the primary purpose of such tools is to more adequately characterize variability and uncertainty in risk assessments. Such tools can be considered in public health assessments, but you should work with the appropriate experts in these types of analyses to determine their applicability, use, and interpretation at a particular site. More information about probabilistic risk assessment tools can be found through EPA's Web site (http://epa.gov/osa/spc/htm/probpol.htm).

Remember, the purpose of the public health assessment is to put environmental exposures into proper perspective, and estimating appropriate exposure doses is an important step in this process.

7.3.1.3 What Are Some Sources of Input Parameters?

In the absence of site-specific information, refer to exposure estimates that have been derived based on population studies, such as those contained in EPA's Exposure Factors Handbook (http://www.epa.gov/ncea/pdfs/efh/front.pdf) (EPA 1997). EPA's Exposure Factors Handbook (EFH) provides a summary of population studies and presents a range of exposure estimates based on the results of these studies. Information that can be obtained from EPA's EFH includes, for example, drinking water or food intakes, breathing rates, body weights, and time spent at different activities, such as showering, swimming, or gardening. Select the values that best represent site conditions and would be adequately protective of the surrounding community. Note, however, that if doses are estimated using the standard default assumptions, the dose estimate will exceed its health guideline by the same magnitude by which the substance concentration exceeded its environmental guideline.

At some sites (e.g., as part of an RI/FS), a risk assessment may have been conducted to determine cleanup goals. In these cases, it may be worthwhile to review the risk assessment to understand what exposure variables and assumptions assessors used to estimate risks and evaluate site exposure conditions. For public health assessment purposes, you should

independently choose site-specific exposure input parameters based on the results of your exposure evaluation, though risk assessments can be used as a reference.

7.3.1.4 What Factors Should Be Considered When Selecting Input Parameters?

The following text defines each of the input parameters used in the exposure dose equation and discusses key factors to consider when selecting appropriate variables. To ensure adequate protection of public health, begin by choosing conservative input parameters. As appropriate, refine the analysis by considering more realistic parameters consistent with what is known about site-specific exposures.

- *Substance concentration.* The maximum detected substance concentration is selected to assess potential exposures from substances in site media, at least as a first screen. You, however, should recognize that use of the maximum detected concentration of a substance to estimate the exposure dose may result in an overestimate of likely exposure. You may determine that the arithmetic or geometric average concentration may be appropriate to assess exposure conditions, especially when concentrations vary temporally or spatially (see text box on the following page).

  When reporting exposure concentrations, specify whether the estimates are based on maximum substance concentrations, an average of measurements taken from the same location, or a range of substance concentrations detected.

  In general, consider the following questions when selecting an appropriate substance concentration. These questions attempt to determine whether the maximum detected concentration best characterizes actual exposures.

  - Where are the highest substance concentrations located?
  - Are the most contaminated areas accessible to the public?
  - How frequently was the substance(s) detected?

- *Intake rate.* The intake rate is the amount of a contaminated medium to which a person is exposed during a specified period of time. The amount of water, soil, and food ingested on a daily basis; the amount of air inhaled; or the amount of water or soil that a person may contact through dermal exposures are all examples of intake rates. Select intake rates that best characterize the exposed population.

  Usually standard default values represent intake rates that tend to overestimate exposures (see Appendix G for default values). Consider, however, the unique behavior or exposure rates of site populations when selecting an appropriate intake rate. In some instances, using default assumptions may underestimate exposures: using intake rates for the general population (e.g., a recreational fisher) to represent a subsistence fisher population, for example, may lead to underestimates of actual intake. Studies of

Choosing the Most Appropriate Exposure Point Concentration

Typically, data are initially screened by selecting the maximum detected concentration in a given media. Using the maximum detected value provides you with a protective approach, estimating likely 'worst-case' exposure situations. The maximum detected substance concentration, however, may not always be the most appropriate value for comparisons based on site-specific conditions.

For example, you should be wary of selecting maximum detected concentrations that would be considered data outliers and would not represent exposure conditions (see Chapters 5 and 6). When substance concentrations change over time (as is often the case with chronic exposures) or over portions of an area, you may select an average concentration, or range of concentrations at a site, to better represent substance concentrations.

Arithmetic average. The arithmetic average is more commonly called 'the average,' derived by adding data from all observations and dividing by the number of observations.

Geometric average. The geometric average is a weighted average derived by multiplying data from all observations, then taking the root of the number of observations.

When calculating averages, be mindful of calculating arithmetic averages or geometric averages. An arithmetic average is only appropriate when your data are 'normally' distributed (i.e., the distribution looks like a bell curve). An arithmetic average may be appropriate when averaging quarterly drinking water monitoring data because it is sampled consistently (i.e., the weight of data from each sampling event should be equal) and exposed populations would be expected to come in contact with a variety of contaminant levels represented by regular monitoring. A geometric average is better suited when values are not evenly distributed (e.g., there are many low value data points, a few mid-value data points, and scant high value data points, or contact with contaminants in one area is much more likely than contact with contaminants in another area). A geometric average would better represent exposures to surface soil contamination in a case where hot spots are sampled rather than an evenly spaced grid.

Other statistical measures may be used to estimate exposure point concentrations. One common approach is to calculate an average and then use the 67^{th} or 95^{th} percent upper confidence limit of the average to account for variability in the data and ensure that the average is not underestimated. You should consult with a statistician to determine the most appropriate method to statistically summarize your data.

subsistence populations have found ingestion rates as high as 170 grams of fish per day, whereas studies of the general public have estimated a fish intake rate of 20 grams per day (EPA 1997). It is very important to make sure that consumption rates accurately reflect the habits and consumption behaviors of the local population.

Questions to consider when selecting an appropriate intake rate include: Does the population include unique subpopulations or conditions that may affect intake rates, such as gender, age, health status, cultural practices, climate, site activities, season, region, or urbanization level?

- What behaviors or practices might impact intake rates? For example, are people gardening in areas of contaminated soil or visiting contaminated areas of industrial facilities?

- What are the drinking water and food sources in the affected area? Do people use private wells or municipal water supplies? Do people consume local or homegrown produce and livestock?

- *Bioavailability factor*. The amount of a substance that is absorbed into a person's body is expressed as the bioavailability factor. The bioavailability factor is the percent of the total amount of a substance ingested, inhaled, or contacted that actually enters the bloodstream and is available to potentially harm a person. For screening purposes, the bioavailability factor is typically assumed to be 1—that is, all of a substance to which a person is assumed to be absorbed. Further, comparison values are often based on exposures, and not absorbed doses. The bioavailability factor may be revisited if you conduct a more in-depth analysis of exposures and substance toxicology, as described in Chapter 8.

- *Exposure factor.* How often and how long a person is exposed to a contaminated medium is expressed as the exposure factor. The exposure factor is derived by considering frequency of exposure, exposure duration, and time of exposure.

  The *frequency of exposure* can be estimated as the average number of days in a year in which exposure occurs. ATSDR assumes daily exposures when developing environmental guidelines. Actual pathway- and media-specific exposures may occur with less frequency, such as with recreational use of a site, an occupational setting, or local climate conditions that limit accessibility. You should gather information about the frequency of exposure because the same total dose of a substance can cause different toxic effects depending on whether the dose is administered during a short or prolonged period.

  The *exposure duration* is the length of time a population has been exposed to site contaminants. Examining the site's history will usually allow you to estimate the maximum duration of exposure. Exposure duration can also be based on the activities of the exposed population, which may be exposed only infrequently or for a short duration. For example, patients in a hospital served by a contaminated water supply will have an exposure duration only as long as their stay at the hospital.

  The *time of exposure* is used to express exposure in terms of an average daily dose that can be compared to health guidelines and toxicity study results. For noncarcinogenic substances, the dose is estimated by using a time input parameter equal to the exposure duration. For example, when estimating the dose for a child exposed to a contaminant in a playground for 3 years, the time input parameter would equal 1,095 days (365 days/year x 3 years). For carcinogenic effects, doses are generally estimated by calculating an average daily dose during a lifetime (which is generally assumed to be 70 years). The time input parameter for carcinogenic effects is therefore 25,550 days (365 days/year x 70 years). This approach for carcinogens assumes that a high dose received during a short

period is the same as a corresponding low dose during a lifetime (EPA 2003). As with all assumptions, you are cautioned that they may not be applicable in all situations.

Questions to consider when selecting appropriate input parameters for the exposure factor include:

- What is the likelihood that people will actually come in contact with the highest detected concentrations of substances?
- Are exposures likely to be incidental, frequent/regular, or excessive?
- What is the likelihood that exposures to environmental media will occur at default levels? Is the level likely to be more or less?
- How might the site-specific climate affect exposure frequency?
- What land use factors, such as the location of the water supply, parks, or schools, will affect exposure frequency?
- When was contamination first released from the site (e.g., initial and final dates of operation or receipt of wastes)?
- Are there measures in place that may have ended exposures (e.g., water treatment systems, site access barriers, or remedial actions)?
- Who are the exposed populations and when could exposures have begun (e.g., construction date of residential neighborhoods)?

- *Body weight.* Body weight is used in the exposure dose equation to express doses that can be compared across a population. When exposed to the same amount of a substance, people with lower body weights will receive a relatively higher dose of the substance than people with higher body weights. This effect is best seen when examining exposures to adults and children. For example, a child weighing 10 kg receives a higher dose of manganese per kilogram of body weight when drinking contaminated water than an adult drinking the same water. The default assumption is that the average adult weighs 70 kg (154 pounds) and a child weighs 10 kg (22 pounds or about the size of a 1-year old child). These default assumptions may not apply when assessing exposures to a population of women or older children.

  Some questions to consider when selecting an appropriate body weight include:

  - Does the receptor population represent the average U.S. population?
  - What is the age group and respective body weights of the exposed population (e.g, toddlers, young teens, or adults)?

7.3.2 Selecting Health Guidelines

After site-specific exposure doses are estimated, these doses are then compared with the most appropriate health guideline. This step assists you in screening out substances that are not expected to result in adverse health effects (i.e., below health guidelines) from those that require further evaluation (i.e., above health guidelines). Different health guidelines are available for exposure routes (ingestion, inhalation), exposure durations (acute, subchronic/ intermediate, and chronic), and health endpoints (carcinogenic, noncarcinogenic). Appendix F provides detailed information about available health guidelines and their derivations.

Health guidelines for ingestion exposures are expressed as a dose, in mg/kg/day. For air exposures, the health guidelines are expressed as exposure concentrations (usually in parts per billion [ppb] or micrograms per cubic meter [Fg/m^3])[3]. Health guidelines are protective of human health and are developed for both noncarcinogenic and carcinogenic effects. Health guidelines for noncarcinogenic effects are derived from human or experimental animal data and modified, as necessary, by a series of "uncertainty" factors (also known as safety factors) that ensure that guidelines are set at levels safely below those that could result in adverse health effects. Health guidelines for cancer are derived by the U.S. Environmental Protection Agency (EPA) and represent hypothetical estimates of cancer risk at low levels of exposure.

ATSDR and EPA have developed health guidelines for noncarcinogenic effects resulting from substance exposures. MRLs are the health guidelines derived by ATSDR. Reference doses (RfDs) and reference concentrations (RfCs) are health guidelines derived by EPA. In addition, EPA has derived factors to measure the relative potency of various carcinogens—known as oral cancer slope factors and inhalation [air] unit risks (for oral and inhalation exposures, respectively). ATSDR sometimes uses these EPA-generated values to derive cancer risk evaluation guides (CREGs).

When available, select ATSDR's MRLs. If no MRL is available for a substance, EPA's RfDs or RfCs should be used. Other sources can be consulted if no ATSDR or EPA health guidelines are available (e.g., EPA's National Center for Environmental Assessment [NCEA] provisional values). In general, consider the following when selecting the most appropriate health guidelines:

- *Exposure route.* If substance-specific health guidelines are not available for the exposure route of concern at a site, guidelines developed for other exposure routes may be used. However, care should be exercised when drawing conclusions from those comparisons. For example, when guidelines are not available for dermal contact or for inhalation, MRLs for ingestion exposures may be used for screening purposes. You should consult with a toxicologist and consider the impact of extrapolating from one route of exposure to another in these cases.

- *Exposure duration.* ATSDR develops MRLs for acute (14 days or less), intermediate (15–365 days), and chronic (365 days or more) exposures. EPA's RfDs and RfCs are

[3]Note: In the case of air concentrations, parts per billion (ppb) do not equal micrograms per cubic meter (Fg/m^3). See Appendix F for more information.

developed assuming chronic exposures. MRLs, RfDs, and RfCs are available for ingestion or inhalation exposures. A health assessor should take care in selecting the health guidelines that best represent the exposure duration assumed in their estimation of site-specific dose.

- *Health endpoints.* For possible noncarcinogenic health effects, the derived site-specific doses are compared to health guidelines for noncarcinogenic health effects, most commonly ATSDR's MRLs or EPA's RfDs and RfCs.

  For possible carcinogenic outcomes, you should generally carry the site-specific doses to a more in-depth evaluation, as described in Chapter 8. However, quantitative risk assessment methods for evaluating theoretical excess cancer risks can be used to provide initial information about a carcinogen, as described in the text box on the following page. Results of such a quantitative assessment should *not* be used, however, as the sole basis for any health conclusions for a site.

7.4 Other Factors That Influence the Screening Analysis

Generally, the screening analysis is a simple comparison of exposure point concentrations or exposure doses against environmental or health guidelines, as described in Section 7.2. and 7.3. However, some other site-specific factors may need to be considered before including or excluding a substance from a list for further evaluation. Remembering these issues as the screening analysis progresses will prevent you from inadvertently dismissing a substance that should be identified for further evaluation or doing the opposite—inadvertently conducting a lengthy evaluation of a substance that could have been quickly identified as not likely to cause adverse health effects at detected levels and conditions of likely exposure.

As you proceed with the screening analysis, consider the following site-specific factors:

- *Community concerns.* As mentioned throughout this manual, community concerns are important to the public health assessment process. Therefore, when a community has expressed special concern about a particular substance or exposure, whether comparison values are exceeded or not, you should include this substance for evaluation and discussion. Guidance on responding to community concerns is provided in Chapter 4.

- *Specific populations.* Although environmental and health guidelines are designed to be protective for most of the population, including sensitive populations and children, it is important to remember that they may not apply to all populations of potential interest. For example, subsistence fishers may be exposed at a higher rate than the general population for which fish comparison values are derived, or people in extremely warm climates may ingest extremely high quantities of water. These factors should be accounted for when estimating site-specific doses. In addition, some people might be more sensitive to the effects of a substance, such as asthmatics or the elderly, and should be identified when evaluating site-related exposures. Consult with your toxicologist to determine which if any of the substances detected at your site might warrant special

Quantitative Screening Analysis for Carcinogens

Under quantitative risk assessment methodology, site-specific cancer doses and concentrations are multiplied by EPA's cancer slope factors (CSFs) or inhalation unit risks (IURs), respectively, to estimate a theoretical cancer risk. The following illustrates this calculation.

Theoretical Cancer Risk = Dose (or air concentration) H CSF (or IUR)

Where:

Theoretical Cancer Risk	=	Expression of the cancer risk (unitless)
Dose	=	Site-specific cancer dose (mg/kg/day) or concentration (Fg/m^3)
CSF or IUR	=	Cancer slope factor ([mg/kg/day]$^{-1}$) or inhalation unit risk ([Fg/m^3]$^{-1}$)

This calculation estimates a theoretical excess cancer risk expressed as the proportion of a population that may be affected by a carcinogen during a lifetime of exposure. For example, an estimated cancer risk of 1 x 10^{-6} predicts the probability of one additional cancer over background in a population of 1 million.

Because of conservative models used to derive CSFs and IURs, using this approach provides a theoretical estimate of risk; the true or actual risk is unknown and could be as low as zero (EPA 2003). When considering numerical risk estimates, you should understand that CSFs and IURs are generated using mathematical models applied to epidemiologic or experimental data for carcinogenic effects. The mathematical models extrapolate from higher experimental doses to lower environmental doses. Often, the experimental data represent exposures to chemicals at concentrations orders of magnitude higher than concentrations found in the environment. In addition, these models often assume that there are no thresholds for carcinogenic effects—a single molecule of a carcinogen is assumed to be able to cause cancer. The doses associated with these estimated hypothetical risks may be orders of magnitude lower than doses reported in the toxicology literature to cause carcinogenic effects. As such, a low cancer risk estimate (less than 10^{-6}) may indicate that the toxicology literature would support a finding that no excess cancer risk is likely. A higher cancer risk estimate (greater than 10^{-6}), however, indicates that you should carefully review the toxicology literature before making conclusions about potential cancer risks. Chapter 8 describes the more in-depth evaluation to follow when assessing cancer outcomes.

Although ATSDR recognizes the utility of numerical risk estimates in risk analysis, the agency considers such estimates in the context of the variables and assumptions involved in their derivation and in the broader context of biomedical opinion, host factors, and actual exposure conditions. The actual parameters of environmental exposures must be given careful consideration in evaluating the assumptions and variables relating to both toxicity and exposure (ATSDR 1993).

attention in light of site exposure conditions (e.g., detected contaminants and demographics).

- *Multiple pathways of exposure.* People can be exposed to substances found in more than one environmental medium (e.g., in both water and soil). Substance concentrations in a specific medium, however, might not exceed comparison values. Therefore, consider substances detected in more than one medium that could compound potential exposures. For example, you may want to further evaluate the possible combined effects of a particular substance found in drinking water, surface soil, and air, even though media-specific environmental guidelines may not be exceeded. You may also want to retain a substance found below its environmental guideline in one medium (e.g., soil) if this substance was also found above its environmental guideline in another medium (e.g. water). Be cautious, however, when assessing chemicals across pathways. Effects are not always additive. Exposure frequencies and absorption rates for a single substance can vary by medium and route of exposure.

- *Multiple-chemical exposures.* Community members are often concerned about exposure to multiple chemicals. Generally, if detected levels of chemicals are individually below conservative screening values, then exposure to these chemicals collectively is not expected to be of health concern. Even so, you may decide that further evaluation of multiple-chemical exposures is necessary. In these instances, you should perform further analysis, as described in Chapter 8, in consultation with a toxicologist, as necessary.

Chapter 8 expands on how you should weigh these factors in your evaluation of site exposures and determining public health implications.

7.5 Presenting Screening Analysis Findings in the Public Health Assessment Document

The environmental guideline comparison and health guideline comparison are screening tools that serve as the first step in assessing and understanding potential harmful effects posed by exposures to site contaminants. It is, therefore, important to clearly and effectively communicate the methods used and the findings of the screening evaluation.

A concise summary of the screening analysis process should be included in PHAs. This summary should be written in nontechnical terms and present the uses and limitations of the screening analysis process. The document should state that these methods are screening tools used to rapidly assess large volumes of data, emphasizing that the process does *not* identify adverse health outcomes. This concept must be clearly stated and explained: ATSDR has found that in instances where this information is not clearly laid out, it is easy for people to misinterpret comparison values as indicators of illness or harm.

The PHA should also clearly state all assumptions that you used in your evaluation to select the substance concentrations, environmental guidelines, dose estimate variables, or health guidelines. Including an appendix detailing your dose calculations is an effective means of presenting your methods and assumptions.

The *Discussion* section of the PHA is the most appropriate place to discuss the results of the screening analysis. In presenting the results, provide a discussion of what substances were selected for further evaluation and why they were selected. Also, briefly describe what substances were determined to pose no public health hazards and eliminated from further evaluation. Results of the screening analysis can be easily summarized in a table, as described in Chapter 5. At some sites, no substances will be identified as needing further evaluation. Your public health conclusions will therefore be based on the results of the screening analysis process, and the *Discussion* section of the PHA should outline the information you used to draw conclusions. At other sites, you will identify substances requiring further evaluation, and the *Discussion* section of the PHA will be expanded to include the findings of the more in-depth evaluation of those substances (see Chapter 8).

References

ATSDR. 1993. Cancer policy framework. Atlanta: US Department of Health and Human Services. January 1993. Available at: http://www.atsdr.cdc.gov/cancer.html

EPA. 2003. Draft final guidelines for carcinogen risk assessment final (external review draft). U.S. Environmental Protection Agency, Risk Assessment Forum, Washington, DC, NCEA-F-0644A. March 2003.

EPA. 1997. Exposure factors handbook. Volumes 1, 2, and 3. Available at: http://www.epa.gov/ncea/pdfs/efh/front.pdf.

Other Resources

Comparison Values

ATSDR. 1996. Minimal risk levels for priority substances and guidance for derivation, republication FR 61, 33511-15. 1996.

NCRP. 1999. Recommended screening limits for contaminated surface soil and review of factors relevant to site-specific studies. NCRP Report 129. Bethesda: National Council on Radiation Protection and Measurements. January 1999.

The Hazardous Substance Database (HazDat) at ATSDR's intranet site lists environmental and health guidelines. Health guidelines are also posted at ATSDR's Web site (http://www.atsdr.cdc.gov/mrls.html). Information in HazDat and posted on ATSDR's Web site is updated regularly.

California's Acute Reference Exposure Levels are available on-line (http://www.oehha.ca.gov/air/acute_rels/allAcRELs.html).

EPA's Information Risk Information System (IRIS) database lists health guidelines developed by EPA (http://www.epa.gov/iris/index.html). Information in IRIS is updated regularly.

EPA's maximum contaminant levels (MCLs), maximum contaminant level coals (MCLGs), and health advisories (HAs) are posted on EPA's Web site (http://www.epa.gov/safewater/mcl.html and http://www.epa.gov/waterscience/drinking/). Information posted on these Web sites is updated regularly.

EPA Region 9's Preliminary Remediation Goals (PRGs) can be found at the EPA Region 9 Web site (http://www.epa.gov/Region9/waste/sfund/prg/index.htm).

EPA Region 3's Risk-based concentrations (RBCs) list environmental and health guidelines and can be found at the EPA Region 3 Web site (http://www.epa.gov/reg3hwmd/risk/riskmenu.htm). These tables are updated in April and October each year.

EPA. Proposed Acute Exposure Guideline Values are available on-line (http://www.epa.gov/fedrgstr/EPA-TOX/2000/March/Day-15/o-t6397.htm).

FDA's guidelines and action levels are available at the FDA Web site (http://www.fda.gov/).

State-derived guidelines may be available. These values may be posted at state Web sites or may be available through the state's health and environmental agencies.

Toxicity Equivalents (TEQs)

ATSDR's approach to toxic equivalency factors (TEFs) and toxicity equivalents (TEQs) for dioxins is outlined in ATSDR 1998. Toxicological Profile for Chlorinated Dibenzo-*p*-dioxins. Atlanta: US Department of Health and Human Services.

An expert meeting was convened by the World Health Organization (WHO) in 1997 to derive consensus toxic equivalency factors (TEFs) for dioxins/furans and PCBs. The results of this meeting were reported in Van den Berg M et al. 1998. Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. Environ Health Perspect 106:775-792.

EPA released an SAB Review Draft of their Part II: Health Assessment for 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin (TCDD) and Related Compounds (SAB Review Draft) in September 2000. EPA/600/P-00/001. Available at: http://www.epa.gov/ncea/pdfs/dioxin/part2/drich9.pdf

The relevant potency of carcinogenic polycyclic aromatic hydrocarbons (PAHs) is presented in ATSDR. 1995. Toxicological Profile for Polycyclic Aromatic Hydrocarbons (PAHs). Atlanta: US Department of Health and Human Services. August 1995.

EPA. 1993. Provisional guidance for quantitative risk assessment of polycyclic aromatic hydrocarbons. Office of Research and Development. EP/600/R-93/039. July 1993.

Chapter 8
Health Effects Evaluation: In-depth Analysis

As part of the *exposure evaluation* (described in Chapters 5 and 6), you have identified who might come in contact with environmental contaminants, how those persons might be exposed, and the extent to which they might be exposed (over space and time). As an initial step in the *health effects evaluation* (described in Chapter 7), you have compared, measured, or modeled exposure point concentrations to ATSDR's media-specific comparison values. In some cases, you have estimated *site-specific* exposure doses and compared them to health guidelines. By now, you have clearly ruled out those pathways and substances that pose no health hazards, and you have retained those requiring more careful examination.

This chapter provides guidance on how to perform the more in-depth analysis needed at sites where, during the exposure evaluation and screening analysis, health hazards have not been ruled out. To this point in the public health assessment process—with the exception of knowing the numeric value of the health-based comparison value—no information about the substance(s) of interest has been required. As depicted in Figure 8-1, the process described in this chapter involves looking more closely at substance-specific information in the context of site exposures. The goal of this analysis is to provide perspective on what it means when a health-based screening value has been exceeded, and in some cases, how to address specific community health concerns regarding that situation. The analysis will help answer two important questions health assessors face:

- Are public health actions needed to prevent exposures?
- Are site-related exposures expected to cause harm?

This chapter will guide you in evaluating and integrating exposure data (i.e., site-specific exposure conditions that have been studied throughout the public health assessment process) and substance-specific health effects data (e.g., toxicologic, epidemiologic, and health outcome data). The output of the analysis is a *qualitative description* of whether site exposure conditions are of sufficient nature, frequency, and magnitude to affect public health adversely. The outcome will also assist in determining an appropriate public health response.

Because of uncertainties regarding exposure conditions and the adverse effects associated with environmental levels of exposure, definitive answers on whether health effects actually will or will not occur are not always possible. However, providing a framework that puts site-specific exposures and the potential for harm in perspective is possible and is one of the primary goals of the public health assessment process. The narrative describing your findings should therefore lay out this framework.

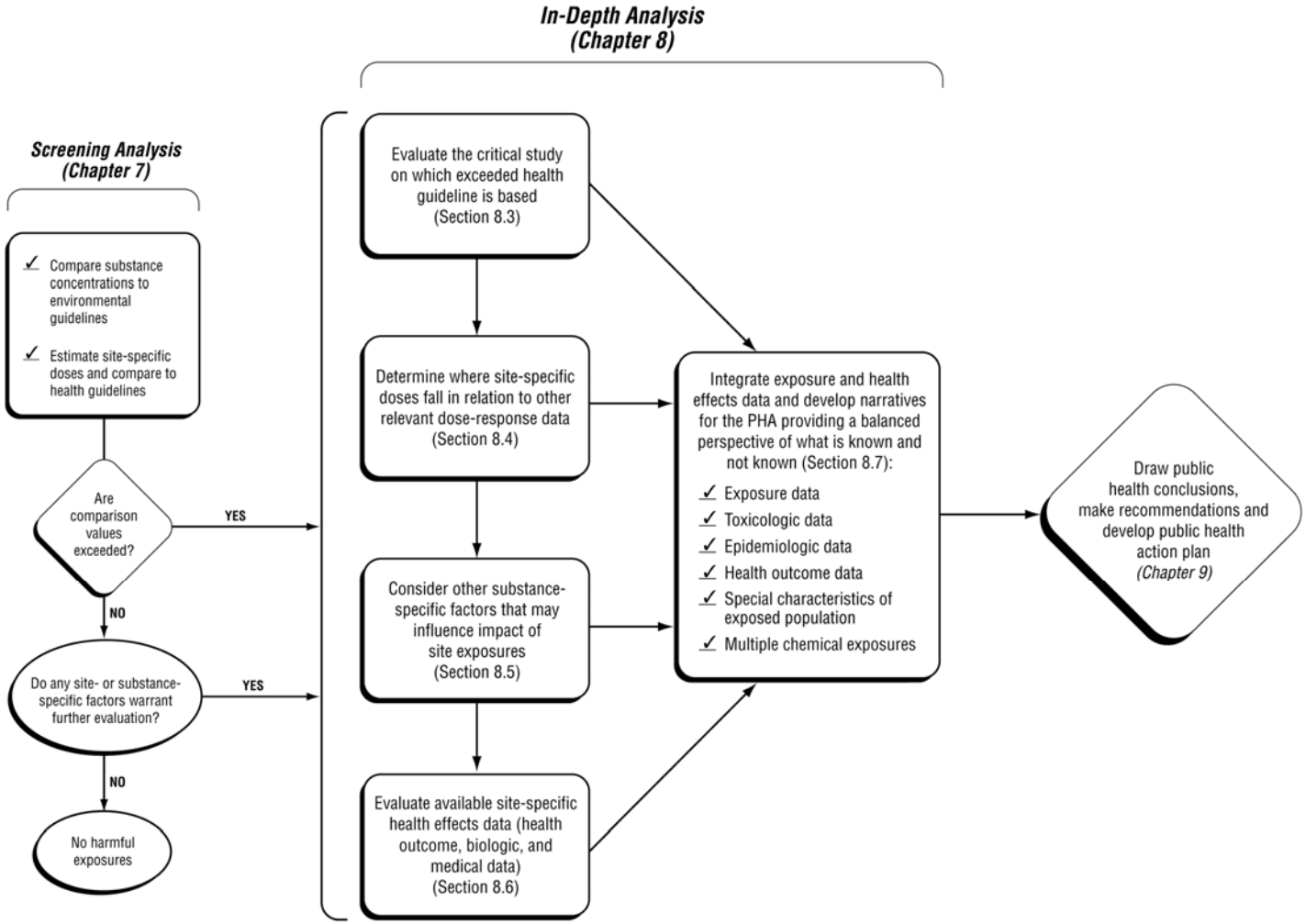


Figure 8-1. Overview of In-depth Analysis

After discussing the criteria that will trigger an in-depth analysis (Section 8.1) and the tools and resources available to support your analysis (Section 8.2), this chapter will guide the health assessor through the following steps:

- Evaluating the experimental or human study(ies) on which the exceeded health guideline value was based. (Section 8.3)
- Determining where site-specific dose estimates fall in relation to other dose-response data. (Section 8.4)
- Reviewing other substance-specific factors that could increase or decrease the potential for harmful effects, such as our understanding of the overall behavior of the substance within the human body and the mechanism by which it exerts its toxic effect, knowledge of substance-specific effects among susceptible populations, and multiple chemical exposures. (Section 8.5)
- Determining whether relevant site-specific health effects data should be evaluated in the public health assessment, such as mortality and morbidity data (also called health outcome data), or biologic monitoring data. (Section 8.6)
- Integrating relevant information and presenting it in the PHA document. (Section 8.7)

Not all public health assessments will require you to consider all the elements of the in-depth analysis described in this chapter. The level of analysis will differ across sites and will depend on the scope and complexity of site-related issues, such as the magnitude of exposures, the substance(s) under evaluation, and specific community health concerns.

One of the primary goals of ATSDR's public health assessment process is to provide reliable, understandable information to the public. The information in this chapter is designed to guide the health assessor in conducting the more in-depth analysis needed to communicate that added perspective.

As you review and integrate exposure and health effects data, *professional judgment* is needed in weighing what is known and unknown, including uncertainties and data limitations. You may need assistance from other members of your site team or other technical specialists, including those with expertise in toxicology, epidemiology, medicine, and health physics. This chapter will guide you on how to work with these specialists to define the appropriate level of analysis for your site and in evaluating the strength and relevance of available information. As the health assessor, you will be responsible for integrating and communicating the findings of this analysis in the public health assessment document.

8.1 When to Conduct an In-depth Analysis

During the screening analysis (Chapter 7), after careful consideration of site-specific exposure conditions, you eliminated those substances and pathways *not expected* to result in adverse health effects. You then determined whether exposure to measured or modeled levels of

contaminants required further evaluation. In many cases, you will not need to go any further. However, you should proceed with a more detailed analysis, as outlined in this chapter, if any of the following occur[1]:

- Site-specific exposure dose estimates exceed health-based guideline values (e.g., MRLs are exceeded or theoretical cancer risk levels exceed 10^{-6}).

- No relevant and reliable screening value could be found or generated for a substance. As noted in Chapter 7, exceptions can include essential nutrients and other constituents naturally found in environmental media (e.g., calcium, iron, magnesium).

- The community has expressed concern about a particular substance or exposure. Even in cases where comparison values have not been exceeded, a more in-depth review of the health effects data might be needed to adequately address the community health concern.

8.2 Tools and Resources Needed to Support an In-depth Analysis

In general, an in-depth analysis will require the examination and interpretation of reliable substance-specific health effects data (toxicologic, epidemiologic, medical, and health outcome data). Much of the data will relate to dose-response relationships for the substance and pathways of interest. You also will determine whether health outcome data should or can be obtained (i.e., information from pre-existing databases such as local or state disease registries). In some cases, community or site-specific survey data might be available for evaluation as part of the public health assessment.

ATSDR's toxicological profiles serve as an important resource for health effects data. In most cases, these profiles will provide the information needed to support your analysis and draw public health conclusions. Each peer-reviewed profile identifies and reviews the key literature that describes the toxicologic properties and adverse effects associated with a substance, including information on populations that might be unusually susceptible to a particular substance. These profiles also contain other substance-specific data, such as information on bioavailability and interaction with other chemicals. Limitations and uncertainties of individual studies and the overall database are highlighted. The box on the following page summarizes the content of ATSDR's Toxicological Profiles.

Other compilations of toxicologic data include resources such as the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) database, International Agency for Research on Cancer (IARC) Monographs, and National Toxicology Program (NTP),

[1] ATSDR recognizes that resource issues or regulatory mandates in some states can influence the public health assessment approaches used by these states. For example, conclusions and recommendations for public health actions might be based on a comparison of site-specific exposure estimates to health-based screening values or state standards, rather than the more in-depth analysis described in this chapter. In such cases, the public health assessment document must clearly communicate what this regulatory approach does and does not mean. That is, preventing or reducing exposures to substances detected at levels exceeding screening values might be a protective public health action, but in many, if not most cases it does not imply that exposure levels have or will cause actual harm. This needs to be explicitly stated in the PHA document.

ATSDR's Toxicological Profiles

ATSDR's Toxicological Profiles contain information for more than 200 chemicals (http://www.atsdr.cdc.gov/toxpro2.html) commonly found at hazardous waste sites. This includes "interaction profiles" for chemical mixtures that may be found together in environmental media at hazardous waste sites (e.g., arsenic, hydrazines, jet fuels, strontium, and trichloroethylene).

In general, the profiles present:

- An examination, summary, and interpretation of available toxicologic information and epidemiologic evaluations on a substance to ascertain the "levels of significant human exposure" for the substance and the associated acute, subchronic, and chronic health effects.

- A determination of whether adequate information on the health effects for each substance is available or in the process of development.

Each profile presents a public health statement that answers basic health questions in plain language. In addition to including information on the chemical's use, physical/chemical properties, and pertinent regulations and advisories, each profile presents a detailed summary of the toxicology of the chemical through a review of the peer-reviewed literature, including an analysis of the adequacy of the database and the identification of data gaps. Note that Appendix B of each Toxicological Profile includes a User's Guide.

Except in rare cases (e.g., PCBs), health effects are discussed by route of exposure (inhalation, oral, and dermal), by type of effect (death, systemic, immunologic and lymphoreticular, neurological, reproductive, developmental, genotoxic, and cancer), and by exposure duration (acute, subchronic, and chronic). Toxicokinetics (absorption, distribution, metabolism, elimination/excretion, and PBPK/PBPD models, when available) also are described. When information is available, the profile also discusses chemical mechanism of action and interactive effects with other chemicals.

The profile includes a description of potentially sensitive or unusually susceptible populations, including children. Potential for human exposure (including discussions on environmental releases, typical environmental levels, and environmental fate), biomarkers of exposure and effect, and methods for measuring the chemical are detailed when possible.

Each profile also presents the basis for any MRLs derived for that particular substance (including the study[ies] used, critical endpoint[s], and uncertainty factors applied).

Health assessors are encouraged to consult with the chemical manager within ATSDR's Division of Toxicology to determine the status of substance-specific profiles and any ongoing research, especially for chemicals with profiles that have not been recently updated.

as well as some non-governmental resources. For more in-depth evaluations or in the absence of secondary sources such as those mentioned above, standard toxicology textbooks and *peer-reviewed* scientific journals of environmental toxicology or environmental health can be consulted. A listing of and links to such resources are provided at the end of this chapter.

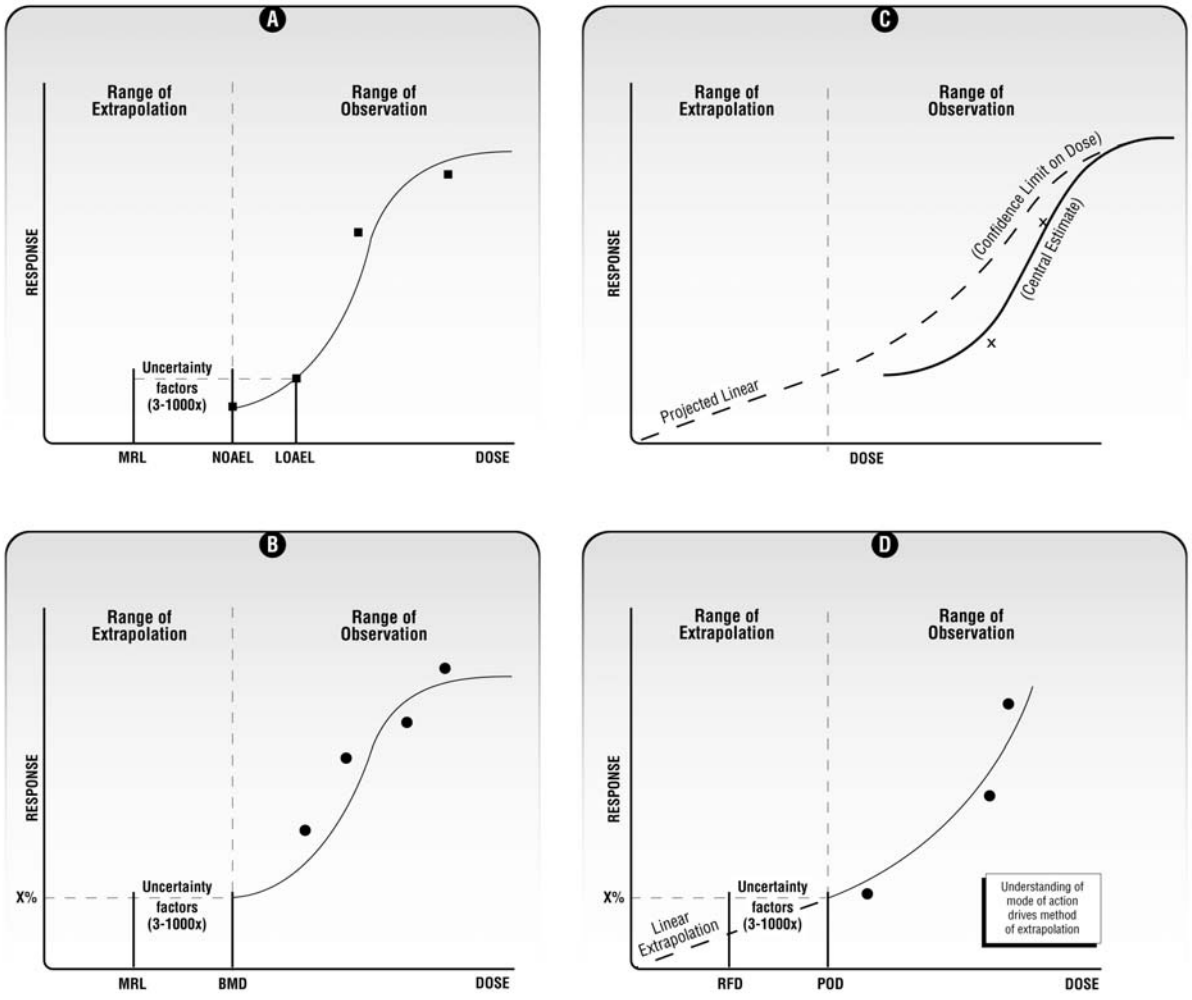
When identifying the most relevant and up-to-date sources of data to support your analysis, you might need to consult with the appropriate experts on your team. Conducting a critical review of toxicologic or epidemiologic data requires specialized training and a thorough understanding of underlying scientific principles. Similarly, a health physicist will need to assist in identifying appropriate resources for evaluating radiological hazards. The ATSDR Division of Toxicology chemical manager is another resource in determining the status of any ongoing substance-specific research. If available secondary resources (such as toxicological profiles) have not been recently updated, it is important to identify the current state of the knowledge for a particular substance. (While ATSDR is continually reviewing substance-specific toxicologic data, some of the profiles could be a few years old.) New information regarding observed effect levels or low-dose behavior might be important in interpreting site-specific doses (see sections that follow).

8.3 Evaluating Studies on Which Exceeded Health Guidelines are Based

As described in Chapter 7 and in Appendix F, the health guidelines used in your screening analysis are generally *extrapolated* doses from *observed* effect levels in animal studies. Health guidelines are usually based on a "critical" or "key" study—generally, the study reporting the most sensitive endpoint at the lowest dose level. Depending on the available data and the type of toxic response, observed effect levels are then adjusted by a series of uncertainty factors or through the use of statistical models to ensure that they are amply health-protective (see Figure 8-2). Setting screening values at levels well below those known to cause harm is consistent with the fundamental concept of public health: prevention.

Simply being exposed to a hazardous substance does not make it a hazard. The magnitude, frequency, timing, and duration of exposure and the toxicity characteristics of individual substances affect the degree of hazard, if any.

When a health guideline is exceeded, a first step in understanding the public health significance of exceeding that guideline is to review and understand the basis for that guideline. Understanding the applicability and strength of the study data will be a primary tool in evaluating whether site exposures are expected to cause harm. *The goal of the analysis is to determine where site-specific doses lie in relation to the observed effects levels reported in the studies of interest and whether differences between study data and the exposure scenario being evaluated make health effects more or less likely.* When developing health guidelines such as MRLs, ATSDR toxicologists and others extensively study the toxicologic literature and weigh the scientific data (including the factors highlighted below). Reviewing the basis for an MRL and other health guidelines as part of this analysis in no way diminishes the importance of the health guideline; rather, it serves as a means of gaining perspective on how strongly the supporting toxicologic data suggest that *harmful* exposures have occurred or might occur under your site-specific exposure conditions.



BMD = Benchmark dose
MRL = Minimal risk level
LOAEL = Lowest-observed-adverse-effect level
NOAEL = No-observed-adverse-effect level
MOA = Mode of action
POD = Point of departure
RFD = Reference dose

A = NOAEL/LOAEL approach
B = BMD approach
C = Low-dose linear extrapolation
D = POD/MOA evaluation

Figure 8-2. Schematic of Various Low-dose Extrapolation Methods

Two key steps in this analysis involve (1) comparing site exposure doses with observed effect levels reported in the critical study (Section 8.3.1) and (2) carefully considering study parameters in the context of site exposures (see Section 8.3.2). You will generally find information on the critical study in ATSDR's toxicological profiles, in the section entitled *Health Effects: Relevance to Public Health* and in the appendix presenting *ATSDR Minimal Risk Levels and Worksheets,* or in EPA's IRIS database.

8.3.1 Compare Site-Specific Doses to Observed Effect Levels

Non-cancer effects

This step in the process involves comparing your substance-specific exposure dose to effect levels that are reported in the critical study used to derive the screening value that has been exceeded.[2] The health assessor should review the section of the toxicological profile in which the MRLs are derived. The assessor should note whether the MRL is based on a human or animal study and whether the MRL is derived from a no observed adverse effect level (NOAEL) or lowest observed adverse effect level (LOAEL). The assessor should then compare the site-specific exposure dose to the NOAEL or LOAEL[3].

If the site-specific exposures are well below a NOAEL that is based on a human study, the likelihood for adverse health effects in the exposed population would be low. If, however, the NOAEL is based on an animal study, exposure doses near the NOAEL could be of concern because of uncertainty in the relative sensitivity of animals as compared to humans. (In the absence of contrary information, it is prudent to assume that humans are more sensitive to the chemical than are animals.)

In some instances, an MRL is derived from a LOAEL, rather than from a NOAEL. The likelihood of adverse health effects increases as site-specific exposures approach a LOAEL derived from either a human or animal study. Because, by definition, LOAEL doses cause adverse health effects, exposures that approach or exceed a LOAEL are of concern and should be identified as a public health hazard.

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[2]The evaluation of non-cancer and cancer endpoints are described separately in this manual because of the non-cancer/cancer dichotomy used historically in quantitative risk assessment and in the derivation of many health-based screening values. (See text box below for a brief discussion on the movement toward harmonizing the approaches used to evaluate non-cancer and cancer endpoints and its relevance to the in-depth analysis described in this chapter.)

[3] In some cases, the health guideline can be based on benchmark dose" (BMD) or "point of departure." The benchmark dose method involves fitting mathematical models to the available dose-response data (from single or multiple studies) and using the results to select a dose associated with a specified low level of risk (e.g., a 5% or 10% increase in the incidence of stomach lesions). Scientists have long recognized the limitations of relying on the NOAEL from a single study when deriving health guideline values (Crump 1984; Kimmel and Gaylor 1988). The approach is limited to a single dose within a study and is dependent on study design. It does not account for the variability in the estimate of the dose-response and does not account for the slope of the dose-response curve.

A Harmonized Approach for Assessing All Toxic Endpoints

Historically, different approaches have been used in conducting quantitative risk assessment for non-cancer and cancer endpoints. For non-cancer risk assessment, the more traditional toxicology principle of dose "thresholds" has been applied when evaluating potential risks, where the potential for adverse health effects is evaluated based on relevant observed effect levels known as the "no-observed-adverse-effect level" (NOAEL) or the "lowest-observed-adverse-effect level" (LOAEL). For cancer risk assessment, on the other hand, the approach used by risk assessors has been to assume that no threshold exists. This stems back to early assumptions that the process of chemical carcinogenesis is similar to that of radiation carcinogenesis and that any exposure is assumed to carry with it a risk of cancer (Bogdanffy et al. 2001). Under this assumption, risk assessors extrapolate down to low doses using statistical models based on an assumed dose-response relationship (generally considered linear to zero). Such modeling can predict risks associated with doses thousands of times lower than those at which tumors are actually observed (referred to in ATSDR's toxicological profiles as "cancer effect levels").

Advancing scientific knowledge regarding the mechanism by which substances act at low doses suggests that the traditional use of threshold and non-threshold models for non-cancer and cancer risk assessment, respectively, needs to be re-examined (EPA 2003a). For example, scientists are learning that some carcinogens are not genotoxic (that is, cancer is not initiated by interaction with DNA). In such cases, threshold dose levels can be identified and used for comparison purposes in interpreting exposure doses, similar to our comparison to "NOAELs." Further, research on modes of chemical toxicity may establish links between non-cancer responses to toxic agents and subsequent overt manifestations of toxicity such as cancer (Bogdannffy et al. 2001).

The guidance provided in this chapter is built on this broader understanding of toxic action. It guides the health assessor through a series of considerations related to toxic potential that will help determine whether the potential for harm is more or less likely given what is known and not known about the characteristics of a particular substance under site-specific exposure conditions.

The health assessor should also consider the relevance of the MRL study to the site-specific exposure conditions and the exposed population. If the MRL was based on a NOAEL in adults, and the population at the site includes a sensitive population such as children, the NOAEL might not apply to all segments of the population. The assessor should also consider the exposure scenario of the MRL study. In experimental studies, administration of a high bolus dose of a chemical to an animal could have a different effect than low-dose chronic or intermittent exposures in humans. Also, the assessor should consider the confidence in the MRL study; if similar findings have been reported in other studies, confidence in the study is enhanced. Section 8.3.2 of this chapter discusses other factors to consider when evaluating the relevance of the MRL study.

As you review and integrate exposure and health effects data, professional judgment is needed in weighing what is known and unknown, including uncertainties and data limitations. You may need assistance from other members of your site team or other technical specialists, including those with expertise in toxicology, epidemiology, medicine, and health physics. The assessor is also encouraged to consult with other health assessors to gain insight into how similar situations have been addressed previously.

Cancer effects

In some cases, quantitative risk assessment might have been used in your screening analysis or by regulatory agencies evaluating your site. Regulators could call for cleanup of a site when theoretical cancer risks fall within the 10^{-6} to 10^{-4} range, but understanding the variables and assumptions involved in the derivation of these estimates and explaining in qualitative terms what exposure doses mean based on a review of the scientific literature is the purpose of the in-depth analysis.

As with all toxic endpoints, you need to look at site-specific doses in relation to observed effect levels and then provide context. Consider each of the following factors when evaluating cancer outcomes. This information should be used in the public health assessment to (1) qualitatively describe the cancer-causing potential of a particular substance, and (2) compare site-specific dose estimates with doses or exposure concentrations shown to result in cancer in experimental studies or epidemiologic studies. This process is aimed at weighing the available evidence—in light of uncertainties—and offering perspective on the plausibility of cancer outcomes under site-specific exposure conditions.

- *Cancer classification.* When communicating the potential for cancer hazards, state how strongly associated a substance is with cancer outcomes. Various government agencies and organizations use a "weight-of-evidence" approach in evaluating substance-specific carcinogenicity. The U.S. Environmental Protection Agency (EPA), the National Toxicology Program (NTP), and the International Agency for Research on Cancer (IARC) classify carcinogens based on the strength of the scientific evidence linking the substance with cancer outcomes under the reported conditions of testing.

  Discussions of carcinogens should therefore include these classifications. The most current cancer classification information can be obtained from ATSDR's comparison value tables, which are updated quarterly. More detailed information on the carcinogen classification for a specific substance can obtained through EPA, IARC, or NTP.

  When discussing a chemical's carcinogenicity, explain in plain language what the different classification categories mean. For example, "human studies clearly link the substance of interest with certain cancers" or "while some animal studies have shown increased tumors after exposure to the substance of interest, human data do not suggest a link between the substance and cancer in humans." Note that ATSDR evaluates the relevance of animal data to humans on a case-by-case basis. In the absence of compelling data to the contrary, however, a substance that has been shown to cause cancer in animals is considered to be carcinogenic in humans.

- *Identifying effect levels or a point of departure.* For known or potential human carcinogens, understanding the doses at which cancer effects might be expected under site-specific exposure conditions requires an understanding of the dose-response curve for the substance of interest. Most available toxicologic data report cancer effects at doses much higher than those likely to be seen at hazardous waste sites. A first step therefore is to look at dose levels in this range of observation. In some cases (similar to the

benchmark dose described above), toxicologists model available dose-response data to identify a "point of departure" (or an estimated or modeled dose that is near the lower end of the observed range). For example, a 5 or 10 percent effect level is often selected as the point of departure. This point of departure is then used as a stepping-off point for evaluating possible cancer effects at lower doses.

As stated previously, various mathematical models have been developed to predict the potency of substances at low doses. These models are based on scientists' understanding of the slope of the dose-response curve at high doses, and a series of assumptions about substance-specific behavior at doses below the range of observation (e.g., below the point of departure). When applying these models, scientists have by default historically assumed no threshold (or linear dose-response). As scientists learn more about the mechanism or mode of action by which carcinogens act, they are learning that this might not always be the case (EPA 2003a; Bogdanffy et al. 2001).[4]

Health assessors are not expected to conduct the types of modeling analyses described above. However, considering the following questions will help the assessor understand the behavior of a particular carcinogen. This perspective is then communicated in the public health assessment document.

- *At what levels have cancer effects been reported in the literature?* Proceed with caution, but comparing site-specific doses with the lowest reported cancer effect levels (CELs) can offer some perspective. Realize that CELs presented in the toxicological profiles represent only a snapshot of observed effect levels. As discussed above, it is not known whether lower doses will elicit a carcinogenic response. Also, review EPA's IRIS summaries and toxicological reviews to understand the basis for EPA's cancer slope factors and the studies used to support risk assessment decisions, including identified effect levels or calculated points of departure.

- *What is known about a substance's mode of action that might increase or decrease the likelihood of a cancer response at low doses?*

  As emphasized in EPA's guidelines for cancer risk assessment, knowing the manner in which cancer is initiated or promoted by a substance (i.e., the mode of action) will help in determining the following: (1) whether a "safe" level or threshold may exist for that particular substance, or (2) whether evidence or sufficient uncertainty exists to suggest that even at very low doses cancer potential cannot be ruled out (EPA 2003a).

  In cases where low dose extrapolations have been used to quantify a theoretical estimate of cancer risk, it is critical to put the calculated risk into perspective

[4] See Appendix F for further discussion on how EPA derives its cancer slope factor and its current approach to cancer risk assessment.

when discussing site-specific cancer hazards. Remember that any such estimate is based on several conservative assumptions to account for uncertainties. The true risk might be much lower; it might even be as low as zero (ATSDR 1993; EPA 2003a). Therefore, the health assessment team is encouraged to compare site doses with observed effect levels reported in the toxicologic and epidemiologic literature and discuss those site doses qualitatively in the context of issues presented throughout the remainder of this chapter.

Evaluating carcinogens in this manner—assuming scientific data are available to support the analysis—provide the type of information needed to better communicate hazard potential to the community. A balanced discussion of what is known and not known will help provide more meaningful perspective to the community.

As our understanding of substance-specific toxic action grows, public health conclusions can change. Toxicologists at ATSDR and at other agencies, such as EPA, are reviewing available toxicologic information on an ongoing basis to help ensure the most accurate and scientifically defensible assessment of substance-specific hazards. The examples below illustrate the potential significance of identifying, understanding, and communicating the current understanding of a substance's toxic action.

In examining tumor responses in mice exposed to chloroform, scientists have discovered that chloroform appears to work through a non-genotoxic mode of action—that is, tumor responses are produced only at dose levels that result in cytotoxicity. Therefore, NOAELs have been identified both via ingestion and via inhalation routes of exposure below which no increases in cancer would be expected (Jorgenson et al. 1985; Larson et al. 1994 and 1996). As a result of these studies, EPA has determined that the oral reference dose (for non-cancer effects) for chloroform is protective against an increased risk of cancer, and EPA is currently working to revise its assessment for inhalation exposure (EPA 2001). Using the newer inhalation data instead of the default linear dose extrapolation method could result in marked increases in predicted "safe" exposure concentrations. Based on this newer understanding, Larson et al. (1996) contrast a safe exposure concentration of 0.01 parts per million (ppm) of chloroform in air to the current IRIS value of 0.000008 ppm, even after applying an uncertainty factor of 1,000.

On the other hand, remaining uncertainties related to arsenic behavior at low doses have prompted regulators to lower the drinking water standard for arsenic.

The expertise of a toxicologist should be sought when seeking and interpreting any such data, but recognize that understanding the basis for the health guidelines that have been exceeded will, again, enable you to better communicate health hazard information.

What if no health guidelines exist?

For some substances, no health guideline has been derived. This could be due to inadequacies and uncertainties in the available scientific literature. In such cases, consult with the toxicologist on your team to review the most current dose-response data and the status of any pertinent research. If appropriate study data can be identified, draw inferences using the guidance provided in the remainder of this chapter. If no or limited data are identified, review exposure potential and determine whether the absence of toxicity data is considered a critical information gap to assessing possible site hazards. If so, the team might recommend the need for further research (see Chapter 9).

Remember, the narrative of the PHA should clearly state what is known and what is unknown about the toxicity of the substance in question. You need to explain clearly and justify your conclusions and recommendations.

8.3.2 Assess the Relevance of the Critical Study

Whenever reviewing dose-response data, an understanding of the underlying study is pivotal. If the dose comparisons discussed above reveal the need for further analysis, judging the relevance of the critical study used in developing a health guideline to the site-specific exposure situation will provide another piece of information to guide health conclusions. (These factors are relevant when reviewing other studies as well). As the health assessor, you will add site-specific knowledge and insight that will be critical to this evaluation.

You should be able to perform the basic steps of a data review. Assessing the relevance of available studies requires both technical expertise and professional judgment. Numerous considerations beyond the scope of this guidance manual affect the quality of experimental data and its relevance to site-specific exposures. Most relate to experimental design. This list, and associated examples, should not be viewed as a complete guide for evaluating all toxicologic studies but as a general guide to aid you in the context of the public health assessment process. Again, work with the appropriate experts on your team when evaluating the importance and implications of such questions. In collaboration with the toxicologist and epidemiologist on your team, consider the following types of questions when evaluating how study features might make harmful effects more or less plausible.

- *Is the critical study based on human or animal data?*

  Clearly, a study based on human data holds the greatest weight in describing relationships between a particular exposure and a human health effect. Fewer uncertainties exist about potential outcomes documented in well-designed epidemiologic studies.

  Exceeding a guideline value based on human data provides relatively strong evidence for the potential for harmful effects. Similarly, falling below a NOAEL reported in a human study could provide support for a conclusion that adverse effects are unlikely. However, before making this determination, the health assessor should consider the quality of the study and the size of the exposed group. Similarities and differences between available study data and your site-

specific exposure conditions (e.g., exposure route, chemical form) should also be considered.

- *How relevant is the dosing method to site exposures?*

  The relevance of the findings of an experimental study to environmental exposures will be influenced by how the test animal received its dose (e.g., gavage/water, gavage/oil, water, food, or vapor). Often, the exposure route in experimental studies is different from the route by which people living near a site could be exposed. Identify and discuss the differences to provide the reader with a sense of how differences can influence the likelihood of adverse health effects.

  For example, a laboratory study in which animals were administered a substance via gavage or drinking water might not directly apply to a soil-exposure scenario. This is because solubility is often an important component of how much and how quickly substances are absorbed, which might impact the nature of the toxic response. The form of the substance tested in water and gavage can differ considerably from the form present in soil. For similar reasons, a dietary animal study might not adequately represent exposures from drinking water.

  As another example, pregnant rats gavaged with oil solutions of trichloroethylene (TCE) might be consuming much more TCE per dosing than pregnant women drinking from TCE-contaminated wells. The dose received by pregnant rats in oil could far exceed the dose even possible in drinking water because of differences in the solubility of TCE in oil as compared to water.

- *How might dosing regimens influence the interpretation of the study data?*

  In addition to the method of dosing described above, the dosing regimen can influence the absorption and ultimately the effects observed in experimental studies. You will want to examine how closely, in relative terms, the study conditions match site-specific exposure conditions. Some questions to ask include: Were animals dosed continuously or intermittently? Were animals dosed over the short or long term?

  For example, the same dose administered in the shorter term (e.g., 28 days) might produce different effects than those produced after a longer-term dose administration (e.g., 90 days). Because different dosing regimens can produce different effects or affect the severity of the observed effect, one can be more confident the more closely study data match site-specific conditions. If only acute or subchronic dose data are available, state the uncertainties of applying such data to longer-term exposures.

- *Is the form of the toxicant in the selected study the same or different from the form detected at the site?*

  The form or valence state of a substance can affect its bioavailability, its distribution within the body, and ultimately its toxicity. If study data are not available for the form of the substance present at your site, determine and explain in the PHA whether the chemical form at your site could be more or less bioavailable, or more or less toxic, than the form used in the study.

  > For example, the oral intermediate MRL for uranium is derived from a drinking water study. This is an important consideration when estimating doses for the soil ingestion pathway. A review of human data indicates that the fractional absorption of soluble uranium compounds is an order of magnitude greater than that of insoluble uranium compounds (ATSDR 1999a). In weathered soils, insoluble uranium compounds will predominate. Therefore, using the MRL to assess exposure to uranium in soil would be overprotective, because of the reduced bioavailability of uranium in soil as compared to water.
  >
  > As another example, most arsenic in fish is in an essentially non-toxic organic form known as arsenobetaine (fish arsenic). Inorganic arsenic, which is considerably more toxic, makes up only a small amount (1–20%) of total arsenic in fish (ATSDR 2000; Francesconi and Edmonds 1997; FDA 1993). Therefore, if you were evaluating arsenic exposures via fish ingestion, you would need to account for this factor.

- *Are the effects observed in animals expected in humans?*

  If dose levels from animal studies (e.g., in mice, rats, monkeys) are being used to evaluate site exposures, determine whether any human or any *in vitro* studies are available that suggest a similar effect in humans. In addition, metabolism or mechanistic data, if available, could provide insight as to whether observed effects might be unique to, or different in, the study animal as compared to humans. If such data do not exist, assume that similar effects would occur in humans.

  > Some possible scenarios include: the metabolism of a chemical in animals could produce more or less toxic intermediates than in humans; the metabolism in humans could occur by another pathway and produce more toxic, non-toxic, or less toxic intermediates; or toxic intermediates could be produced at the high levels of exposures administered in the animal studies, but not at lower exposure levels. (See also discussion on toxicokinetics and mechanistic data in Sections 8.5.1 and 8.5.2, respectively).

- *How relevant are observed health endpoints to specific community health concerns?*

  While health-based guidelines are typically designed to be protective of the most sensitive effect, it is important to familiarize yourself with the range of effects associated with a given chemical in the dose range of concern. This could provide added perspective as well as help in addressing community health concerns.

  > For example, if an MRL is based on increased kidney weight in rodents and the community is concerned primarily about blood-related disorders, you might want to look beyond the critical study for substance-specific data related to hematologic effects following exposure to the substance of concern (see Section 8.4).

- *Does the bioavailability of the substance differ in the study matrix versus the environmental matrix being evaluated?*

  The bioavailability of a contaminant depends on its chemical properties as well as properties of the matrix. The bioavailability of a substance influences how much is absorbed by the human body and ultimately the potential for harmful effects. Bioavailability should be factored into the analysis when there is evidence that the chemical form at the site is more or less bioavailable than is the chemical form used in the studies being used for comparison purposes. The bioavailability of a compound is discussed in toxicokinetics section of the toxicological profile.

  > Substances in solid matrices (e.g., soil) might be less well absorbed while passing through the digestive tract than would the same substances in water. This could be due to the solubility of the substance and the property of the matrix. Some forms of a salt can bind tightly to soil, thereby reducing its bioavailability. For instance, some forms of arsenic bind tightly to soil and are therefore not readily absorbed in the human digestive system. On the other hand, the same form of arsenic in drinking water can be released from the matrix and more readily absorbed (Alexander 2000). Ultimately, the rate of substance dissolution will determine its uptake and availability (Hardman et al. 1995).

- *What uncertainties/limitations exist?*

  Identify any problems or limitations with the studies used to support your analysis. In most cases, uncertainties and limitations will be discussed in the *Health Effects* section of the toxicological profiles and in the discussion of the MRL derivation. IRIS summaries also discuss uncertainties and confidence in the critical studies evaluated by EPA.

  The PHA should describe any limitations, uncertainties, and data gaps found in the available literature. Describe in qualitative terms the uncertainty factors used in the development of health guidelines. Also discuss the level of confidence in the studies as well as their overall applicability to site-specific exposures. The higher the confidence or level of certainty, the more weight the study will hold in your analysis.

8.4 Reviewing Other Dose-Response Data

As previously discussed, health guidelines are generally based on the lowest observed adverse effect levels reported in the literature, very often from a single study. In addition to the critical study, other studies can provide substance-specific, dose-response data. For substances of potential concern at a given site, the health assessor would never be expected to perform an exhaustive review of these studies. However, reviewing the larger toxicologic and epidemiologic database (e.g., the levels of significant exposure summarized in the toxicological profiles) provides additional supporting evidence for public health assessment discussions.

In the in-depth analysis, one looks beyond single points on the dose-response curve to gain a fuller understanding of the range of effects and effect levels observed in experimental studies. Both the shape and slope of the dose-response curve can help explain where site-specific exposures lie in the larger scheme of things. This will often help provide the perspective community members seek, and it will help you decide which, if any, harmful effects might be possible. In some cases, consistent findings might be seen across studies. For other substances, findings might be more disparate.

The most important thing for the health assessor to keep in mind is how to describe in plain language what is known and not known about the toxicity of a particular substance. Questions to consider include:

- *Where does the NOAEL or LOAEL for the critical study fall in relation to other studies?* Although the critical study will weigh most heavily in your analysis, it might be helpful to describe the similarity or disparity of dose levels and health endpoints observed across studies. Your PHA should introduce information that will further support your discussion and eventual conclusions. For example, many of the reported effect levels in other studies for the substance of interest may be in the in the same general range as the critical study, strengthening the evidence that effects might be seen in that dose range.

  Recognize the importance of not taking dose-response data at face value. The criteria described in Section 8.3.2 should be considered carefully. Remember, the critical study has been identified—after careful review of the scientific literature—as the best for developing protective health guidelines. The purpose of this exercise is not to discredit that effort, but to encourage consideration of the bigger picture.

- *If the health guideline is based on animal data, do any human data exist that shed more light on the issue?* If extensive epidemiologic data are available for a particular substance, these data will likely have been reviewed and considered in the derivation of the health guideline for that substance (e.g., the MRL for methyl mercury). However, as a minimum, available epidemiologic data can be used to augment the findings of animal studies. For example, an occupational study can show that exposure to a particular substance is associated with the same toxic endpoint seen in animal studies. This observed species concordance would provide greater weight to the available animal dose-response data used to evaluate human health effects.

The exposure levels and associated outcomes, when available, can sometimes be used for comparison purposes with site exposures. For example, take the following scenario: Community members are concerned about low levels (2 parts per billion [ppb]) of a particular contaminant in drinking water that they have been drinking for approximately 10 years. They believe leukemia rates are elevated. Two independent studies of community drinking water supplies with 100 ppb of the same contaminant revealed no elevated leukemia or any other cancers in populations exposed for 30 years. In this case, the epidemiologic data might provide evidence supporting the fact that site exposures are unlikely to produce cancer effects at site exposure levels, notwithstanding possible study shortcomings. Furthermore, an understanding of toxicologic and epidemiologic data can help determine the biologic plausibility of a particular health outcome. Note that, depending on the community concern and other factors, an evaluation of health outcome data can be considered in such a case (see Section 8.6.1).

Because of the inherent limitations and uncertainties associated with environmental epidemiologic evaluations (generally due to the lack of adequate exposure data or sample size), epidemiologic data described in a toxicological profile or other sources should be used with caution. The health assessor should therefore call upon an epidemiologist to assist in evaluating the applicability and usability of literature-based or site-specific epidemiologic data.

Criteria have been established to guide epidemiologists in evaluating the strength of human data and should be kept in mind when you review and communicate such data in the context of your site-specific data (see text box below).

8.5 Evaluating Other Substance-specific Factors that Can Increase or Decrease the Potential for Harm

As depicted in Figure 8-3, multiple factors—other than the detected environmental concentration or exposure dose—influence whether an exposure could result in harmful health effects and what the type and severity of those health effects will be. A substance will only produce adverse or toxic effects if it or its metabolites reach specific sites in the body at a concentration and over a duration sufficient to produce an adverse effect. Whether exposure could lead to an adverse health outcome depends on the duration and characteristics of exposure and on the characteristics of the receptor population (e.g., developmental stage, existing disease state, genetics) that could make them more or less susceptible to site-related exposures. These factors are generally considered in the development of health guidelines and during the screening analysis, but might need to be examined more closely at this stage of the public health assessment process and described in your PHA narrative.

This section provides a brief overview of these factors and how they could weigh into your public health conclusions.

8.5.1 Biologic Uptake

Substance-specific toxicokinetic or pharmacokinetic properties (e.g., absorption, distribution, metabolism, and elimination) largely influence whether a substance will reach a target organ and

Evaluating Epidemiologic Studies

Understanding the strengths and weaknesses of the various types of epidemiologic studies (e.g., occupational studies, community-based studies) will help determine the suitability of a particular study in supporting and drawing public health conclusions. For studies presented in toxicological profiles, these points are generally highlighted. The factors which experienced epidemiologists generally consider when reviewing the quality and overall utility of studies include:

- *Are study objectives clearly presented?*
- *Is the study design appropriate for the research questions that are being asked?*
- *Is the methodology for data collection and analysis well-documented?*
- *Were exposed and control groups properly selected and characterized?*
- *Have exposures been adequately characterized?*
- *Was there sufficient length of follow-up to allow for observance of disease?*
- *Were the causes of morbidity and mortality confirmed?*
- *Were confounding factors and bias adequately considered?*
- *Was the sample size adequate to identify an effect?*
- *Were the appropriate statistical methods used?*
- *Were methods adequate for addressing missing data?*
- *Are study results clearly documented, including study limitations?*

In addition, a number of criteria assist epidemiologists in judging the causal significance of associations revealed in studies. These criteria, presented below, can help guide you as you evaluate and explain potential or dismissed causal relationships in your public health assessment. You can use these concepts in describing the evidence that a study(ies) might or might not provide — that is, the strength of the evidence linking a particular substance with a particular health outcome of interest. Individual criteria, if met, can support a causal relationship but can not prove it. The more criteria that are met, the more likely it is that an observed health effect is causally related to the exposure under study. Because the characterization of exposure is the weakest link in most epidemiologic studies, it will likely be the greatest limiting factor in establishing a causal relationship.

- Time sequence—*exposure* must *precede the onset of the disease. A logical sequence of events must be demonstrated.*
- Strength of association—*the stronger the association, the more likely it is causal. The magnitude of the relative risk (comparison of disease incidence in those exposed to incidence in those who are not) can be a valuable measure of the strength of the association.*
- Dose-response relationship—*the probability or severity of the effect should increase with increasing intensity and duration of exposure.*
- Specificity of association—*if the effect is unusual and is specific to the studied exposure, a causal relationship is more easily demonstrated.*
- Consistency—*a relationship should be reproducible (i.e., observed in other studies or analyses).*
- Biologic plausibility (or coherent explanation)—*the link between the "cause" and the effect should make sense biologically, by what is known about the disease and the exposure under study. The findings should be validated by what is known about animal models.*

Sources: Hill 1965; Rothman 1986; Susser 1973

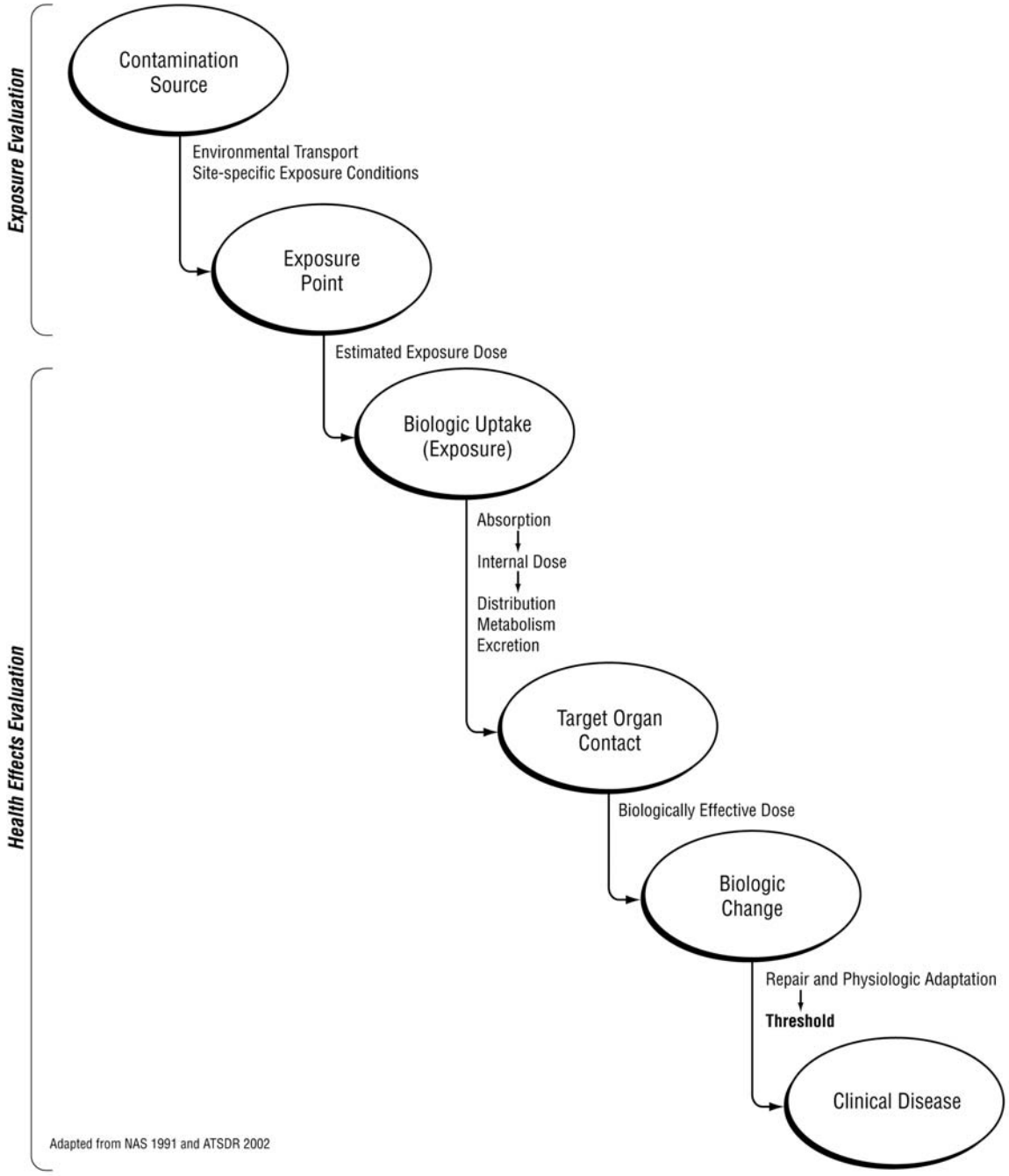

Figure 8-3. Factors Affecting Whether Environmental Contamination May Result in Harmful Effects

produce a toxic effect. If available, such information can be obtained from the toxicological profile or other data sources for toxicokinetic summaries. Determine what is known and not known about the extent to which a substance is absorbed. Also, how it is distributed through the bloodstream, changed to different forms, excreted, or ultimately delivered to target organs. When available, toxicokinetic data can be used in various ways to support your health effects evaluation. For example, it can used in interpreting the relevance of animal studies to human exposures—that is, by determining whether any distinct differences between animals and humans have been documented. For example, does the metabolism of the substance in animals produce more or less toxic intermediates than in humans? Is the substance absorbed more or less in animals compared to humans? Note that, in absence of data to the contrary, bioavailability is assumed to be the same in animals and humans under similar exposure conditions. For some substances, quantitative data can allow you to compare the bioavailability of a substance in experimental animals and humans.

8.5.2 Mechanistic Data

Knowledge continues to grow on how various toxic substances produce biologic changes and the significance of those changes. In fact, this growing knowledge is modifying how human health hazards are assessed.

While this type of analysis is best left to the toxicologists, reviewing documentation (e.g., toxicological profiles, IRIS) on the nature of biologic changes triggered by a particular substance can be helpful in evaluating the behavior of that substance at low doses. Further, understanding the basic or specific biologic changes that ultimately lead to clinical disease in a test animal can aid in determining how well animal models might predict the same type of adverse effect in humans. A toxicologist might ask, for example, if the animal mode of action is plausible in humans, taking into consideration the kinetic and dynamic factors discussed above.

For a limited number of chemicals where biologic uptake and mode of action have been well studied and defined, physiologically based pharmacokinetic (PBPK) models have been developed to estimate dose levels in various body compartments and organs (e.g., lead). These models involve a series of mathematical equations that describe the pharmacokinetics of a chemical. Inputs into the models include the exposure dose and model parameters, such as tissue volumes, blood flow rates, partition coefficients, and metabolic rates. The output is the predicted internal dose (or target tissue dose). PBPK models are also beginning to be used to evaluate chemical mixtures (ATSDR 2001a; Krishnan et al. 2002).

Pharmacodynamic (PD) models are also available; these mathematical models describe the quantitative relationship between the target tissue dose and cellular and molecular changes associated with adverse health effects. Increasingly, PD models account for damage, repair, and compensation, and predict dose-response over a range of doses, both within and between species.

When PBPK or PD models are available and are applied, they can help to reduce the uncertainty in the health evaluation. Also, the models eliminate the need for cross-species extrapolation because they can account for differences in rates of biologic processes. For some substances, toxicologists have used such models in deriving health guideline values. The data used to support

the model (e.g., metabolism and distribution data) can provide added perspective of how closely linked a particular dose might be to an adverse health effect. Although health assessors would not be expected to apply all of these types of models, an understanding of the general underlying principles can support the site-specific analysis, as described above.

Models also exist to estimate the radiation dose to specific organs and tissues, as well as total body dose. Like chemical exposures, ionizing radiation can produce many different effects, depending on (1) the type of radiation, (2) the radionuclide and its metabolic products, and (3) the dose received by the critical or most sensitive organ. When evaluating exposures to radiological contamination, enlist the help of a health physicist. See text box below for special considerations for radiological contaminants.

Radiation Exposures

People can be exposed to radiation either externally or internally. External exposure occurs when a person is exposed to a source of penetrating radiation (beta particles of specific energies and gamma radiation) outside the body. Internal exposure occurs when radioactive materials are inhaled, are ingested, are absorbed through the skin, or taken in through wounds. The potential for health effects depends in part on the radiation dose delivered, the rate of delivery, and where in the body particular radionuclides concentrate. All radionuclides are partly absorbed from the lungs and intestinal tract into the bloodstream. From there they circulate throughout the body and either redeposit in other organs or are cleared by the kidneys for urinary excretion. In general, most radionuclides taken into the body by ingestion are excreted in the feces.

Some radionuclides accumulate in specific tissues when taken internally, in the same manner as their non-radioactive forms. In general, the cells of the body that are most sensitive to ionizing radiation are those that have the most rapid rate of cell division. The cells in the body that are most sensitive to radiation are the progenitors of the blood cells, followed by the cells lining the gastrointestinal system (Hall 2000). The reader is cautioned, however, that effects resulting from radiation exposure can be difficult to ascertain. Proper knowledge of radiological dose assessment is essential before conducting a health assessment. Again, it is strongly recommended that a health physicist be consulted on these matters.

In addition, the health assessor should recognize that radionuclides can pose significant chemical toxicity that is not related to their radiotoxicity. For example, the most sensitive health endpoint for exposure to uranium is its chemical toxicity to the kidney rather than its radiotoxicity.

8.5.3 Sensitive Populations and Life Stages

Some substances have been shown to cause greater harm in particular populations or when exposure occurs at a particular point in life (e.g., fetal development). It is ATSDR policy that children's health issues must be considered at *all* sites (ATSDR 1998).

It is important to remember that sensitive populations are considered when MRLs and other health-based comparison values are developed. An uncertainty factor (e.g., a factor of 10) is generally applied to help ensure sensitive populations are amply protected. In addition,

comparison values are developed to specifically account for children's exposures. Identifying or accounting for potentially sensitive or more highly vulnerable populations should also be a key component of your exposure pathway analysis (Chapter 6) as you estimate site-specific doses (Chapter 7). Thus when comparison values are not exceeded, health assessors can be confident that it is highly unlikely that even the most sensitive populations would be adversely affected. However, when site-specific doses exceed comparison values, site- and substance-specific factors should be re-examined to evaluate to what extent, if any, a particular population is at increased risk of harm. Information on potentially sensitive populations can be found in the toxicological profiles in the section titled, *Populations that are Unusually Susceptible*. As stated, ATSDR places particular emphasis on children as a potentially sensitive population. For information on children's susceptibility, the health assessor should read those sections of the toxicological profiles that specifically discuss the susceptibility and exposure of children to chemicals (Children's Susceptibility and Exposures of Children).

Characteristics of certain populations might make them more sensitive to environmental exposures—because of underlying disease, other physiologic factors, or non-site related exposures. Many of these issues should be first addressed and highlighted during the exposure pathway and screening analyses (see Chapters 6 and 7). At this point in the analysis, you need to determine whether special characteristics of the substance and of the site community might affect public health conclusions.

- *Age.* Children differ from adults in their exposures and *can* differ in their susceptibility to certain hazardous substances. Understanding when exposures occurred during critical periods of development is therefore important. The box below highlights some special considerations when evaluating children's health issues. Note that ATSDR and others continue to research the significance of early-life exposures to toxic substances, both for cancer and non-cancer outcomes. Much of the impetus for such an approach is the growing knowledge and understanding of how a substance exerts its effect (i.e., its mode of action) and how, if exposure occurs during early-life stages, a particular mode of action can increase the risk of a toxic response (EPA 2003b).

  The literature suggests that elderly populations may have significantly heightened susceptibility to some contaminants because of lower functional capacities of various organ systems, reduced capacity to metabolize foreign compounds, and diminished detoxification mechanisms. It is difficult to generalize, however, due to variations across individuals and different rates in biological system breakdown (Hardman et al. 1995). Another important consideration is that older individuals may have much different exposures than younger adults and children.

- *Sex.* Some substance-specific adverse health effects can be mediated by hormonal influences and other factors that are sex-linked. In general, sex-linked differences in toxic susceptibilities have not been extensively investigated. However, it is well documented that, because of various physiologic modifications in the body that occur during pregnancy, pregnant women are often at significantly greater risk from exposure to beryllium, cadmium, lead, manganese, and organophosphate insecticides than are other members of the general population (Calabrese 1986).

Special Considerations Related to Child Health

Per ATSDR policy, children's health issues must be considered at *all* sites (ATSDR 1998). ATSDR recognizes that developing fetuses, infants, and children can be more sensitive to exposures than are adults in communities faced with contamination of water, soil, air, or food. That is why where possible, ATSDR develops health guidelines to account for possible adverse health effects in children. Identifying possible site-specific exposures to children is a critical step in your exposure evaluation (see Chapter 6). As with adults, when site-specific doses exceed health guidelines for children, a closer examination is necessary.

When evaluating the possible public health significance of child exposures at your site, consult the toxicological profile or other data sources to identify substance-specific data that might indicate a higher or lower likelihood of harmful effects in children. Consider the following types of questions (ATSDR 1999b).

- *What health effects have been observed in children? At what doses?*
- *Are there epidemiologic or medical studies to suggest a special effect on children? Do exposure data exist?*
- *What health effects have been observed in adults exposed during childhood?*
- *What conclusions, if any, can be drawn from animal studies (are animal models relevant to children)?*
- *Do differences in pharmocokinetics/pharmacodynamic parameters and metabolism make children more susceptible to a particular chemical than adults?*
- *What is known about a chemical's characteristics (physical, chemical, toxicological) that would influence the development of the fetus (e.g., can the chemical or its active metabolites cross the placenta)?*
- *Can the chemical or its active metabolites reach—and be excreted in—breast milk?*
- *Is the developmental process altered by the chemical of interest (e.g., neurological development). What is the critical window of exposure (e.g., is it during the prenatal or postnatal period)?*
- *Is information related to childhood cancer available (related to prenatal or postnatal exposure)?*

For more background information on the important topic of children's health, see the references and resources listed at the end of this chapter. Also consult with the toxicologist on your team.

- *Genetic background or ethnicity.* Some research suggests that certain genetic factors can increase the risk of developing chemically-induced health effects, though further research is needed (Calabrese 1994). Factors that can affect the susceptibility of exposed groups include acetylation phenotype (i.e., fast versus slow acetylators), sickle cell trait, and glucose-6-phosphate (G6PD) deficiency (Rios et al. 1993). In addition, individual variability in the induction of metabolic enzymes could cause people to respond

differently to the same environmental exposure. For health assessment purposes, the susceptibility of the most sensitive subgroups should be considered.

- *Health and nutritional status.* Understanding the location and characteristics of subgroups, such as the elderly and those of lower socioeconomic status, will help identify pre-existing health conditions (e.g., asthma, nutritional deficiencies) that might influence the impact of site exposures. Locations of schools, playgrounds, recreational areas, retirement homes, or convalescent homes on or near a site should be carefully noted as important indicators of the presence of potentially sensitive populations.

- *Cultural practices.* Various practices (e.g., ceremonies among American Indian and Alaska Native populations, subsistence fishing, medicinal use of plants) can lead to increased exposures. These factors should be considered as part of your exposure assessment and when estimating site-specific exposure doses (see Chapters 6 and 7).

8.5.4 Multiple Chemical Exposures

The approaches outlined in this manual focus largely on evaluating chemical-specific and pathway-specific exposures. That is, health effects are examined for individual chemicals for specific exposure pathways (e.g., ingesting benzene in drinking water). In reality, exposures can involve multiple chemicals and can occur through more than one exposure pathway. Approaches for evaluating the effect of multiple pathways are discussed in Chapter 7. This section highlights how to approach multiple-chemical scenarios.

The health impact of exposure to chemical mixtures can be of particular concern at hazardous waste sites, since most contain multiple chemical contaminants. While in many cases it might suffice to evaluate exposures on a chemical-by-chemical basis, in some cases you might need to examine the combined action of chemicals (e.g., additive, antagonistic, synergistic, and other interactive effects).

A first step in understanding the potential significance of multiple chemical exposures is to read the *Interactions with Other Chemicals* section of the toxicological profile about any known interactions among the substances detected at your site. These profiles can provide insight regarding what is known and what is not known about interactions among various pollutants. For many chemicals, however, information on toxic interactions is lacking, and the available literature focuses on the effects of chemical interactions at exposure doses that are much higher than those that are typically encountered at hazardous waste sites. Furthermore, even though limited information for some chemical mixtures is available, no empirical data set could account for the infinite array of chemicals in varying proportions that can be found at sites.

When conducting public health assessments, it is particularly important to understand potential toxic interactions at environmentally relevant doses of chemicals. However, relatively few studies have been conducted to assess toxic interactions in these low dose ranges. A series of important studies on the toxicity of low dose chemical mixtures was conducted by the TNO Nutritional and Food Research Institute in the Netherlands (Jonker et al. 1990; Jonker et al. 1993). In these experiments, rats were dosed with mixtures of chemicals at doses near their

individual NOAELs and LOAELs. The results of these experiments indicated that there was no discernable toxic response until the dose levels of the individual chemicals approached or exceeded their individual thresholds. However, when the chemicals were administered at their individual LOAEL doses, there was clear evidence of additive toxic effects. Furthermore, additive toxicity was observed even though the chemicals had different mechanisms of toxicity.

Other studies have provided evidence that exposure to chemical mixtures, in which the chemicals were administered at doses that were near their individual thresholds, can produce additive toxic effects. For example, rats exposed to a mixture of subthreshold doses of 1,1,1-trichloroethane, trichlorethylene, and tetrachloroethylene experienced signs of liver toxicity (Stacey 1989). In an oral feeding study, rats were dosed with cadmium and lead. Neither metal, by itself, significantly affected hemoglobin or hematocrit levels; but when the metals were administered as a mixture, significant decreases in these parameters were observed (Mahaffey and Fowler 1977).

However, there is no evidence of additive toxicity from exposure to chemical mixtures when the individual chemicals are administered at doses that are well below their individual thresholds (Seed et al. 1995; Wade et al. 2002). Nevertheless, the threshold doses for many toxic endpoints in animals are not well defined. Therefore, it is prudent for the health assessor to consider the potential for toxic effects from exposure to chemical mixtures at all sites. In the health assessment, the assessor should indicate that he/she has evaluated exposures to chemical mixtures and considered the potential for chemical mixture interactions.

As part of this evaluation, the health assessor should calculate a Hazard Index (HI) for the mixture of chemicals at a site. A HI is defined as the sum of the quotients of the estimated dose of a chemical divided by its MRL or comparable value. In mathematical terms,

$$HI = \frac{Dose_1}{MRL_1} + \frac{Dose_2}{MRL_2} + \frac{Dose_3}{MRL_3} + \ldots\ldots \frac{Dose_n}{MRL_n}$$

For additional information on calculating an HI, see ATSDR's *Guidance Manual for the Assessment of Joint Action of Chemical Mixtures*. This manual is available on CD-ROM and on the ATSDR Web site.

If the HI is less than 1.0, it is highly unlikely that significant additive or toxic interactions would occur, so no further evaluation is necessary. If the HI is greater than 1.0, then further evaluation is necessary as described below.

For chemical mixtures with a HI greater than 1.0, the assessor should compare the estimated doses of the individual chemicals to their NOAELs or comparable values. If the dose of one or more of the individual chemicals is within one order of magnitude of its respective NOAEL (0.1 x NOAEL), then there is a potential for additive or interactive effects. Under such circumstances, the assessor should conduct an in-depth mixtures evaluation as described in ATSDR's *Guidance Manual for the Assessment of Joint Action of Chemical Mixtures*.

If the estimated doses of the individual chemicals are less than one-tenth of their respective NOAELs, then significant additive or interactive effects are unlikely, and no further evaluation is

necessary. In some instances, however, the assessor might choose to evaluate further the potential for additive or interactive effects because the chemicals in the mixture have the same target organ or mechanism of action, because of exposures to potentially sensitive populations, because of uncertainty in the NOAEL, or for other reasons. In these instances, the assessor can conduct an in-depth quantitative mixtures analysis as described above.

Another valuable resource for information on chemical mixtures is the *Interaction Profiles* for priority chemical mixtures. ATSDR is developing these profiles for chemical mixtures that are of special concern to ATSDR, such as *Persistent Chemicals Found in Fish* (ATSDR 2002). These documents use a weight-of-evidence approach to evaluate the influence of interactions in the overall toxicity of the mixture. The documents also develop target organ doses that can be used to evaluate the impact of the chemical mixture on different target organs.

8.6 Evaluating Site-specific Health Effects Data

Another line of evidence that can provide additional site-specific perspective is the availability of meaningful health outcome data or human exposure data. In certain cases, data from health outcome data evaluations can provide evidence — ranging from weak to strong — of plausible associations between substance- or site-specific exposures and human health effects. In some cases, biologic data (e.g., site-specific substance concentrations in blood or urine) collected as part of exposure investigations, might be available and offer some insight on the extent of actual exposure (beyond the exposure-dose estimates generated from environmental concentrations). In rare cases, individual medical reports might be available, documenting symptoms or the results of clinical examinations. Note, however, that in most cases there is a lack of data to correlate biologic levels with health effect levels. This section describes how to determine whether such data can help support your public health conclusions.

8.6.1 Health Outcome Data

This section provides guidance to health assessors for addressing health outcome data in the public health assessment process. Health outcome data are existing data that measure disease mortality or morbidity. Health outcome data analyses or reviews are descriptive epidemiologic analyses.

In all public health assessments, ATSDR is required by the Superfund law to *consider* the evaluation of mortality and morbidity data (e.g., health outcome data). The law indicates that a public health assessment *should* include relevant health outcome data analyses when exposure to site contaminants *could have resulted* in the development or exacerbation of health effects. The guidance presented below reflects the deliberations of the ATSDR Work Group, whose members examined the decision criteria used to evaluate the appropriate use of health outcome data in the public health assessment process.

Decisions about how to use or analyze health outcome data — or whether to use it at all — should be made with the assistance of various disciplines. To reach a prudent decision, a health assessor might include input from epidemiologists, statisticians, toxicologists, community involvement specialists, health educators, and environmental scientists such as engineers or geologists.

Inclusion of a health outcome data evaluation in a public health assessment can achieve the following if it is determined that it is appropriate to include such an evaluation:

- Comparison of the occurrence of disease between a population potentially exposed to site contaminants and an appropriate reference population, such as the county, the state, or the United States.

- Assistance in addressing community concerns about the occurrence of disease in potentially exposed individuals.

- Identification of the potential need for follow-up health actions such as exposure investigations, analytical epidemiologic studies, or health surveillance.

Traditionally, at the outset of the public health assessment process, the health assessor in concert with the site team gathers community concerns and informs community members about ATSDR products and services. During this period the site team should provide to community members information about the utility of analyzing health outcome data. Specifically, community members should be informed of how ATSDR uses health outcome data, when it is available, and the criteria and rationale used to determine whether a health outcome data evaluation would enhance the public health assessment decision-making process. Therefore, regardless of whether health outcome data are used in the public health assessment itself, the analysis of the criteria for each site, as described below, is in essence the first step in the evaluation of health outcome data.

The team should use the answers to the following questions as a guide in determining whether a public health assessment should include analysis and interpretation of site-related health outcome data. See also Figure 8-4.

The criteria below focus on site-related exposure considerations only. Regardless of what path you follow, your PHA discussions must clearly describe the rationale for the decision, and how your exposure evaluation factored into the decision. In some cases, community concern about illness in their community could be a sufficient trigger to pursue health outcome data, even in the absence of a potential or completed exposure pathway. Assuming data are available for the disease(s) of concern and the geographic unit under evaluation, a health outcome data evaluation would determine whether disease rates are elevated in the community. While no possible site-specific link might exist, information regarding the presence or absence of elevated disease rates could either help allay fears or identify a disease trend in the community warranting follow-up.

The decision to proceed under such circumstances is left to the discretion of the site team, but is generally not considered part of the public health assessment process.

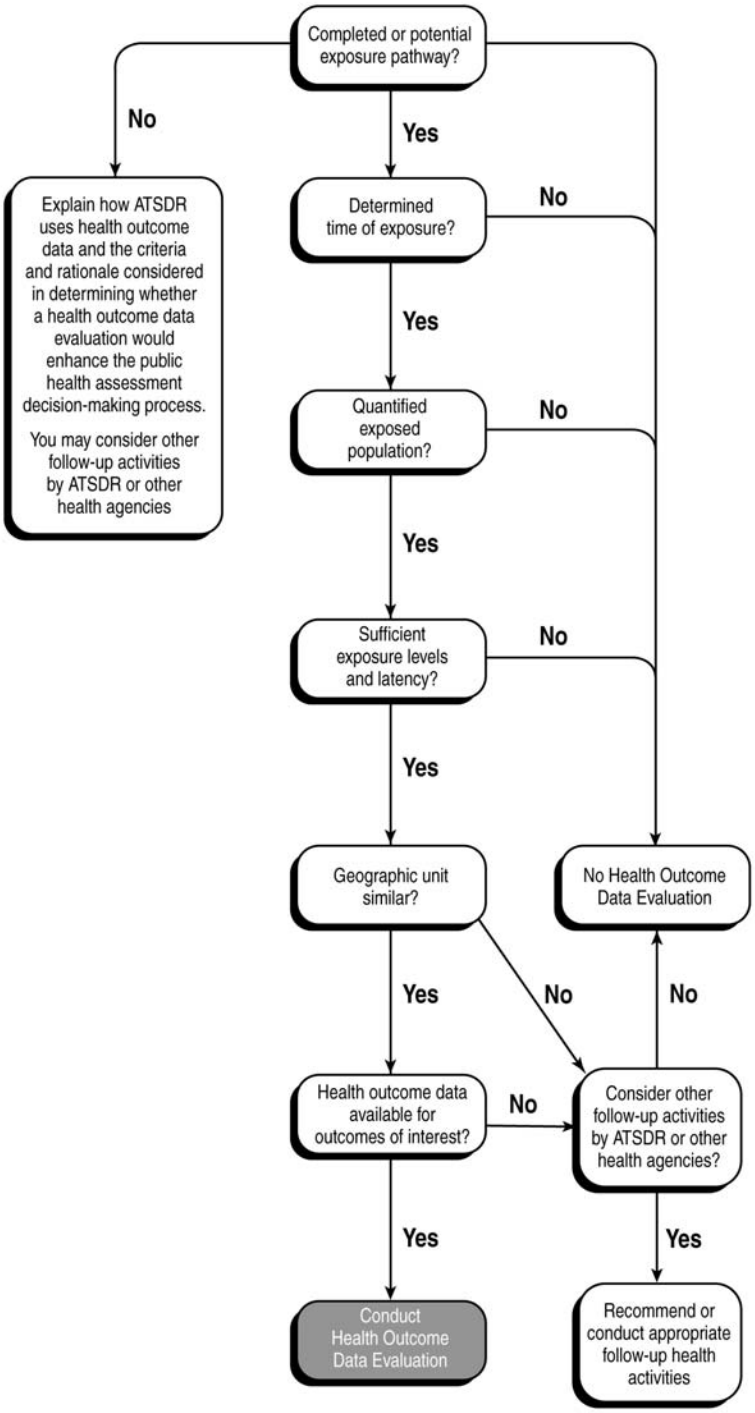

Figure 8-4. Health Outcome Data Evaluation Decision Tree (for evaluating site-related exposures)

1) **Are there one or more current (or past) potential or completed exposure pathways at the site as defined in section 6.6?** If there are *none*, conducting a health outcome data evaluation will not be helpful in assessing potential harm related to the site.

2) **Can you determine the time period of exposure?** If the length of exposure and places where exposure did occur, or is occurring, cannot be estimated, the requirement to consider analysis of site-related health outcome data is complete.

   A reasonable estimate of the length of exposure is necessary for determining whether the health outcomes evaluated are site-related. This ensures that the health outcome data being analyzed could be the result of exposure to site contaminants. The relevant exposures could have been for a few days or many years before the onset of disease, depending on the chemical involved, the age of the individual exposed, the specific health outcome, and other factors. The health assessor should ensure that the available health outcome data are from the time period when site-related health effects are likely.

3) **Can you quantify the population that was, or is, being exposed?** The evaluation of possible links (or associations) between site-related exposures and illness or disease in a population is not scientifically reasonable unless a reliable estimate can be made of the number of people exposed and the total number of people in the study population. The availability of demographic information within the exposed and non-exposed study population (e.g., age, number of years at residence, smoking status) is also an important consideration. If such an estimate cannot be made, the requirement to consider analysis of site-related health outcome data is complete.

   Statistics might be available showing the number of people identified with certain health outcomes in a selected population. However, an estimate of the number of people exposed is needed to calculate the rate of health outcomes among the exposed population. This information is required to adjust the mortality or morbidity (i.e., incidence/prevalence) rates in the exposed population to the population(s) used for comparison (i.e., non-exposed) to determine any difference in disease rates. To identify the exposed population, the health assessor needs information on where exposure occurred (i.e., geographic extent of exposure).

   Analysis of health outcome data could be impractical in sparsely populated areas—the population is too small to measure the rate of a disease. For example, if the "expected" rate for a particular disease is 5 in 1,000,000 and the exposed population only numbers 100, the absence of this disease over a short time period in the exposed population in itself will not provide much perspective. Moreover, if the disease of interest is very rare it could require a large population or, at the very least, several years of mortality or incidence data to allow any useful interpretation. Alternatively, the presence of one or two cases of a rare disease in a small, exposed population does not automatically link the exposure to the disease. It is important to identify the time period in which the cases occurred and

any known risk factors, other than the exposure, that could be present in the exposed population.

4) **Are the estimated exposure doses(s) and the duration of exposure sufficient for a plausible, reasonable expectation of health effects**? Analysis of site-related health outcome data is not scientifically reasonable unless at least a qualitative estimate of exposure doses can be made. If such an estimate cannot be made, the requirement to consider analysis of site-related health outcome data is complete; no further analysis is appropriate.

Analysis should not be done if quantitative exposure data for the exposure period of interest and the exposure doses calculated from those data are below the NOAEL, or if there is no NOAEL, the LOAEL for the chemicals being evaluated.

Qualitative exposure estimates come from exposure scenarios in which strong circumstantial evidence suggests that exposure occurred for long enough and at a sufficient enough concentration for health effects to be possible. Such evidence could include monitoring data from nearby areas, violations of air-release or water-discharge permits, reports from residents, observations by the health assessor or other knowledgeable individuals, or other relevant information. Qualitative estimates should be based on more than one type of evidence and should be made in consultation with knowledgeable environmental staff.

5) **Are health outcome data available at a geographic level or with enough specificity (i.e., census tract or census block) to allow for correlation with the exposed population?** To be able to analyze for health effects that might be site-related, the health assessor needs to be able to make an approximate identification of the exposed population within the data source or database to be utilized. If this is not possible, the requirement to consider analysis of site-related health outcome data is complete; no further analysis is appropriate.

To assess potential site-related effects, health assessors need to be able to separate the health outcomes for the exposed population from the unexposed population (at least as much as possible). If the area for which the disease rate can be calculated using the health outcome data is much larger than the area exposed, then exposure mis-classification bias will be introduced, and disease risks will be severely underestimated. For populations with past exposures, a site with high population turnover (in- and out-migration) could be the basis for not analyzing health outcome data because of the possibility of exposure mis-classification.

6) **Do the validated data sources or databases have information on the specific health outcomes or disease(s) of interest likely to occur from exposure to the site contaminants and are those data accessible?** When analyzing health outcome data that could be site-related, the health assessor should focus on specific, sufficiently known (or

suspected) health outcomes in the available morbidity or mortality databases (e.g., specific cancers, specific birth defects).

> *The health outcomes likely to occur from exposure to site contaminants might not be in the available databases. For example, if exposure to a contaminant is linked to birth defects but not to cancer, it is not appropriate to evaluate cancer data because they are available and birth defect data are not.*

If a health outcome data analysis is performed, there should be a coordinated effort among all the staff involved with the site to inform or educate community members. Also, the community should be informed about the strengths and limitations of descriptive epidemiologic analyses.

In particular, the community must be made aware that descriptive epidemiologic analyses cannot establish cause and effect. Elevated disease rates alone cannot be considered conclusive evidence that living near a waste site is the sole cause for the occurrence of a specific disease. Health outcome or descriptive epidemiologic analyses are only an initial step in determining the nature and extent of disease in the community around a site, and what that might mean.

If it is decided that a health outcome data analysis should be included in the public health assessment, the team should seek assistance from an epidemiologist knowledgeable in analyzing mortality and morbidity data.

Every public health assessment should include a brief description of the requirement to consider health outcome (mortality and morbidity) data and the reasons why a health outcome data analysis was or was not included in the document. If a health outcome data analysis is included, then the public health assessment should have a concise description of the methodology used and the results and limitations of the analysis.

8.6.2 Biologic Data

In some cases, biologic data might be available to further define or quantify exposures to site contaminants. Biologic data for exposed or potentially exposed populations can provide additional evidence when evaluating potential health effects. Depending on the levels detected, it could support or disprove plausible biologic outcomes. Site-specific, biologic sampling results must be interpreted with caution. Specifically, issues that you and the other experts on your team need to consider include:

1) Biologic data, like environmental data, need to be collected by trained professionals and analyzed in a standard way.

2) Detected levels might not be the result of site-related exposures (e.g., increased blood lead levels could be the result of lead paint exposures or traditional medicines).

3) For chemicals with short biological half-lives, results will likely only represent recent exposures.

4) The correlation between detected levels and clinical effects might not be understood.

5) The people tested might not be representative of the exposed population (i.e., results from a small sample group may not reflect the range in exposures across the entire exposed population).

Biologic testing is most commonly conducted using blood or urine samples. However, background or reference ranges for many chemicals in blood or urine have not been well defined. The utility of hair analysis as a biomarker of exposure to environmental contaminants is not well established except for methylmercury (ATSDR 2001b; Harkins and Susten 2003).

When biomonitoring data are available, they can provide additional perspective for the health assessor. Measured levels can be compared to levels shown in the literature to be associated with overt clinical effects from case studies or more subtle effects that might be inferred from population-based studies. Useful information sources on biomarkers include ATSDR's toxicological profiles (sections related to biomarkers) and Case Studies in Environmental Medicine. In addition, human exposure data for selected environmental contaminants are being collected as part of the CDC's National Health and Nutrition Examination Survey (NHANES).

In 2003, CDC's National Center for Environmental Health reported biomonitoring data for 116 environmental chemicals in the non-institutionalized, civilian U.S. population (CDC 2003). In the future, the list of chemicals will be expanded to include other important environmental contaminants. These data are valuable in comparing an individual's exposure to a chemical to exposure levels in the general U.S. population. However, these data only reflect national exposure levels, and they are not indicators of potential adverse health outcomes. Health assessors should consult with medical professionals and toxicologists for guidance in interpreting the health significance of biomonitoring data.

8.6.3 Medical Data and Information

Medical data, such as individual medical reports or logs of health conditions reported by community members, could be presented to ATSDR for evaluation in the public health assessment process. This type of data could provide some additional insights to health issues in the site community. But any form of medical data must be used and interpreted with caution. First, if the data are privileged or confidential, precautions must be taken to respect the individual's right of privacy (see Chapter 3, Section 3.5). Second, the documentation of a particular medical condition in an individual(s) does not inform you of causes or patterns of disease in the community. It is necessary to identify plausible biologic links between exposure and reported medical concerns. Credible reports of illness or disease, along with available health outcome data, can be used to support recommendations for public health actions, such as targeted biologic sampling or a health study.

8.7 Presenting Findings in the Public Health Assessment Document

As you and your team consider the topics highlighted in this chapter, you will face the challenge of integrating and communicating the findings of the analysis in a clear and concise way in the public health assessment document. As mentioned repeatedly, the goal of the in-depth analysis is to put site-specific exposures into perspective. This requires integrating the exposure and health effects data that have been identified throughout the public health assessment process and describing in qualitative terms those exposures most likely to be of public health concern and most likely to require public health action. As part of this process, you will probably need to integrate conclusions generated by a variety of analyses and, possibly, performed by various specialists.

The *Discussion* section of the public health assessment document should include narratives describing the exposures that could be of greatest concern. It should also state clearly those exposures that are not of public health concern. Keep the main discussions brief and include only information that will help the reader understand the public health conclusions. The focus should be on the possible health concerns of the potentially exposed populations. Do not present a mini-toxicological profile with information that has little relevance to the site or to the exposure situation under discussion (e.g., describing all physical characteristics of the chemical, all reported adverse effects, etc.). Include in-depth toxicologic evaluations and dose calculations in an appendix, as determined by the information needs of your audience.

Because sites differ, the emphasis of discussions can vary depending on site-specific conditions. No specific formula can evaluate the range of exposure conditions that might be observed across sites. No specific weighting factors can be assigned to each factor considered throughout the analysis. The process is one of judgment. Still, use of the guidance presented throughout this chapter and, when assimilating the findings of the analysis, consideration of the following questions will help ensure the scientific evidence is explained in a clear and consistent manner across sites. You will be building on information from other steps in the public health assessment process.

- *What pieces of evidence were used in the analysis and why?* Describe exposure conditions (see Chapters 5, 6, and 7) and health effects data. Tie in exposure condition information that might provide additional perspective (e.g., how exposure levels compare to background and the likelihood of exposures). Explain all assumptions used to estimate site-specific doses (see Chapter 7). Identify the overall availability of pertinent health effects data for the substance and pathway of concern.

- *What information evaluated by the site team will help provide dose perspective?* Describe how site-specific exposure levels compare to observed health effect levels reported in relevant studies. Consider possible acute and chronic adverse health effects. Where possible and appropriate, present ranges of effect levels reported in the literature.

  Be as explicit as possible about why exposure levels are or are not expected to be a potential problem. For example, do not state that “groundwater contaminant exposure

levels were too low to be of health concern." Instead, indicate that "exposures to detected groundwater contaminants are not expected to result in adverse health effects because dose estimates were 5,000 to 10,000 times lower than those shown to cause harmful effects in both human and experimental animal studies." Qualifying terms such as "low" or "high" by providing a comparison will help provide perspective. Also, state any assumptions used in your dose estimates (e.g., ingestion rates, exposure duration).

- *What site- or substance-specific factors might affect the ultimate toxic potential of the substances of interest* (e.g., bioavailability, persistence in the environment, interaction with other substances)? Highlight any factors identified during your exposure or health effects evaluations that might make a particular exposure more or less likely. For example, explain why the presence of a particular metal in soil is not expected to be bioavailable and therefore unlikely to cause harm. On the other hand, explain why long-term exposures to detected levels of PCBs in fish, for example, might, under site-specific conditions, warrant more concern.

- *Are there any populations that might be at increased risk?* At a minimum, your document should have a stand-alone section describing child health issues. Carefully examine demographic information for particular groups on or near the site who, based on your review of substance-specific information, might be especially sensitive to toxic effects. Any suspected high-risk groups should be specifically identified in the public health assessment report. Where possible quantify the number and proximity of people in high-risk populations, recognizing that such information might not be readily available.

- *What conclusions can be drawn looking at the overall site- and substance-specific information?* Depending upon site-specific exposure conditions, you and your team will have a variety of information to sort through and pull together. Ultimately, you will need to make a qualitative judgment about the direction in which the available information leads you. That is, how strong is the evidence suggesting the potential for harm compared to that suggesting no potential for harm? As mentioned earlier, finding a *definite* answer to whether a harmful effect will occur is generally not possible. Again, your job — to the extent possible — is to put the exposures in perspective. This will enable you and the site team to identify those exposures, if any, that warrant further public health action (see Chapter 9).

- *How do missing information or uncertainties limit the conclusions that can be drawn?* The strengths, weaknesses, and uncertainties of contributing evidence should be highlighted and organized to support your public health conclusions. Clearly state those instances when, because of weak or missing exposure or health effects data, an answer is not possible.

The two hypothetical scenarios presented below help illustrate the concepts presented in this chapter, including sample narratives. The first example offers a somewhat exaggerated set of conditions to emphasize the components of an in-depth analysis and the decision-making process. The second example presents a scenario in which exposure doses fall closer to observed effect levels, but in the past only; it illustrates the way in which observations and uncertainties would be communicated.

EXAMPLE #1: Chemical X (incidental soil ingestion)

Site-specific dose = 0.0005 mg/kg/day
MRL = 0.0001 mg/kg/day
NOAEL = 0.1 mg/kg/day
LOAEL = 1.0 mg/kg/day
CEL = 1,120–2,000 mg/kg/day

Health effects data

- MRL based on drinking water study in rats with a NOAEL of 0.1 mg/kg/day (increased liver weight at 1 mg/kg/day)
- Uncertainty factor of 1,000 accounts for animal to human extrapolation (10), human variability (10), and potentially sensitive subpopulations (10)
- Data strongly suggest Chemical X produces more toxic metabolites in rats than in humans
- Two epidemiologic studies lacking adequate exposure data indicate no reported effects linked with exposures to Chemical X naturally occurring in water supplies at approximately 20 mg/kg/day.
- The toxicological profile presents several other rodent studies with NOAELs and LOAELs 10–100 times higher than those presented in the MRL study.
- Soluble Chemical X forms in water are more bioavailable than soil-bound Chemical X forms which tend to be less soluble and only slowly released from soil matrices.
- Available studies do not suggest reproductive or developmental effects.

Exposure data (see Chapters 5, 6, and 7)

- Exposure dose assumes frequent trespassing in a largely grass-covered area.
- Exposure dose assumes exposure to maximum detected concentrations of Chemical X; exposure to average concentrations would yield a dose of 0.0002 mg/kg/day.

Suggested narrative

ATSDR concludes that site exposures to detected levels of Chemical X are not expected to result in harmful health effects. Even assuming that trespassers frequent the site and are exposed to the highest detected concentrations of Chemical X, estimated exposure doses are more than 200 times lower than doses reported to show *no* harmful effects in experimental (animal) studies and 2,000—20,000 times lower than the lowest doses shown to cause mild health effects in various studies (ATSDR 2000). Also, because Chemical X is more "bioavailable" (that is, more likely to be absorbed and distributed in the body) in water than in a soil matrix, using drinking water studies to evaluate soil exposures may not be entirely appropriate (Smith et al. 1999). However, what it suggests is that even higher exposure doses of Chemical X from site soils would likely be needed to produce the same effects reported in the drinking water studies. The likelihood of exposure to Chemical X from soils is further reduced by the presence of grassy cover throughout the area of concern. Little human data are available to provide added perspective, but two studies of people ingesting Chemical X in their drinking water reported no adverse health effects at doses 40,000 times higher than our site doses (Stillwater 1998). Lastly, scientific studies have shown that Chemical X might behave differently in rodent species than in humans. Studies show that the primary breakdown product (metabolite) of Chemical X thought to be responsible for its toxic effects is not produced in humans (ATSDR 2000). All of these factors taken together strongly suggest that detected levels of Chemical X pose no hazard to area residents.

EXAMPLE #2: Chemical Y (groundwater ingestion)

Site-specific dose - 0.02 mg/kg/day
MRL = 0.005 mg/kg/day
NOAEL = not available
LOAEL = 0.15 mg/kg/day
CEL = 200 mg/kg/day (mice)

Health effects data

- MRL based on epidemiologic study looking at residential drinking water scenarios with a LOAEL of 0.15 mg/kg/day (hypertension)
- Uncertainty factor of 30 accounts for extrapolation form a LOAEL to a NOAEL (10) and for human variability (3).
- Further review of study data indicate that the study population may have had some underlying disease and possible other exposures to Chemical Y, resulting in a possible overestimation of the reported effect level.
- Experimental studies in animals report a range of effects at dose levels at least 10 times higher than the LOAEL reported above.
- Cancer effects are reported in laboratory animals, but no evidence in humans has been documented.

Exposure data (see Chapters 5, 6, and 7)

- Exposure dose assumes daily drinking of average concentrations of Chemical Y in the most contaminated well. For the past 5 years this well has not been used for drinking water purposes.
- Dose estimates incorporate site-specific considerations (ingestion rates associated with a very warm climate and possible uptake into homegrown vegetables irrigated with the well water)
- Estimated exposure doses in 10 other nearby wells fall below the MRL (based on average concentrations detected in each well). No private wells are located downgradient of the site.
- All other residences in the site vicinity are connected to public water supplies.

Suggested narrative

After a review of available exposure and health effects data, ATSDR concludes that exposure to Chemical Y in a single well downgradient of the site *poses a past hazard*. Estimated exposure doses fall below observed effect levels in human studies, but by only less than 10 times. No documentation exists regarding completely "safe" levels (i.e., no NOAEL has been reported at doses below 0.15 mg/kg/day). Given the narrow range between estimated doses and observed effects in humans and the uncertainties about lower dose exposures, a hazard cannot be ruled out. We know that Chemical Y is classified by EPA as a possible human carcinogen, but evidence of cancer effects have been reported in animals only and at doses at least 10,000 times our site-specific doses. Cancer effects are therefore not of concern.

Because the affected well was decommissioned and all residences in areas downgradient of the site are served by public water, *no current or future hazard exists*. Further, site cleanup has reduced the concentration of Chemical Y in the groundwater beneath the site. Detected contaminant concentrations, including Chemical Y, in all other wells in the site vicinity are thousands of times lower than those believed to cause adverse health effects. Therefore, these wells present no past, current, or potential future hazard.

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Other Resources

Internet Resources

ATSDR Science Page, presented by the Office of the Associate Administrator for Science (http://www.atsdr.cdc.gov/cx.html), with links to government and non-government scientific resources.

National Library of Medicine (http://www.nlm.nih.gov/databases): PubMed and Toxnet

EPA Integrated Risk Information System (IRIS) (http://www.epa.gov/iris/), including peer-reviewed toxicologic reviews for selected substances.

EPA Region III Risk Information page, including Region III risk-based concentrations (http://www.epa.gov/reg3hwmd/risk/riskmenu/htm).

International Agency for Research on Cancer (IARC) Monographs (http://monographs.iarc.fr)

National Toxicology Program (NTP) (http://ntp-server.niehs.nih.gov/)

Toxicology Excellence for Risk Assessment (TERA) (http://www.tera.org/)

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Toxicology Terminology

Adverse effect. A change in physiologic function or cellular structure that is detrimental to the organism. An abnormal or harmful effect.

Biologically effective dose. The amount of the absorbed dose reaching the cells or target sites where adverse effect occurs and needed to produce a biologic response. The potential for an observed adverse effect once a biologic response is elicited is dependent on a host of factors including the type of action, repair mechanisms, metabolism, etc.

Cancer effects level. The lowest dose level observed to produce a significant increase in the incidence of cancer or tumors (as shown in human epidemiologic or experimental animal studies).

Effect. Any change in physiologic function or cellular structure.

Exposure. The amount of substance or radiation present in the environment that represents a potential to cause harm to living organisms.

Exposure dose. The mathematical estimation of the amount of a substance encountered in the environment per unit of body weight and time.

Internal or absorbed dose. The amount of the exposure dose that actually enters the body (i.e., penetrates barriers such as the skin, gastrointestinal tract, lung tissue). The route of exposure, type and form of a substance, among other factors influence how much of a substance is absorbed into the bloodstream.

LOAEL (Lowest Observed Adverse Effect Level). The lowest dose level at which an adverse or toxic effect has been observed (from human epidemiologic or experimental animal studies).

Mechanism of action. The specific cellular or molecular events (changes, interactions, and alterations) that lead to a specific adverse effect.

Mode of action. The overall means by which a chemical produces its adverse effect (e.g., enzyme inhibition, DNA adduct formation). A more general term than *mechanism* of action (see above).

NOAEL (No Observed Adverse Effect Level). Highest dose level (below the LOAEL) at which no adverse or toxic effect has been observed (from human epidemiologic or experimental animal studies–from an individual study).

Non-threshold. Based on the theory that a single molecular event can trigger an adverse outcome. Many carcinogens are assumed to function under this principle. The response is considered to be linear throughout the dose range. The theory leads to a mathematical model that generates a single number, the cancer slope factor (CSF) which relates risk to dose, regardless of the size of the dose (the CSF is used in quantitative risk assessments).

Pharmacodynamics. The study of biochemical and physiological effects of substances and their mechanisms of action.

Threshold. The lowest dose of a substance at which a measurable adverse effect is observed.

*Toxicokinetics (Pharmacokinetics).*The study of the kinetics (movement) of toxic substances within the body. Specifically, the study of the absorption, distribution, metabolism (biotransformation), and excretion of a substance.

Toxicology. The study of the adverse effects that chemicals may have on living organisms. It involves understanding *how* a substance gets into the body, how it is able to exert what adverse effects, how to prevent or mitigate those effects, and the amount of substance required to result in each adverse effect (i.e., the dose-response relationship).

Chapter 9
Determining Conclusions and Recommendations

Communicating your conclusions and recommendations (i.e., communicating the bottom-line public health messages) in a clear and concise way is critical. Throughout the public health assessment process, you are synthesizing information that will support and enable you to draw public health conclusions. In addition, you are identifying public health actions that might be needed to eliminate or prevent exposures, or you are identifying critical data gaps.

This chapter describes the process by which you, with the input of the site team, take the findings of exposure and health effects evaluations and draw conclusions regarding the degree of public health hazard, if any, posed by the exposure situations you have studied at a site (Section 9.1). The chapter also describes how to develop recommendations and a "public health action plan" (PHAP) (Section 9.2). An overview of the process is shown in Figure 9-1.

This chapter also describes ATSDR's "conclusion categories" and the criteria for selecting the appropriate category for a particular site. In addition, guidance is provided for developing recommendations and a PHAP that will help ensure that needed follow-up actions are achieved. The chapter also provides tips for the content and wording of conclusions and recommendations.

While this chapter focuses to a great extent on how the health assessor draws and communicates overall conclusions, it cannot be emphasized enough that public health conclusions and recommended public health actions are often made throughout the public health assessment process.

9.1 Determining Conclusions

Based on the results of the exposure and health effects evaluations, the team will characterize the degree of public health hazard at the site based on the following factors:

- The existence of past, current, or potential future exposures to site-specific contaminants (including radionuclides) or physical or safety hazards.
- The susceptibility of the potentially exposed population.
- The likelihood of exposures resulting in adverse health effects.

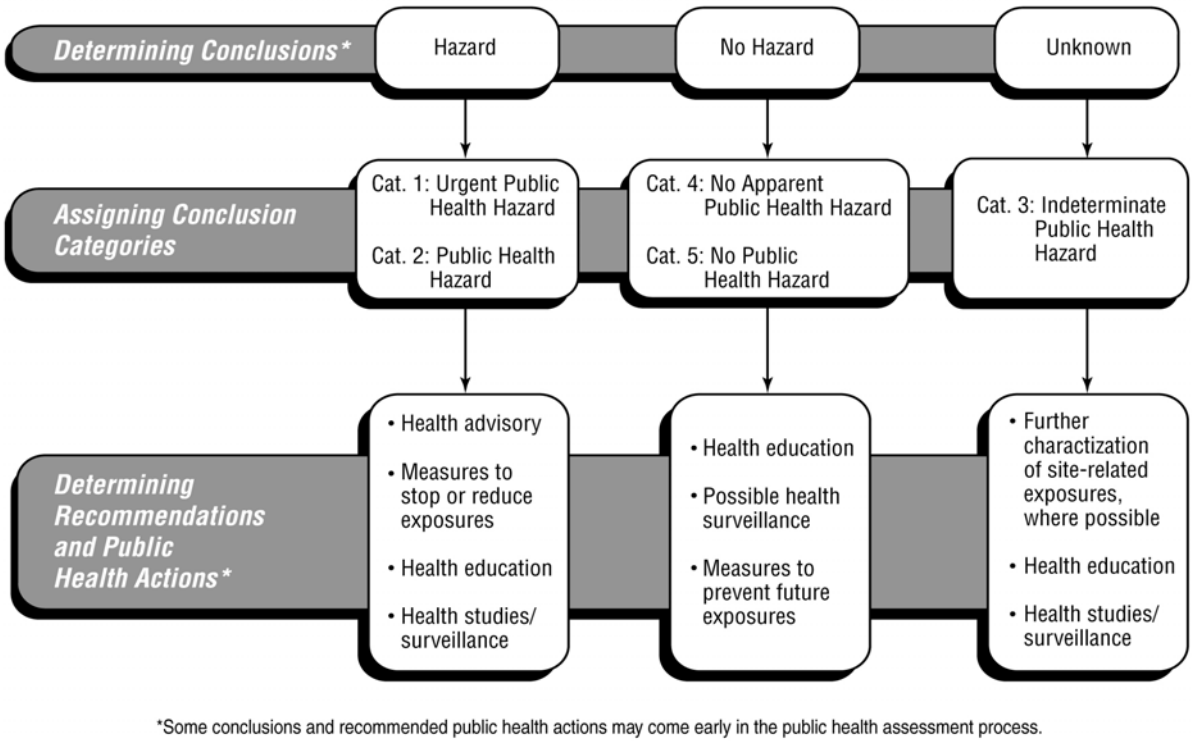

Figure 9-1. Overview of Conclusion and Recommendation Process

Based on the available information, you will need to make a statement about the health hazards associated with the site—for completed, and in some instances potential, exposure pathways and the time period of potential concern. In short, you need to determine whether conditions:

- Pose a hazard.
- Pose no hazard.
- Cannot be fully evaluated because *critical* information is missing.

One of these three choices will apply to all conditions encountered. Once you formulate your conclusions, an ATSDR "conclusion category" is assigned. Section 9.1.1 describes the process for drawing conclusions and for determining the appropriate conclusion category. Section 9.1.2 describes how to present the conclusions in the public health assessment document in a clear and succinct manner.

9.1.1 Selecting a Conclusion Category

The analyses conducted throughout the public health assessment process provide the basis for conclusions regarding the level of public health hazard a site or hazardous substance release might pose. The conclusions are dependent on the characteristics and circumstances of exposure (i.e., route, extent, magnitude, and duration). In cases where completed or potential exposure pathways are identified, conclusions should be based on the result of the health effects screening and public health implications analyses.

Within the overall framework of 'hazard,' 'no hazard,' and 'cannot be fully evaluated' (see Figure 9-1), ATSDR has established five distinct descriptive conclusion categories to help ensure a consistent approach in drawing conclusions across sites and to assist the public health assessment team in determining the type of follow-up actions that might be warranted. The conclusion categories also serve as a consistent reporting mechanism of site-specific hazards in ATSDR's Hazardous Substance Database (HazDat).

These five categories are:

- Category 1 Urgent public health hazard
- Category 2 Public health hazard
- Category 3 Indeterminate public health hazard
- Category 4 No apparent public health hazard
- Category 5 No public health hazard

The definitions for each category are presented in Table 9-1. A more extensive description of ATSDR's conclusion categories and the specific criteria that should be used in selecting a category are presented in Appendix H. Appendix H also includes possible follow-up activities associated with each of the categories (see also Section 9.2).

Categories 1 and 2 indicate that conditions are such that there is a reasonable possibility that adverse health effects have occurred or are likely to occur in *sufficiently exposed* members of the population. Category 4 indicates that adverse health effects are not likely in the population; exposures might be possible, but neither duration nor the degree of exposure is sufficient to result in adverse health effects. Category 5 indicates that no public health hazard exists because *no* exposure is occurring.

Table 9-1. Summary of Conclusion Categories

Category	Definition*
1: Urgent Public Health Hazard	Applies to sites that have certain physical hazards or evidence of short-term (less than 1 year), site-related *exposure to hazardous substances that could result in adverse health effects and require quick intervention to stop people from being exposed*.
2: Public Health Hazard	Applies to sites that have certain physical hazards or evidence of chronic (more than 1 year), site-related *exposure to hazardous substances that could result in adverse health effects*.
3: Indeterminate Public Health Hazard	Applies to sites *where critical information is lacking* (missing or has not yet been gathered) to support a judgment regarding the level of public health hazard.
4: No Apparent Public Health Hazard	Applies to sites where exposure to site-related chemicals might have occurred in the past or is still occurring, but *the exposures are not at levels likely to cause adverse health effects.*
5: No Public Health Hazard	Applies to sites where *no exposure* to site-related hazardous substances exists.

* See Appendix H for complete definitions.

9.1.1.1 What Factors Influence the Selection of a Category?

Determining the appropriate hazard category requires professional judgment. You need to decide what category best describes site conditions. A category is assigned after considering site-specific exposure potential, health effects information, and community health concerns. As discussed in earlier chapters, you must consider and integrate the total body of information available for the site when assessing public health hazards and, ultimately, in selecting the appropriate conclusion category. To reiterate, these include:

- Presence of completed or potential exposure pathways.
- On-site and off-site environmental contaminant concentrations.
- Potential for multiple source exposures.
- Contaminant interactions.
- Presence of potentially exposed populations, including sensitive or highly susceptible populations.
- Opportunities for acute or chronic exposures.

- Nature of toxic effects associated with site contaminants and the conditions of exposure associated with these toxic effects.
- Community-specific health outcome data.
- Community health concerns.
- Presence of physical hazards.

Throughout the public health assessment process, you must determine whether *critical* data are available and sufficient to support a public health conclusion. If critical data are found to be missing, you will need to consider recommending actions that might help fill those data gaps (see Section 9.2).

9.1.1.2 How Are Categories Assigned?

As repeated throughout this manual, sites are unique. Professional judgment is therefore needed in deciding how best to present the conclusions and assign a conclusion category(ies). It is rare that an entire site would be found to pose the same level of public health hazard. You should therefore generally focus on those exposure pathways and locations that pose a hazard. In doing so, you will assign conclusion categories to the exposure pathways that pose a hazard and the populations impacted. When site conditions have varied over time, it may be appropriate to assign a separate conclusion category for past, current, and future exposure conditions. For example, indicate that before municipal water was made available to the community the *groundwater pathway* posed a *past public health hazard* for those individuals drinking water from private wells within ½ mile south of a particular site. You would then note that *current and future pathways* pose *no public health hazard* because the potential for exposure to contaminants in groundwater was eliminated with the municipal water hook-up.

Sometimes for administrative purposes (e.g., HazDat reporting), a single conclusion category is selected for an entire site based on the completed exposure pathway that poses the highest degree of hazard. For example, if exposures to site-related contaminants via air and soil are shown to pose no public health hazards, but exposures to detected levels of contaminants in water do pose health hazards, then the *site* is categorized as posing a "public health hazard." In this example, it is critical, however, to also clearly describe the conclusions and absence of hazards for the air and soil pathways.

Instances often arise in which actual or potential exposures are identified but no health hazards are determined to exist (i.e., Category 4—No Apparent Public Health Hazard). For example, an estimated exposure doses might exceed a health guideline or a regulatory action level, but your integrated analysis might indicate that adverse health effects are not likely because of site-specific exposure conditions and substance-specific properties. Take, for example, a site where the maximum exposure point concentration of a particular metal exceeds an ATSDR comparison value by a factor of 10. Upon closer examination and integration of site-specific exposure and health effects data, you may determine that harmful exposures are not occurring based on the following:

- An analysis of the temporal and spatial distribution of the data reveals that assuming exposure at the maximum detected concentration overestimates likely exposures.

- Limited bioavailability of the metal greatly reduces exposure potential.

- In light of the above, estimated doses are determined to be several orders of magnitude lower than adverse effect levels seen in the relevant scientific literature.

Such a scenario might cause confusion, however, in cases where EPA or another regulatory agency is proposing or taking measures to reduce exposures by cleaning up the site (e.g., soil removal or groundwater treatment) based solely on a comparison to screening or comparison values. In such cases, you will need to offer perspective as to why detected concentrations that exceed regulatory levels of concern might not be a public health concern. Reiterate that comparison values and regulatory action levels are not indicators of adverse effects but are generally used as levels considered amply safe when setting cleanup goals (see Chapter 7 and Chapter 8). Explain why prudent public health practice calls for reducing exposures even when the assessment does not indicate that health hazards exist. For example:

> Groundwater contains elevated levels of some substances, but people have not been exposed to contaminants at concentrations or for durations that would result in adverse health effects. To ensure the continued protection of public health, groundwater is being treated to reduce contaminant concentrations and eliminate/reduce the opportunity for any future exposures.

9.1.1.3 What If Insufficient Information Exists?

Data needed to draw conclusions might not always be available. In some cases, additional data might be required to confirm or further support the decision made. It is important to carefully examine the criticality of missing data. When concluding that more data are needed to support a conclusion, determine whether the needed data can be obtained and, if so, obtained in a timely manner. In some cases, the data might never be available (e.g., past exposure data) so you will need to use the best available data (e.g., more recent sampling data or modeled data) to evaluate potential hazards and draw conclusions.

If you determine that insufficient data exist to draw a conclusion, clearly indicate this in the public health assessment document. In addition, recommend additional actions when possible (see Section 9.2) and/or state that a definitive conclusion cannot be drawn due to the absence of critical data.

Not all data gaps are data needs. Before recommending sampling or further investigation, carefully assess and distinguish what would be good to know versus what is needed to draw a public health conclusion, as well as issues that the community needs to know or that it might reasonably expect to be addressed. Provide as much perspective as possible using available data.

9.1.1.4 Is a Conclusion Category Always Needed?

Conclusion categories are required in all site-specific public health assessment products assessing the public health implications of exposure pathways or site conditions (e.g., PHAs, public health consultations [PHCs]). If you are solely providing comments, technical assistance, or general scientific information as part of a public health-related activity, a conclusion category is not necessary. Specific instances where you will not need a conclusion category include:

- Presenting comments on a site-related document (e.g., a remedial investigation/feasibility study, a work plan, or other similar documents).

- Providing technical assistance in determining contaminants to test, detection limits, monitoring levels, or other similar assistance.

- Providing general information on hazardous substances, diseases, or issues that are not directly related to a specific site.

9.1.2 Presenting Conclusions in the Public Health Assessment Document

The *Conclusion* section of the public health assessment document should present a definitive statement about the health threat, if any, posed by a site. Key issues should be highlighted. When possible, you should clearly state what is known and unknown by exposure pathway. When stating conclusions, present a clear narrative statement regarding the likelihood of adverse health effects under site-specific conditions. The health decision needs to be supported by a clear "story."

Specifically, the following should be explicitly and unambiguously stated:

- Potential health effects from exposure to site contaminants (past, current, future) by exposure pathway. Also indicate any pathways eliminated from the evaluation due to the absence of exposure.

- Responses to predominant community health concerns.

- Results of health outcome data evaluations.

- The effect that missing or insufficient information has on the analyses and conclusions.

All conclusion statements should be succinct and not repeat large portions of statements presented in the *Discussion* section. The first conclusion should emphasize the main thrust of the public health assessment and address the key issues presented in the *Purpose and Health Issues* section. Subsequent conclusions should follow the main points from the *Discussion* section. In most cases, it is advisable to present conclusions in order of public health priority or importance. Conclusion statements must be fully consistent with information presented in the public health assessment document and should not introduce any new information.

Conclusion categories must be presented in proper context. You must *clearly* describe the basis of the selected conclusion category(ies). As mentioned above, ATSDR designed its conclusion

categories to help assessors consistently formulate conclusions. You should therefore understand and follow the criteria set forth for selecting a conclusion category. When communicating conclusions, however, it is of utmost importance to clearly describe the essential message of the public health assessment in plain language, both in terms of what is and is not known, *before* presenting the specific conclusion category. For example, the essential message of ATSDR's "no apparent" category is that *no hazard* exists although some exposure might be occurring. In such a case, a statement such as the following is appropriate:

> Based on all available information, ATSDR concludes that although some exposure might be occurring as a result of site conditions, exposures are not at levels likely to cause adverse health effects and thus the site does not pose a public health hazard. Because exposure is still possible, ATSDR has categorized the site as a "No Apparent Public Health Hazard."

Such wording provides a definitive statement regarding hazard and clearly indicates the ATSDR category for HazDat.

All conclusions must be supported by information presented in the *Discussion* section. Limit the use of the conclusion categories to the *Summary* and *Conclusion* sections of the document. The *Discussion* section, for example, should not include the phrase "no apparent" health hazards.

The language and tone used in presenting conclusions should be sensitive and explanatory, especially when presenting conclusions related to community concerns (see Chapter 4).

9.2 Determining Recommendations and Developing a Public Health Action Plan (PHAP)

After reaching conclusions about a site, you may recommend that actions be taken to protect public health. PHA recommendations should emphasize prevention of releases and prevention of exposure and any precautions required to ensure that public health is protected. Because ATSDR is an advisory agency and not a risk management agency, your recommendations may identify actions that *other* entities (e.g., site owners, state health or environmental agencies, as well as divisions within ATSDR) will need to take to implement the recommendations. As the health assessor or team leader you should work with the members of your team in determining the most appropriate recommendations. The criteria described in this section should guide your decisions.

In general, your recommendations are made to identify:

- Practical ways to stop, reduce, or prevent exposure (Section 9.2.1).
- Activities to further characterize the site and possible exposure (Section 9.2.2).
- Health activities that are service- or research-oriented (e.g., medical monitoring, health education, health studies/health surveillance, substance-specific research) (Section 9.2.3).

Recommendations for actions needed to protect the health of those living or working on or near the site will vary from site to site. Depending on the site-specific situation, both short- and long-term public health needs should be considered. Short-term recommendations may include supplying bottled water or conducting an emergency removal action. Recommendations to meet long-term public health protection needs include those related to institutional controls for restricting site access, deed restrictions on land use, and continuous environmental monitoring for specified periods.

In addition to stating recommendations, Public Health Action Plans (PHAPs) are included in all PHAs[1]. Your PHAP will outline actions or activities that have already been taken to protect public health, activities that are currently underway, and activities that will be conducted in the future. PHAPs are also included in some health consultations, depending upon site conditions and community interest. That is, your PHA must include a plan that clearly describes the implementation and timing of the recommended public health action(s). Actions described in the PHAP might vary from health investigations in the community near the site to environmental characterization activities to better identify populations at risk of exposure.

For a site that poses an urgent public health hazard, ATSDR may respond by quickly issuing a public health advisory to EPA. Appropriate state, tribal, and local entities are also notified, and ATSDR works with them and others to ensure the public is protected. A health advisory should be considered whenever chemical contamination or physical hazards associated with a site necessitate an expeditious response to protect public health. The health advisory recommends measures to be taken to reduce exposures and to eliminate or substantially mitigate the public health hazard(s) (see Appendix H for health advisory-related public health actions). A health advisory should be issued as soon as possible after the health assessor has determined that an urgent public health hazard exists—that is, it does not have to and should not wait until the public health assessment process is completed. For more information see ATSDR's Web site at: http://www.atsdr.cdc.gov/HAC/healthad.html.

As shown in Table 9-2 and detailed in Appendix H, the type of action(s) recommended by ATSDR is dependent on the site's conclusion category and corresponds directly to the specific conclusion(s) drawn about a site. The type of actions typically recommended and the factors you should consider when developing and presenting recommendations are described in the following subsections.

[1]If the site poses no public health hazard (Conclusion Category 5), a PHAP may not be necessary.

Table 9-2. Summary of Conclusion Categories With Recommended Public Health Actions

Conclusion Category	Type of Action
Category 1: Urgent public health hazard	Measures to immediately stop or reduce exposures (e.g., provide alternative drinking water). The PHA should describe actions already taken and those planned.*
Category 2: Public health hazard	Measures to reduce or prevent chronic exposures. The PHA should describe actions already taken and those planned.*
Category 3: Indeterminate hazard	Measures to fill critical data gaps so that a public health call is possible. The PHA should describe needed actions.*
Category 4: No apparent public health hazard	No action(s) may be necessary. Depending on the level of community concern and site issues, some of the same actions taken for Categories 1 and 2 should be considered.*
Category 5: No public health hazard	No actions are likely.

* See also Appendix H

9.2.1 Actions To Cease or Reduce Exposures

Actions that prevent or reduce exposures should be recommended when a public health assessment identifies current exposures to contaminant levels associated with adverse health effects. You may recommend that removal or remedial measures be taken to eliminate any current exposures or to prevent potential future exposure.

Recommended actions may include:

- Removing physical hazards (e.g., unsafe structures, unexploded ordnance).
- Informing affected populations of contamination or exposure.
- Establishing institutional controls on land use.
- Restricting public use of or access to a site.
- Restricting use of drinking water supplies and/or providing alternate water supplies.
- Establishing measures to restrict contaminant migration.
- Remediating contaminant sources.
- Establishing safety plans and monitoring during removal actions/remediation.

- Evacuating or temporarily relocating populations.

9.2.2 Actions for Site Characterization

At times, site information is not available or is insufficient and cannot be used to adequately characterize site environmental conditions, the type and extent of contamination, and locations of populations that might be exposed to site-related contamination. In cases where data critical to your public health conclusion are missing, brief explicit recommendations should be made outlining the information required and why it is critical. Working with other stakeholders, identify the data needed, where it should be collected, who should collect it, and who should receive and evaluate the data.

Recommended actions may include:

- Conducting additional or continued environmental monitoring
- Conducting private well or public water system surveys
- Conducting surface water use surveys
- Conducting plant or animal consumption surveys
- Conducting land use surveys
- Further characterizing demographics of potentially affected populations
- Characterizing human activities on or near the site
- Characterizing contaminant source(s)
- Characterizing explosion potential
- Characterizing hydrogeology
- Characterizing radionuclide activity

If efforts to obtain the data in a timely manner are unsuccessful, start the collection process as described, and complete the PHA using the information you do have. When critical data become available, you can then use it to update the PHA, to write an addendum to the PHA, or to release a PHC that incorporates your new understanding of the site.

For example, with a site where no groundwater sampling data are available or they are of insufficient quality or quantity, you might state:

> ATSDR has evaluated regional groundwater flow patterns (site-specific potentiometric maps are not available) and determined that it is possible that on-site groundwater may flow towards off-site private drinking water wells. The discovery of groundwater contamination at the site is recent and therefore, no groundwater sampling data are

available to date. As such, ATSDR cannot make any public health conclusions about possible exposure to contaminants in drinking water.

and

EPA has signed an administrative order with the site owners who will be collecting on-site groundwater samples during the summer of this year, under EPA oversight. ATSDR will evaluate the sample results to complete the pathway evaluation. Additional efforts to conduct private well sampling for homes located within ½ mile south of the site later in the year are being undertaken by the county health department. ATSDR will also review these data once available.

9.2.3 Health Activities

Depending on the degree of exposure or hazard identified, coupled with the overall level of community health concern, various follow-up health activities may be considered. Recommendations will stem from your site-specific public health conclusions and include activities aimed at further evaluating the health status of the site community or educating the community and other stakeholders about the health effects (physical and psychological) related to the site.

Recommended actions may include:

- Conducting biologic tests for exposure or changes in body function
- Conducting health education
- Performing health studies or health surveillance
- Conducting substance-specific research

Table 9-3 provides a description of various types of health activities and highlights the factors that need to be considered in making a decision about their appropriateness. No specific formula exists for determining which, if any, of these activities should be recommended. However, the questions in the table can help guide site-specific decisions.

The site team should consider the criteria presented in Table 9-3 in consultation with the appropriate technical experts and/or the agency divisions or other stakeholders ultimately responsible for implementing the activity. This is often accomplished during the course of the public health assessment process. For example, no recommendation to conduct a health study should be made as a matter of course without conferring with an epidemiologist and the Division of Health Studies to assess the feasibility and appropriateness of such a study. The team also will determine who will conduct the recommended actions (e.g., health education specialists, local health departments, area physicians) and coordinate with the appropriate groups. For example, if the assessment reveals the need to educate local physicians, the health educators on the team would need to become involved and might ultimately provide the needed education.

Table 9-3. Factors to Consider When Selecting Health Activities

Activity	Considerations	Consult With
Biologic Monitoring *The measurement of a substance, its metabolite, or another marker of exposure in human body fluids or tissues to confirm human exposure to a hazardous substance.* **Biomedical Testing** *Testing of persons to find out whether a change in a body function might have occurred because of exposure to a hazardous substance.*	• Are adequate quality-controlled and sensitive laboratory test(s) available to detect the presence of hazardous substance(s), its (their) metabolite(s), or other biologic marker(s) known to be closely associated with exposure and measurable in some biologic tissue or fluid? Alternatively, is there a measurable and sensitive health outcome that can be identified through existing data sources, such as medical records? • Is the outcome to be measured biologically plausible and relevant? • Are previous experience and scientific knowledge inadequate or insufficient to predict whether biologic uptake of hazardous substances or illness will occur under the environmental conditions present at the site? • Is the identified cohort of potentially exposed persons willing to participate in the study?	EICB
Community Health Education *Programs designed with a community to help it know about health risks and how to reduce these risks.* **Community Stress Education** *Community education designed to help community members better cope with the stresses of potential environmental contaminant exposure.* **Health Professional Education** *Information for doctors, nurses, or other health care providers about environmental exposures and their prevention, substance-specific risks, community health warning signs, and/or special diagnostic techniques for detecting possible site-related illnesses.*	• Does a human population live/work along completed or potential pathway(s) of exposure associated with a hazardous waste site? • Is there concern for public health as a result of reports about exposures and/or reports of disease in the community? • Has a specific request been received from individuals, health care providers, special interest groups, industry, academia, or government agencies for health education related to an NPL site, a non-NPL site or facility, an emergency response site, or another site or facility? • Has the community expressed concerns that local, private medical practitioners or public health professionals lack information on the potential health effects of site hazards? • Have public health professionals expressed concern about environmental exposure-related stress in the community?	DHEP

Table 9-3. Factors to Consider When Selecting Health Activities

Activity	Considerations	Consult With
Case Study *A medical or epidemiologic evaluation of one person or a small group of people to gather information about specific health conditions and past exposures.* **Cluster Investigation** *A review of an unusual number, real or perceived, of health events (for example, reports of cancer) grouped together in time and location. Cluster investigations are designed to confirm case reports; determine whether they represent an unusual disease occurrence; and, if possible, explore possible causes and contributing environmental factors.* **Epidemiologic Study** *A study of the distribution and determinants of disease or health status in a population; the study of the occurrence and causes of health effects in humans.* **Health Investigation** *The collection and evaluation of information about the health of community residents. This information is used to describe or count the occurrence of a disease, symptom, or clinical measure and to evaluate the possible association between the occurrence and exposure to hazardous substances.* **Health Statistics Review** *The analysis of existing health information (i.e., from death certificates, birth defects registries, and cancer registries) to determine if there is excess disease in a specific population, geographic area, and time period. A health statistics review is a descriptive epidemiologic study.*	• Is human exposure believed to be occurring or could it have occurred because of human interaction (such as direct contact, inhalation, or ingestion) with a site-related completed exposure pathway known to be contaminated by hazardous substance(s)? Alternatively, does a reasonable concern exist for the potential of an as-yet-unidentified route of exposure? • Has a reasonable concern for adverse health effects been hypothesized for individuals at potential risk as a result of reports of disease in the involved population? Or, has there been an indication or allegation that adverse health conditions that might be related to exposure to hazardous substances are occurring in the population? • Can case information about adverse health effects or exposure to hazardous substances be obtained for comparison to the population under study to develop a hypothesis about the relationship between the exposure to hazardous substances and adverse health effects? • Can information be located or collected to verify disease(s) and document the geographic and temporal occurrence of the cases? • Does biologic plausibility support a relationship between hazardous substance(s) at the site and disease(s) being reported? • Is the age-adjusted rate of the incidence of a specific cancer significantly higher than the prevalent rate in an appropriate reference population? • Do community health concerns exist related to the site? • Is information available on relevant health outcome data for the involved population? Or, can data manipulation yield relevant health outcome information about the population (if data were not collected in a fashion that is readily applicable to the population)? *For additional information, see ATSDR's 1996 Guidance for ATSDR Health Studies, available at: http//:www.atsdr.cdc.gov/HS/gd1.html*	DHS

Table 9-3. Factors to Consider When Selecting Health Activities

Activity	Considerations	Consult With
Public Health Surveillance *The ongoing, systematic collection, analysis, and interpretation of health data.* **Registries** *Systematic collection of information on persons exposed to a specific substance or having specific diseases.*	• Has a registry already been established for the contaminant(s) of concern? • Does the site fit within the general guidelines considered in site selection for a registry as established in the *National Exposure Registry Policies and Procedures Manual (Revised)* (ATSDR 1994)? That is, has human exposure been documented; is the size of the potentially exposed population is acceptable; has the presence or absence of reported health problems been verified; and is the community interested in participating?	
Substance-specific Applied Research *A program designed to fill important data needs for specific hazardous substances.*	• Does an ATSDR Toxicological Profile (or other comparable review document) not exist for the substance of interest? • Although a current Toxicological Profile exists for a contaminant of concern at the site, is information required for this site contaminant listed as a data need? • Although a current Toxicological Profile exists for a contaminant of concern at the site, is information required for this site not addressed in the profile? • Although a Toxicological Profile exists for the contaminant of interest at the site, does the profile need updating? • Would filling identified data needs allow more accurate assessment of human risks from site exposures?	DT

DHEP: Division of Health Education and Promotion
DHS: Division of Health Studies
DT: Division of Toxicology
EICB: Exposure Investigations and Consultation Branch

9.2.4 Factors To Consider When Developing Recommendations and the PHAP

As discussed above, when developing recommendations you should focus on identifying measures that will prevent or eliminate exposures to harmful levels of hazardous substances or provide a means for obtaining more information to improve your assessment of possible public health hazards. You are not required to determine what specific action is needed or exactly how it should be implemented to reach your objective, but you should work closely with other divisions within ATSDR and other entities that might ultimately be responsible for implementing the recommended actions (e.g., other federal, state, or local agencies; tribes; the community; private parties).

As you work through possible recommendations, keep the following questions in mind:

- What feasible, reasonable action is needed?
- Who will implement the action? Have you received their buy-in/commitment to implement the action?
- When will the action begin? Is the time frame reasonable?
- What are the desired outcomes and what population will the action affect?
- What is the impact or health consequence of not implementing the action?
- When will the agency reevaluate the site or actions?

Table 9-4 presents a worksheet that can used in formulating recommendations and in developing a PHAP. The worksheet is completed to illustrate considerations under scenario for which biomonitoring has been recommended.

Thinking about your recommendations and the PHAP in this way and communicating with those entities who will ultimately be responsible for implementing the recommendations throughout the assessment process will help ensure that actions can and, hopefully, will be implemented. It will help ensure that objectives are reasonable; the recommendation is achievable; and, ideally, that buy-in or commitment is received from the party responsible for implementing the recommendation. The PHAP generally does not contain actions not agreed upon by other entities responsible for their implementation.

> —Maintaining open lines of communication with all stakeholders regarding recommended public health actions will help ensure needed actions are implemented, and the agency's ultimate goal is achieved—that is, protecting public health.

Table 9-4. Example Worksheet for Developing Recommendations and PHAP (Completed to Show a Biologic Monitoring Action)

Action	Objective(s)	Desired Outcome(s)	Issues That Need To Be Addressed	Who Will Implement? (Name/entity, address, telephone number, e-mail)	Commitment Received (yes/no)	Time Line for Completion
Collect blood samples to test for lead exposure (for children ages 6 months to 7 years)	Identify and test all at-risk children (will capture current exposure status only; will not identify past or potential future exposures)	Determine if and to what extent children are being exposed to lead	• If exposure is occurring, how can it be reduced or eliminated? • If exposure is occurring, can the site be distinguished as the source rather than other sources (e.g., lead paint in homes)? • If no exposure is found, will that change the site conclusion category?	Local health department in cooperation with ATSDR	Yes, with laboratory assistance provided by ATSDR	Summer (time during which greatest soil exposures expected)

9.2.5 Presenting Recommendations and Public Health Action Plan in the Public Health Assessment Document

All public health assessment documents should include a separate section listing recommendations. Recommendations should be active, concise, parallel, and consistent with the summary and conclusions. All recommendations must correlate with conclusions presented in the *Conclusion* section. You may have conclusions that do not result in recommendations, but you cannot have a recommendation without a conclusion. Note that ATSDR records all site-specific recommendations in HazDat.

Every recommendation should state the urgency with which or the time frame in which the recommendation needs to be addressed. This measure of urgency will indicate the gravity of the attendant conclusion and establish priorities for responding to the recommendation. Recommendations that do not have a time frame for completion might be interpreted as having a low priority.

Clearly state the needed action. For added clarity, you can list the recommended action(s) as bullets, and begin each recommended action with a verb (e.g., monitor, restrict, inform). As with the *Conclusion* section, the *Recommendation* section needs to be concise and pertinent to the focus of the assessment.

The *PHAP* section needs to clearly delineate completed, ongoing, and/or planned actions designed to mitigate or prevent adverse human health effects resulting from exposure to hazardous substances that might be associated with a particular site. It should parallel the recommendations and *explicitly* state actions already taken to eliminate or prevent public health hazards, as well as the *specific plan* in place to further investigate or eliminate remaining public health concerns, as detailed below. Clearly indicate the entity (federal, state, local, or tribal agency; community or private party) that has agreed to or should have the responsibility of implementing the recommendation. The PHAP should include the:

- *Actions undertaken.* Indicate public health actions undertaken to respond to recommendations outlined in the public health assessment. For example, if EPA had previously recommended a private well survey be conducted, that information should be provided in this subsection. The actions might have been carried out by one of the various agencies involved, including ATSDR, EPA, state, local, and tribal health and environmental departments. For sites at which ATSDR has been previously involved, also include past public health efforts and activities in the site community.

- *Actions under way or planned.* Delineate public health actions that are being or will be carried out by ATSDR and other agencies involved with the site other than ATSDR based on the recommendations presented in the public health assessment. Again, identify the entity that will undertake the activities outlined in a specific recommendation and indicate when, if possible, the activities will take place.

Table 9-5 presents examples of conclusions and recommendations, including a PHAP, meeting the above-stated criteria.

Table 9-5. Examples of Conclusions, Recommendations, and Public Health Actions

Conclusions
• Trichloroethylene, vinyl chloride, carbon tetrachloride, and pentachlorophenol were detected in on-site groundwater at levels associated with possible acute (e.g., skin irritation) and possible long-term health effects (e.g., certain cancers). *Past exposures (prior to 1989) therefore posed a "public health hazard."* • Because on-site groundwater is no longer used as a drinking water source and water supplies located near the site have not been affected, no current exposures that could result in health hazards are present. *On-site groundwater, therefore, poses "no public health hazard" for current or anticipated future exposures.* • Potentially hazardous levels of lead were detected in on-site surface soils, but nobody is or has been in contact with these restricted contaminated areas in a manner that would be likely to pose health hazards. Therefore, *ATSDR characterizes the site as posing "no apparent public health hazard" under current and anticipated future conditions.* • The full aerial extent of on-site soil contamination is unknown, including adjacent residential areas. Consequently, *ATSDR is unable to evaluate this potential pathway and classifies it as an "indeterminate public health hazard."* • Based on its review of the cancer cluster study conducted by the state health department, ATSDR concludes that no elevated number of cancer cases exists in the vicinity of the site.
Recommendations
• Continue to restrict access to the site to prevent exposure to lead-contaminated soils. *(Cease/Reduce Exposure)* • Clean up site soils before land is developed for alternative uses. *(Cease/Reduce Exposure)* • Continue groundwater monitoring until cleanup goals are met. (*Site Characterization*) • Sample surface soil for lead in the five residential properties located immediately adjacent to the southerly property boundary before children are out of school for the summer. (*Site Characterization*) • Discuss the results of the cancer cluster study with the Farm Lane residents. *(Health Education)*

Table 9-5. Examples of Conclusions, Recommendations, and Public Health Actions

Public Health Action Plan

Actions undertaken

- On-site residents were provided with an alternate safe water supply (municipal water) in 1989 when contamination was first identified.
- In 1992, the PRPs installed a "pump and treat" system to clean up groundwater and prevent the migration of contaminated groundwater.
- EPA's Record of Decision (ROD) for the site requires quarterly groundwater monitoring at and downgradient of the site.

Actions under way

- The PRPs, under EPA oversight, will continue to monitor groundwater on a quarterly basis until cleanup goals are met.
- The site owner will maintain the fencing and site security until cleanup actions are completed.

Actions planned

- The PRPs, under EPA oversight, will sample residential surface soil (top 3 inches) during its next round of groundwater sampling.
- The PRPs, under EPA oversight, will remediate site soils in 2004.
- The state health department will hold public availability sessions (for community members and health care providers) to discuss the findings of the cancer cluster study before the end of the year.
- ATSDR will review new groundwater and soil monitoring data as they become available and modify the conclusions of this public health assessment as necessary.

References

ATSDR. 1994. National exposure registry policies and procedures manual (revised). Atlanta: US Department of Health and Human Services.

ATSDR. 1996. Guidance for ATSDR health studies. Atlanta: US Department of Health and Human Services. http://www.atsdr.cdc.gov/HS/gd1.html. April 1996.

Appendix A

Tribal-Specific Resources and Considerations

Appendix A
Tribal-Specific Resources and Considerations

As discussed throughout the public health assessment guidance manual, it is crucial to consider sensitive subpopulations when conducting your public health assessment. Developing an accurate understanding of exposure scenarios is a significant component in the health effects evaluation and is necessary for determining appropriate and beneficial public health recommendations.

The relationship Tribal populations have with the environment is often different from that of other communities. Tribal lifestyle, cultural, ceremonial and religious practices are intertwined with the environment. These interactions can result in environmental exposure scenarios that are unique to individual tribes. This appendix provides some general information and resources for health assessors when working with tribal communities.

Information about ATSDR's Office of Tribal Affairs is presented first, followed by ATSDR's Policy on Government-to-Government Relations with Native American Tribal Governments, and ATSDR's Consultation and Coordination Policy with Indian Tribal Governments. In addition, Appendix D which provides a community checklist developed by ATSDR's Board of Scientific Counselors Community Tribal Subcommittee, should provide useful questions to consider when working with tribal communities.

ATSDR Office of Tribal Affairs

The United States has a unique legal relationship with American Indian/Alaska Native (AI/AN) governments as set forth in the Constitution of the United States, treaties, statutes, executive orders, and court decisions. The Department of Health and Human Services (DHHS) has established policy to work on a government-to-government basis with tribal governments to address issues concerning tribal self-determination, tribal trust resources, and tribal treaty rights. As a public health agency within the Department of Health and Human Services, the Agency for Toxic Substances and Disease Registry (ATSDR) has established a firm commitment to working with AI/AN governments and organizations.

ATSDR acknowledged that the U.S. government has a unique relationship with tribal governments, and established the Office of Tribal Affairs (OTA) to provide meaningful representation and discretion to plan, conduct, and administer programs, services, and functions that fulfill the agency mission and meet the needs of individual tribal communities. To facilitate an orderly transition from Federal to Tribal services, ATSDR helps AI/AN nations strengthen their capacity to preserve the environment, something at the core of cultural identity and health for tribal nations. ATSDR is the only agency within DHHS without a specific AI/AN mandate (such as Indian Health Services [IHS] and Administration for Native Americans [ANA]) that has a tribal office established to address specific AI/AN environmental health issues.

Currently, OTA is charged with developing agency tribal policy and programs, and responds to request from AI/AN governments, organizations and communities. OTA serves as a central conduit for Tribes to access agency programs and services, assist ATSDR in responding to presidential executive orders, and coordinate activities to support tribal-specific public health needs. Through different means, OTA provides oversight on several projects that include tribal subsistence, environmental health infrastructure, and self governance. OTA represents ATSDR on DHHS, U.S. Environmental Protection Agency (EPA), Centers for Disease Control and Prevention (CDC) and IHS working groups that focus on AI/AN health-related functions.

The office provides ATSDR staff members with training on working effectively with tribal governments. This training provides insights into appropriate protocols for working with Tribal governments and addresses special considerations that should be given when assessing the health of American Indian and Alaska Native people. In addition, an OTA representative often serves on the public health assessment team when a site has a tribal interest.

ATSDR tribal policies on government-to-government relations and tribal consultation, developed by OTA with appropriate tribal consultation, follow in this appendix.

ATSDR Policy on Government-to-Government Relations with Native American Tribal Governments

This policy provides guidelines on the implementation of the government-to-government relationship with the tribes (in response to the 1994 Memorandum on Government-to-Government Relations with Native American Tribal Governments).

The mission of ATSDR is to prevent exposure and adverse human health effects and diminished quality of life associated with exposure to hazardous substances from waste sites, unplanned releases, and other sources of pollution present in the environment. In carrying out its programs, ATSDR works with other Federal, State, and local government agencies, and tribal organizations to protect public health.

The U.S. Government has a unique government-to-government relationship with tribal governments as established by the U.S. Constitution, by treaties, by statute, by court decisions, and by Executive Orders. This relationship respects the U.S. Government's trust responsibility to American Indians and Alaskan Natives and their rights of self-government because of their sovereign status. ATSDR is strongly committed to building a more effective day-to-day working relationship with tribal governments.

In fulfilling the commitment to establish and maintain government-to-government relations with federally recognized tribal governments, ATSDR will be guided by:

(1) Section 126 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the principles set forth in the President's "Memorandum for the Heads of Executive Departments and Agencies Regarding: Government-to-Government Relations with Native American Tribal Governments" (April 29, 1994). In particular, ATSDR will:

- in a manner consistent with the protection of public health, consult with tribal governments to ensure that tribal rights and concerns are considered before ATSDR takes actions, makes decisions, or implements programs that may affect tribes; and

- establish procedures to work directly and effectively with tribal governments;

(2) The needs and culture of individual tribal governments;

(3) ATSDR's prior and ongoing experience with tribal governments, and recognized organizations associated with such governments; and

(4) The need to enhance coordination with other agencies with related areas of responsibility.

ATSDR Consultation and Coordination Policy with Indian Tribal Governments

The agency established the Office of Tribal Affairs and prepared this policy to ensure that regular and meaningful consultation and collaboration with tribal governments occur in the conduct of the agency's public health activities (in response to Consultation and Coordination With Indian Tribal Governments, EO13084).

ATSDR's mission is to prevent exposure and adverse human health effects and diminished quality of life associated with exposure to hazardous substances from waste sites, unplanned releases, and other sources of pollution present in the environment. ATSDR is committed to assisting tribal governments in meeting the environmental health needs of their people. ATSDR continues to work to improve its communication and cooperation with tribes. This new policy is in response to the Presidential Executive Order 13084, Consultation and Coordination With Indian Tribal Governments, May 14, 1998, and affirms the current ATSDR Policy on Government-to-Government Relations with Native American Tribal Governments (61 FR 42255). The policy focuses on environmental health issues related to the release of hazardous substances into the environment. Consultations between ATSDR and tribal governments will continue to ensure effective collaboration in identifying, addressing, and satisfying the needs of tribal communities affected by hazardous substances. Consultation enables ATSDR staff and tribal members to interactively participate, exchange recommendations, and provide input on environmental health activities. As defined by ATSDR, the new policy supports:

(1) a consultative process with tribal nations and their members to work together to address tribal environmental public health needs;

(2) mutual trust, respect, and shared responsibilities between all participating parties; and

(3) open communication of information and opinions leading to mutual interaction and understanding. ATSDR:

- respects and honors the sovereignty of the tribes, the responsibilities and rights to self-governance, and the differences between tribal nations and individuals;
- consults with tribal governments to ensure community concerns and impacts are carefully considered before the Agency takes action or makes decisions affecting tribal communities;
- maintains government-to-government relationships with tribal governments;
- ensures ongoing communication with tribal governments, communities, and individual tribal members to define concerns about possible health impacts from exposure to hazardous substances.

Appendix B

Glossary of Terms

Appendix B
ATSDR Glossary of Terms

This glossary defines words used by ATSDR in communications with the public. It is not a complete dictionary of environmental health terms.

General Terms

Absorption
The process of taking in. For a person or an animal, absorption is the process of a substance getting into the body through the eyes, skin, stomach, intestines, or lungs.

Acute
Occurring over a short time [compare with chronic].

Acute exposure
Contact with a substance that occurs once or for only a short time (up to 14 days) [compare with intermediate duration exposure and chronic exposure].

Additive effect
A biologic response to exposure to multiple substances that equals the sum of responses of all the individual substances added together [compare with antagonistic effect and synergistic effect].

Adverse health effect
A change in body function or cell structure that might lead to disease or health problems

Aerobic
Requiring oxygen [compare with anaerobic].

Ambient
Surrounding (for example, ambient air).

Anaerobic
Requiring the absence of oxygen [compare with aerobic].

Analyte
A substance measured in the laboratory. A chemical for which a sample (such as water, air, or blood) is tested in a laboratory. For example, if the analyte is mercury, the laboratory test will determine the amount of mercury in the sample.

Analytic epidemiologic study
A study that evaluates the association between exposure to hazardous substances and disease by testing scientific hypotheses.

Antagonistic effect
A biologic response to exposure to multiple substances that is less than would be expected if the known effects of the individual substances were added together [compare with additive effect and synergistic effect].

Background level
An average or expected amount of a substance or radioactive material in a specific environment, or typical amounts of substances that occur naturally in an environment.

Biodegradation
Decomposition or breakdown of a substance through the action of microorganisms (such as bacteria or fungi) or other natural physical processes (such as sunlight).

Biologic monitoring
Measuring hazardous substances in biologic materials (such as blood, hair, urine, or breath) to determine whether exposure has occurred. A blood test for lead is an example of biologic monitoring.

Biologic uptake
The transfer of substances from the environment to plants, animals, and humans.

Biomedical testing
Testing of persons to find out whether a change in a body function might have occurred because of exposure to a hazardous substance.

Biota
Plants and animals in an environment. Some of these plants and animals might be sources of food, clothing, or medicines for people.

Body burden
The total amount of a substance in the body. Some substances build up in the body because they are stored in fat or bone or because they leave the body very slowly.

CAP [see Community Assistance Panel.]

Cancer
Any one of a group of diseases that occur when cells in the body become abnormal and grow or multiply out of control.

Cancer risk
A theoretical risk for getting cancer if exposed to a substance every day for 70 years (a lifetime exposure). The true risk might be lower.

Carcinogen
A substance that causes cancer.

Case study
A medical or epidemiologic evaluation of one person or a small group of people to gather information about specific health conditions and past exposures.

Case-control study
A study that compares exposures of people who have a disease or condition (cases) with people who do not have the disease or condition (controls). Exposures that are more common among the cases may be considered as possible risk factors for the disease.

CAS registry number
A unique number assigned to a substance or mixture by the American Chemical Society Abstracts Service.

Central nervous system
The part of the nervous system that consists of the brain and the spinal cord.

CERCLA [see Comprehensive Environmental Response, Compensation, and Liability Act of 1980]

Chronic
Occurring over a long time [compare with acute].

Chronic exposure
Contact with a substance that occurs over a long time (more than 1 year) [compare with acute exposure and intermediate duration exposure]

Cluster investigation
A review of an unusual number, real or perceived, of health events (for example, reports of cancer) grouped together in time and location. Cluster investigations are designed to confirm case reports; determine whether they represent an unusual disease occurrence; and, if possible, explore possible causes and contributing environmental factors.

Community Assistance Panel (CAP)
A group of people from a community and from health and environmental agencies who work with ATSDR to resolve issues and problems related to hazardous substances in the community. CAP members work with ATSDR to gather and review community health concerns, provide information on how people might have been or might now be exposed to hazardous substances, and inform ATSDR on ways to involve the community in its activities.

Comparison value (CV)
Calculated concentration of a substance in air, water, food, or soil that is unlikely to cause harmful (adverse) health effects in exposed people. The CV is used as a screening level during the public health assessment process. Substances found in amounts greater than their CVs might be selected for further evaluation in the public health assessment process.

Completed exposure pathway [see exposure pathway].

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)
CERCLA, also known as Superfund, is the federal law that concerns the removal or cleanup of hazardous substances in the environment and at hazardous waste sites. ATSDR, which was created by CERCLA, is responsible for assessing health issues and supporting public health activities related to hazardous waste sites or other environmental releases of hazardous substances. This law was later amended by the Superfund Amendments and Reauthorization Act (SARA).

Concentration
The amount of a substance present in a certain amount of soil, water, air, food, blood, hair, urine, breath, or any other media.

Contaminant
A substance that is either present in an environment where it does not belong or is present at levels that might cause harmful (adverse) health effects.

Delayed health effect
A disease or an injury that happens as a result of exposures that might have occurred in the past.

Dermal
Referring to the skin. For example, dermal absorption means passing through the skin.

Dermal contact
Contact with (touching) the skin [see route of exposure].

Descriptive epidemiology
The study of the amount and distribution of a disease in a specified population by person, place, and time.

Detection limit
The lowest concentration of a chemical that can reliably be distinguished from a zero concentration.

Disease prevention
Measures used to prevent a disease or reduce its severity.

Disease registry
A system of ongoing registration of all cases of a particular disease or health condition in a defined population.

DOD
United States Department of Defense.

DOE
United States Department of Energy.

Dose (for chemicals that are not radioactive)
The amount of a substance to which a person is exposed over some time period. Dose is a measurement of exposure. Dose is often expressed as milligram (amount) per kilogram (a measure of body weight) per day (a measure of time) when people eat or drink contaminated water, food, or soil. In general, the greater the dose, the greater the likelihood of an effect. An "exposure dose" is how much of a substance is encountered in the environment. An "absorbed dose" is the amount of a substance that actually got into the body through the eyes, skin, stomach, intestines, or lungs.

Dose (for radioactive chemicals)
The radiation dose is the amount of energy from radiation that is actually absorbed by the body. This is not the same as measurements of the amount of radiation in the environment.

Dose-response relationship
The relationship between the amount of exposure [dose] to a substance and the resulting changes in body function or health (response).

Environmental media
Soil, water, air, biota (plants and animals), or any other parts of the environment that can contain contaminants.

Environmental media and transport mechanism
Environmental media include water, air, soil, and biota (plants and animals). Transport mechanisms move contaminants from the source to points where human exposure can occur. The environmental media and transport mechanism is the second part of an exposure pathway.

EPA
United States Environmental Protection Agency.

Epidemiologic surveillance [see Public health surveillance].

Epidemiology
The study of the distribution and determinants of disease or health status in a population; the study of the occurrence and causes of health effects in humans.

Exposure
Contact with a substance by swallowing, breathing, or touching the skin or eyes. Exposure may be short-term [acute exposure], of intermediate duration, or long-term [chronic exposure].

Exposure assessment
The process of finding out how people come into contact with a hazardous substance, how often and for how long they are in contact with the substance, and how much of the substance they are in contact with.

Exposure-dose reconstruction
A method of estimating the amount of people's past exposure to hazardous substances. Computer and approximation methods are used when past information is limited, not available, or missing.

Exposure investigation
The collection and analysis of site-specific information and biologic tests (when appropriate) to determine whether people have been exposed to hazardous substances.

Exposure pathway
The route a substance takes from its source (where it began) to its end point (where it ends), and how people can come into contact with (or get exposed to) it. An exposure pathway has five parts: a source of contamination (such as an abandoned business); an environmental media and transport mechanism (such as movement through groundwater); a point of exposure (such as a private well); a route of exposure (eating, drinking, breathing, or touching), and a receptor population (people potentially or actually exposed). When all five parts are present, the exposure pathway is termed a completed exposure pathway.

Exposure registry
A system of ongoing followup of people who have had documented environmental exposures.

Feasibility study
A study by EPA to determine the best way to clean up environmental contamination. A number of factors are considered, including health risk, costs, and what methods will work well.

Geographic information system (GIS)
A mapping system that uses computers to collect, store, manipulate, analyze, and display data. For example, GIS can show the concentration of a contaminant within a community in relation to points of reference such as streets and homes.

Grand rounds
Training sessions for physicians and other health care providers about health topics.

Groundwater
Water beneath the earth's surface in the spaces between soil particles and between rock surfaces [compare with surface water].

Half-life ($t_{½}$)
The time it takes for half the original amount of a substance to disappear. In the environment, the half-life is the time it takes for half the original amount of a substance to disappear when it is changed to another chemical by bacteria, fungi, sunlight, or other chemical processes. In the human body, the half-life is the time it takes for half the original amount of the substance to disappear, either by being changed to another substance or by leaving the body. In the case of radioactive material, the half life is the amount of time necessary for one half the initial number of radioactive atoms to change or transform into another atom (that is normally not radioactive). After two half lives, 25% of the original number of radioactive atoms remain.

Hazard
A source of potential harm from past, current, or future exposures.

Hazardous Substance Release and Health Effects Database (HazDat)
The scientific and administrative database system developed by ATSDR to manage data collection, retrieval, and analysis of site-specific information on hazardous substances, community health concerns, and public health activities.

Hazardous waste
Potentially harmful substances that have been released or discarded into the environment.

Health consultation
A review of available information or collection of new data to respond to a specific health question or request for information about a potential environmental hazard. Health consultations are focused on a specific exposure issue. Health consultations are therefore more limited than a public health assessment, which reviews the exposure potential of each pathway and chemical [compare with public health assessment].

Health education
Programs designed with a community to help it know about health risks and how to reduce these risks.

Health investigation
The collection and evaluation of information about the health of community residents. This information is used to describe or count the occurrence of a disease, symptom, or clinical measure and to evaluate the possible association between the occurrence and exposure to hazardous substances.

Health promotion
The process of enabling people to increase control over, and to improve, their health.

Health statistics review
The analysis of existing health information (i.e., from death certificates, birth defects registries, and cancer registries) to determine if there is excess disease in a specific population, geographic area, and time period. A health statistics review is a descriptive epidemiologic study.

Indeterminate public health hazard
The category used in ATSDR's public health assessment documents when a professional judgment about the level of health hazard cannot be made because information critical to such a decision is lacking.

Incidence
The number of new cases of disease in a defined population over a specific time period [contrast with prevalence].

Ingestion
The act of swallowing something through eating, drinking, or mouthing objects. A hazardous substance can enter the body this way [see route of exposure].

Inhalation
The act of breathing. A hazardous substance can enter the body this way [see route of exposure].

Intermediate duration exposure
Contact with a substance that occurs for more than 14 days and less than a year [compare with acute exposure and chronic exposure].

In vitro
In an artificial environment outside a living organism or body. For example, some toxicity testing is done on cell cultures or slices of tissue grown in the laboratory, rather than on a living animal [compare with in vivo].

In vivo
Within a living organism or body. For example, some toxicity testing is done on whole animals, such as rats or mice [compare with in vitro].

Lowest-observed-adverse-effect level (LOAEL)
The lowest tested dose of a substance that has been reported to cause harmful (adverse) health effects in people or animals.

Medical monitoring
A set of medical tests and physical exams specifically designed to evaluate whether an individual's exposure could negatively affect that person's health.

Metabolism
The conversion or breakdown of a substance from one form to another by a living organism.

Metabolite
Any product of metabolism.

mg/kg
Milligram per kilogram.

mg/cm2
Milligram per square centimeter (of a surface).

mg/m3
Milligram per cubic meter; a measure of the concentration of a chemical in a known volume (a cubic meter) of air, soil, or water.

Migration
Moving from one location to another.

Minimal risk level (MRL)
An ATSDR estimate of daily human exposure to a hazardous substance at or below which that substance is unlikely to pose a measurable risk of harmful (adverse), noncancerous effects. MRLs are calculated for a route of exposure (inhalation or oral) over a specified time period (acute, intermediate, or chronic). MRLs should not be used as predictors of harmful (adverse) health effects [see reference dose].

Morbidity
State of being ill or diseased. Morbidity is the occurrence of a disease or condition that alters health and quality of life.

Mortality
Death. Usually the cause (a specific disease, a condition, or an injury) is stated.

Mutagen
A substance that causes mutations (genetic damage).

Mutation
A change (damage) to the DNA, genes, or chromosomes of living organisms.

National Priorities List for Uncontrolled Hazardous Waste Sites (National Priorities List or NPL)
EPA's list of the most serious uncontrolled or abandoned hazardous waste sites in the United States. The NPL is updated on a regular basis.

National Toxicology Program (NTP)
Part of the Department of Health and Human Services. NTP develops and carries out tests to predict whether a chemical will cause harm to humans.

No apparent public health hazard
A category used in ATSDR's public health assessments for sites where human exposure to contaminated media might be occurring, might have occurred in the past, or might occur in the future, but where the exposure is not expected to cause any harmful health effects.

No-observed-adverse-effect level (NOAEL)
The highest tested dose of a substance that has been reported to have no harmful (adverse) health effects on people or animals.

No public health hazard
A category used in ATSDR's public health assessment documents for sites where people have never and will never come into contact with harmful amounts of site-related substances.

NPL [see National Priorities List for Uncontrolled Hazardous Waste Sites]

Physiologically based pharmacokinetic model (PBPK model)
A computer model that describes what happens to a chemical in the body. This model describes how the chemical gets into the body, where it goes in the body, how it is changed by the body, and how it leaves the body.

Pica
A craving to eat nonfood items, such as dirt, paint chips, and clay. Some children exhibit pica-related behavior.

Plume
A volume of a substance that moves from its source to places farther away from the source. Plumes can be described by the volume of air or water they occupy and the direction they move. For example, a plume can be a column of smoke from a chimney or a substance moving with groundwater.

Point of exposure
The place where someone can come into contact with a substance present in the environment [see exposure pathway].

Population
A group or number of people living within a specified area or sharing similar characteristics (such as occupation or age).

Potentially responsible party (PRP)
A company, government, or person legally responsible for cleaning up the pollution at a hazardous waste site under Superfund. There may be more than one PRP for a particular site.

ppb
Parts per billion.

ppm
Parts per million.

Prevalence
The number of existing disease cases in a defined population during a specific time period [contrast with incidence].

Prevalence survey
The measure of the current level of disease(s) or symptoms and exposures through a questionnaire that collects self-reported information from a defined population.

Prevention
Actions that reduce exposure or other risks, keep people from getting sick, or keep disease from getting worse.

Public availability session
An informal, drop-by meeting at which community members can meet one-on-one with ATSDR staff members to discuss health and site-related concerns.

Public comment period
An opportunity for the public to comment on agency findings or proposed activities contained in draft reports or documents. The public comment period is a limited time period during which comments will be accepted.

Public health action
A list of steps to protect public health.

Public health advisory
A statement made by ATSDR to EPA or a state regulatory agency that a release of hazardous substances poses an immediate threat to human health. The advisory includes recommended measures to reduce exposure and reduce the threat to human health.

Public health assessment (PHA)
An ATSDR document that examines hazardous substances, health outcomes, and community concerns at a hazardous waste site to determine whether people could be harmed from coming into contact with those substances. The PHA also lists actions that need to be taken to protect public health [compare with health consultation].

Public health hazard
A category used in ATSDR's public health assessments for sites that pose a public health hazard because of long-term exposures (greater than 1 year) to sufficiently high levels of hazardous substances or radionuclides that could result in harmful health effects.

Public health hazard categories
Public health hazard categories are statements about whether people could be harmed by conditions present at the site in the past, present, or future. One or more hazard categories might be appropriate for each site. The five public health hazard categories are no public health hazard, no apparent public health hazard, indeterminate public health hazard, public health hazard, and urgent public health hazard.

Public health statement
The first chapter of an ATSDR toxicological profile. The public health statement is a summary written in words that are easy to understand. The public health statement explains how people might be exposed to a specific substance and describes the known health effects of that substance.

Public health surveillance
The ongoing, systematic collection, analysis, and interpretation of health data. This activity also involves timely dissemination of the data and use for public health programs.

Public meeting
A public forum with community members for communication about a site.

Radioisotope
An unstable or radioactive isotope (form) of an element that can change into another element by giving off radiation.

Radionuclide
Any radioactive isotope (form) of any element.

RCRA [see Resource Conservation and Recovery Act (1976, 1984)]

Receptor population
People who could come into contact with hazardous substances [see exposure pathway].

Reference dose (RfD)
An EPA estimate, with uncertainty or safety factors built in, of the daily lifetime dose of a substance that is unlikely to cause harm in humans.

Registry
A systematic collection of information on persons exposed to a specific substance or having specific diseases [see exposure registry and disease registry].

Remedial investigation
The CERCLA process of determining the type and extent of hazardous material contamination at a site.

Resource Conservation and Recovery Act (1976, 1984) (RCRA)
This Act regulates management and disposal of hazardous wastes currently generated, treated, stored, disposed of, or distributed.

RFA
RCRA Facility Assessment. An assessment required by RCRA to identify potential and actual releases of hazardous chemicals.

RfD [see reference dose]

Risk
The probability that something will cause injury or harm.

Risk reduction
Actions that can decrease the likelihood that individuals, groups, or communities will experience disease or other health conditions.

Risk communication
The exchange of information to increase understanding of health risks.

Route of exposure
The way people come into contact with a hazardous substance. Three routes of exposure are breathing [inhalation], eating or drinking [ingestion], or contact with the skin [dermal contact].

Safety factor [see uncertainty factor]

SARA [see Superfund Amendments and Reauthorization Act]

Sample
A portion or piece of a whole. A selected subset of a population or subset of whatever is being studied. For example, in a study of people the sample is a number of people chosen from a larger population [see population]. An environmental sample (for example, a small amount of soil or water) might be collected to measure contamination in the environment at a specific location.

Sample size
The number of units chosen from a population or an environment.

Solvent
A liquid capable of dissolving or dispersing another substance (for example, acetone or mineral spirits).

Source of contamination
The place where a hazardous substance comes from, such as a landfill, waste pond, incinerator, storage tank, or drum. A source of contamination is the first part of an exposure pathway.

Special populations
People who might be more sensitive or susceptible to exposure to hazardous substances because of factors such as age, occupation, sex, or behaviors (for example, cigarette smoking). Children, pregnant women, and older people are often considered special populations.

Stakeholder
A person, group, or community who has an interest in activities at a hazardous waste site.

Statistics
A branch of mathematics that deals with collecting, reviewing, summarizing, and interpreting data or information. Statistics are used to determine whether differences between study groups are meaningful.

Substance
A chemical.

Substance-specific applied research
A program of research designed to fill important data needs for specific hazardous substances identified in ATSDR's toxicological profiles. Filling these data needs would allow more accurate assessment of human risks from specific substances contaminating the environment. This research might include human studies or laboratory experiments to determine health effects resulting from exposure to a given hazardous substance.

Superfund [see Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) and Superfund Amendments and Reauthorization Act (SARA)

Superfund Amendments and Reauthorization Act (SARA)
In 1986, SARA amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) and expanded the health-related responsibilities of ATSDR. CERCLA and SARA direct ATSDR to look into the health effects from substance exposures at hazardous waste sites and to perform activities including health education, health studies, surveillance, health consultations, and toxicological profiles.

Surface water
Water on the surface of the earth, such as in lakes, rivers, streams, ponds, and springs [compare with groundwater].

Surveillance [see public health surveillance]

Survey
A systematic collection of information or data. A survey can be conducted to collect information from a group of people or from the environment. Surveys of a group of people can be conducted by telephone, by mail, or in person. Some surveys are done by interviewing a group of people [see prevalence survey].

Synergistic effect
A biologic response to multiple substances where one substance worsens the effect of another substance. The combined effect of the substances acting together is greater than the sum of the effects of the substances acting by themselves [see additive effect and antagonistic effect].

Teratogen
A substance that causes defects in development between conception and birth. A teratogen is a substance that causes a structural or functional birth defect.

Toxic agent
Chemical or physical (for example, radiation, heat, cold, microwaves) agents that, under certain circumstances of exposure, can cause harmful effects to living organisms.

Toxicological profile
An ATSDR document that examines, summarizes, and interprets information about a hazardous substance to determine harmful levels of exposure and associated health effects. A toxicological profile also identifies significant gaps in knowledge on the substance and describes areas where further research is needed.

Toxicology
The study of the harmful effects of substances on humans or animals.

Tumor
An abnormal mass of tissue that results from excessive cell division that is uncontrolled and progressive. Tumors perform no useful body function. Tumors can be either benign (not cancer) or malignant (cancer).

Uncertainty factor
Mathematical adjustments for reasons of safety when knowledge is incomplete. For example, factors used in the calculation of doses that are not harmful (adverse) to people. These factors are applied to the lowest-observed-adverse-effect-level (LOAEL) or the no-observed-adverse-effect-level (NOAEL) to derive a minimal risk level (MRL). Uncertainty factors are used to account for variations in people's sensitivity, for differences between animals and humans, and for differences between a LOAEL and a NOAEL. Scientists use uncertainty factors when they have some, but not all, the information from animal or human studies to decide whether an exposure will cause harm to people [also sometimes called a safety factor].

Urgent public health hazard
A category used in ATSDR's public health assessments for sites where short-term exposures (less than 1 year) to hazardous substances or conditions could result in harmful health effects that require rapid intervention.

Volatile organic compounds (VOCs)
Organic compounds that evaporate readily into the air. VOCs include substances such as benzene, toluene, methylene chloride, and methyl chloroform.

Other glossaries and dictionaries:

Environmental Protection Agency (http://www.epa.gov/OCEPAterms/)

National Library of Medicine (NIH)
(http://www.nlm.nih.gov/medlineplus/mplusdictionary.html)

Appendix C

Community Check List

Appendix C
Community Check List

This guidance manual was written to provide guidance to new and experienced health assessors when performing the variety of tasks associated with site-specific activities involved in the public health assessment process. The manual presents specific approaches, methods and resources for the public health evaluation of environmental exposures associated with a hazardous waste site. Chapter 4 has provided many suggestions and procedures that may be utilized in communicating and coordinating with the affected community during this process.

ATSDR's Board of Scientific Counselors, a chartered federal advisory committee, also recognized the importance of community involvement and established a Community Tribal Subcommittee. That subcommittee has prepared the checklist contained in Appendix C; the checklist emphasizes a community/ tribal perspective on the key concepts found within the guidance manual. Agency staff, and others involved in site related activities should consider this as an additional tool during the public health assessment process.

The questions posed in this checklist represent the information needs that communities and tribes may have during the public health assessment process. If these questions are considered at the outset, appropriate information can be provided in the PHA which will satisfy community and tribal understanding of the process, findings, and conclusions. It cannot be stressed enough that ATSDR must engage and involve communities and tribes throughout the public health assessment process.

Community Check List For Site Activities During the Public Health Assessment Process

Introduction

The Public Health Assessment (PHA) prepared by ATSDR and by cooperating states is a critical document for communities affected by hazardous waste sites and/or toxic releases. PHAs not only provide an assessment of potential exposure but also recommend actions needed to protect public health.

Over the past 4 years, the Community/Tribal Subcommittee (CTS) to ATSDR's Board of Scientific Counselors (BSC) has recommended changes aimed at making both the PHA process and documents more responsive to community concerns and needs. Subsequently, the CTS organized a task force (Task Force 5) to provide more detailed recommendations to the PHA process.

The Community Check List for PHAs was developed by Task Force 5 of the CTS and revised by Henry S. Cole, Ph.D. to incorporate comments received from Special Consultants, and officials from ATSDR and the Washington State Department of Health.

The Community Check List can be used not only by communities but by health assessors to help develop and evaluate PHAs. The Check List can:

- Help health assessors (from ATSDR or states) better understand and respond to community concerns and expectations.

- Be used at the start of the PHA so that community members can work with ATSDR or state agencies to improve the PHA process.

- Can be used by community members as a guide when they review the draft PHAs. It can also be used by outside reviewers.

Explanatory notes. The "Community Check List for PHAs" is not meant as a substitute for ATSDR's guidance on PHAs. Instead, the check list may help health assessors better view the site from the standpoint of community members that are looking for meaningful participation and understanding that they are not at risk from chemical exposure. Although the check list can be used to evaluate PHAs, it is not meant to as a detailed scoring system. Some of the elements may not apply to every site. Instead, it is designed to facilitate the planning process and to:

- Make the PHA process more community friendly and culturally sensitive from the outset
- Promote PHAs that are clearly written and responsive to community health needs
- Encourage assessors to obtain sufficient information from which to base conclusions
- Ensure that recommendations for action are fully protective of community health with an adequate margin of safety.

A number of the items on the check list are especially important for particular types of communities or sites. These are indicated in bold as follows:

FF = Federal Facility Site
TC = Tribal community
EJ = Environmental Justice community

Please note that ATSDR and state health assessors should be aware of special protocols applicable to tribal communities due to the sovereign status of tribal nations. Elements pertaining to tribal protocol are contained in Section 6.

Similarly, assessors should be aware of the many special problems and needs regarding environmental justice in minority and low income communities is a factor (see Section 7).

Components of the Check List

1.0 Clear Explanation of the PHA process.

Did agency officials:

- Provide a clear explanation of the PHA process early?
- Propose a timetable for the process?
- Clearly identify the roles of agency officials, contact persons, etc.?
- Identify members of the agency "site team?"
- Explain how PHA's lead to action plans?
- Describe ATSDR's limitations in regards to the actions open to it?

2.0 Community Involvement

2.1 Outreach and method of involvement

- What level of effort was made to identify and reach members of the affected community?

- What attempt did agency officials make to find out <u>how</u> the community wanted to be engaged? **TC, EJ**

- Were tribal protocols identified and respected by the assessment team? **TC**

- If community members initially distrusted the agency, what steps were taken to overcome the problem? **EJ, TC**

- Did community involvement start early in the PHA process?

- Were appropriate methods used to involve people in tribal and environmental justice communities? Were bilingual communications used where a significant portion of the population do not speak or read English? **TC, EJ**

- Were one or more community members involved on the agency's "site team?"

- Was there a formal (e.g. Community Assistance Panel) or informal stakeholder process?

2.2 Concerns, input and communications

- What efforts were made to solicit community concerns?

- Was there a mechanism that allowed or encouraged continual communications and input throughout the process?

- Were key agency officials accessible to community members and responsive to their questions and concerns throughout the process?

- Were community members (and their experts) given an opportunity to review PHA plans and protocols before they were finalized? Were community concerns addressed in such protocols?

- Did the agency share important results with community members "along the way?"

- Were community members given timely notice regarding schedules, dates, deadlines and changes in schedule?

- Did community members receive ample time to review the Draft PHA? Was an extension of comment period granted if meaningful requests were made?

3.0 History, culture, demographics, vulnerable populations and land use

3.1 Obtaining information

Does the PHA:

- Fully describe the location and composition (demographics) of the "affected community?" **EJ, TC**

- Describe the history of the hazardous waste site relative to this community (history of sources, releases, pathways, exposure)?

- Describe the land use in the site area and its history? **TC**

- Does the PHA fully identify cultural practices and socio-economic conditions that can affect exposure to site contaminants and to the effects of such contaminants on health? For example, does the PHA thoroughly document the potential impact of consumption of local game and fish for subsistence (especially important for tribal and rural communities)? **EJ, TC**

3.2 Other Questions

- Did assessors talk to long-time residents in developing the history and profile of the community? **EJ, TC**

- What steps were taken to identify vulnerable populations / susceptible communities, and those most at risk (example, sickle-cell anemia)? **EJ, TC**

- Does the PHA delineate specific eating habits, e.g. consumption rate foods, drinking water, etc.? **EJ, TC**

- Did the agency respect and hold confidential information considered to be proprietary by tribes including information on cultural, dietary and healing practices? **TC**

- Were all available data sources carefully considered and used appropriately?

- Were health agency personnel sensitive and respectful of community members in gathering information and soliciting community concerns? **EJ, TC**

4.0 Identifying potential exposure pathways

4.1 Obtaining information from the community

- Did the assessor(s) conduct “scoping visits” to determine potential exposure pathways?

- Did these visits include meetings or tours with area officials, with community members, with petitioners (at petition sites)? **EJ, TC**

- Did the agency conduct public availability sessions?

- Were potential pathways of concern to community members identified by area residents investigated?

- Did the assessment identify and solicit concerns from appropriate clinics or other practitioners?

- Did the agency work with community members to incorporate appropriate community-based sources of information e.g. specific health concerns, anecdotal evidence, or health surveys conducted by community groups? **TC, EJ**

4.2 Background and multiple sources of exposure

- How is background defined in the PHA? Is it defined as natural levels of contamination? Is it defined as contamination (both natural and manmade) not related to the source or site of concern?

- Did the PHA describe additional sources of contamination (those other than the target site) and exposure that may affect the same community? (Multiple sources)

5.0 Environmental and biological sampling

To properly assess the health of a community based upon past, present and future exposures, the agency must have ample appropriate data.

5.1 Environmental sampling

- Was the environmental data base supplied by regulatory agencies adequate to conduct the assessment and to evaluate exposure pathways identified?

- Did the PHA rely predominantly on data generated by potentially responsible parties? **FF**

- Were gaps in environmental data (e.g. soil, groundwater or air contaminant levels) clearly identified in the PHA?

- What attempts were made to fill data gaps? Did ATSDR recommend additional sampling to the regulatory agency? **FF**

- Did the health agency conduct its own sampling program if regulatory agencies (or federal facilities) failed to provide important data? **FF**

- Did ATSDR or state health agency consider community-based sampling where there were data gaps?

- Did the data base include <u>offsite</u> testing where potential offsite exposure was a concern to the community? **FF**

- Did the sampling contain sufficient number of background samples to define "background?"

5.2 Biological testing

- Did ATSDR conduct biological testing when requested by community members?

5.3 Past exposures

- Did the agency attempt to locate or obtain (see 5.4) materials needed to reconstruct likely historical/past environmental health exposures?

6.0 Tribal Protocols

6.1 Working with Tribal Governments

- Were Tribal Governments contacted and brought into the process at the start?

- Was proprietary (culturally sensitive) information identified (to the extent knowable) prior to beginning a PHA?

- Were protocols agreed upon with Tribal governments in advance? Were, meetings held (as needed) to ensure the tribe is satisfied that such protocols are being followed?

- Were Tribal Governments allowed to negotiate with the Agency regarding proprietary (culturally sensitive) information? Propriety information should be withheld from publication.

- Did the agency encourage and support open meetings of the tribal membership?

- Were community members given timely notice regarding schedules, dates, deadlines and changes in schedule?

- Did the Tribal Government receive ample time to review the Draft PHA? Tribal Government should be allowed to review and comment on Draft PHA before public comment period.

- Were Tribal environmental staff included in the process and allowed to observe and/or participate in data collection activities?

- Were cultural practices included in PHA recommendations? Proprietary (culturally sensitive) information may be included, but only if approved by the Tribal government.

6.2 Collecting information and data in tribal communities

- Was the tribe consulted regarding land use and cultural practices that potentially lead to exposure?

- Did the Agency thoroughly document the potential impact of specific life style factors such as consumption of local game and fish for subsistence?

- Did the agency take steps to identify vulnerable populations / susceptible communities, and those most at risk (i.e. children, elders, and the most traditional members)?

- Did the agency ensure that health agency personnel are sensitive and respectful of community members in gathering information and soliciting community concerns?

- Did the agency utilize a tribal member to work with the agency during the PHA process?

- Did PHA delineate specific consumption rate of foods, drinking water, etc.? This information should be provided by the tribe from data they collect and agree to divulge for purposes of the PHA.

- Did ATSDR, EPA and state agencies consider tribal-based sampling including where there were data gaps?

- Were tribal staff and/or tribal consultants involved with sampling if requested?

7.0 Environmental Justice

Minority and low-income communities are often disproportionately impacted from environmental pollution but have unequal access to environmental and economic benefit. Health assessors should ensure that affected community members from these sites are involved in all aspects of PHA development and to ensure that ATSDR and state agencies address the special needs and circumstances of these communities. Specific questions are as follows:

- Were appropriate methods use to involve people in environmental justice communities? What attempt did agency officials make to find out how the community wanted to be engaged?

- Were bilingual communications used where a significant portion of the population do not speak or read English?

- If community members initially distrusted the agency, what steps were taken to overcome the problem?

- What measures did the agency take to build the capacity of the affected community to ensure full participation?

- Were health agency personnel sensitive and respectful of community members in gathering information and soliciting community concerns?

- Does the PHA fully describe the location and composition (demographics) of the "affected community?"

- Does the PHA delineate specific eating habits, e.g. consumption rate foods, drinking water, etc.?

- What steps were taken to identify vulnerable populations / susceptible communities, and those most at risk (example, sickle-cell anemia)?

- Environmental justice communities often experience many potential sources of contamination and exposure. Does the PHA address the issue of multiple environmental stresses?

- Does the PHA fully identify cultural practices and socio-economic conditions that can affect exposure to site contaminants and to the effects of such contaminants on health including stress factors?

- Do the recommended public health actions adequately consider socio-economic and cultural practices in the affected community? Are they socially and culturally applicable to the specific community of concern?

8.0 The PHA Document

8.1 Exposure pathways and health effects

- Does the PHA document clearly discuss pathways and routes of exposure?

- Does the PHA provide a clear rationale provided for not considering other pathways?

- Did the assessors evaluate all potential pathways of concern to community members?

- Did the assessors fully explain the basis for eliminating pathways as possible causes for concern? Was there adequate data available to eliminate such pathways?

- Are the methods for selecting contaminants of concern clearly identified?

- Did environmental concentrations exceed health-based target levels, regulatory standards or criteria, or cleanup targets?

- How did the finding of concentrations above health-based levels or standards affect the PHA conclusions, especially those associated with potential or completed exposure pathways?

- How did the results of bio-testing affect PHA conclusions?

- Were possible additive or synergistic mechanisms considered in cases of multi-chemical and/or multiple exposure pathways? Did such considerations translate into conclusions and recommendations?

8.2 Adequacy of data and uncertainties

- Are the data presented clearly with supporting information?

- Are the conclusions (especially those on the degree/ categories of public health hazard) supported by the evidence presented in the document?

- Did the PHA document clearly identify and describe data gaps, concerns about data validity and scientific uncertainties and state how these problems impact conclusions?

- Does the PHA acknowledge that it "doesn't know" when it "doesn't know?"

8.3 Responsiveness

- Does the final PHA document fully address comments by community members on the draft PHA? Were changes made that better address community concerns?

- Is the PHA document written in a manner that is clear and understandable to members of the affected community?

- Is a second language version available where a significant portion of the community has difficulty reading or understanding English? **EJ, TC**

9.0 Recommendations/Public Health Actions

- Were community members involved in developing the recommendations and the action plan?

- Were a full range of alternatives considered in selecting recommended health actions?

- Is the action plan sufficient to address health hazards or data needs identified?

- Are the recommendations protective, reliable, and precautionary from the standpoint of public health?

- Does the PHA explain the basis for eliminating more protective options than the alternative(s) selected?

- Does the PHA document fully explain the basis for the options (recommendations) selected for the action plan?

- Did the PHA recommend filling data gaps identified?

9.1 Cultural practices and vulnerable populations

- Does the action plan adequately consider cultural practices? **EJ, TC**

- Does the action plan adequately consider vulnerable populations? Provide an additional level of protection or prevention? **EJ, TC**

9.2 Practicality

- Are there sufficient resources identified to carry out the plan?

- Is the plan affordable or practical for community members?

- Can the plan be implemented in a timely manner? (What is the timeline for implementation?)

Notes:

Use of CERCLA authority to obtain needed information. Although ATSDR and state agencies attempt to obtain information through the voluntary cooperation of PRPs, both Superfund and RCRA contain provisions that allow ATSDR to obtain such information in cases where PRPs fail to provide information needed to conduct PHAs and other Superfund / RCRA mandates.

The following provisions are especially applicable to sites where assessors have had difficulty in obtaining information from PRPs.

- Did the agency use these authorities to require PRPs to submit documents and other information required to assess environmental exposures?

- If not, did the agency conduct an investigation to determine whether such materials exist and should be considered?

Comment - *ATSDR is developing policy on use of these investigative authorities. Once established, this policy may provide structure and procedure for these authorities.*

Appendix D

Guidelines for Effective Communication

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Guidelines for Effective Communication

As mentioned in Section 4.2.5, two challenges for the health assessor and other site team members as they conduct public outreach and involvement activities for the site are communicating clearly and with compassion. This appendix provides guidance on how to communicate with sensitivity and respect in both your verbal and written community interactions (Section D.1) and how to update the community on the public health assessment process in clear, easy accessible ways (through the PHA, fact sheets, and other written materials) that will allow them to understand and trust your findings (Section D.2).

D.1 Communicating with Sensitivity and Respect

To build community trust, you will need to be sensitive to and respectful of community concerns throughout the public health assessment process. This aspect of communication is just as vital for building trust as clear and honest communication. Here are some guidelines for how you can be sensitive and respectful as you interact and communicate with community members:

Listen Well, then be Responsive, Direct, and Empathetic

Listen actively (see box on "Active Listening" below) with respect and without judgment and be sensitive to the needs and concerns of community members. Take all concerns seriously. Show empathy by letting the community know that you have heard, understand, and respect their concerns. Remember that for some residents, concerns are personal: they or a family member may have an illness that they are trying to cope with and understand. Recognize people's non-scientific concerns, such as their feelings and values; the psychological stress that living near a contaminated site may cause for some residents; and residents' perceptions of different risks, which can significantly affect their responses to technical information.

Active Listening

Active listening is a simple but effective method that helps you listen clearly and compassionately to others, demonstrate your understanding and empathy, and diffuse emotional tension. Active listening helps you really focus on what the other person is saying because it clearly separates the process of listening from responding. There are five steps to active listening:

Step 1: As the speaker talks, listen for the main ideas. Look for feelings and pay attention to the speaker's body language. Do not interrupt the speaker. Simply listen empathically with the goal of fully understanding what the speaker is saying. Try to set aside your own feelings and opinions and put yourself in the speaker's shoes. Accept what the speaker says as being fully legitimate from his or her point of view.

Step 2: Periodically, in your own words, repeat back the main ideas the person has said. As appropriate, include an understanding of how the person feels. When paraphrasing, be sure to reflect only your understanding of the speaker's ideas. Do not judge or comment on the speaker's ideas at this point.

Step 3: Listen and look for confirmation that you have accurately paraphrased the key ideas.

Step 4: Let the speaker make any clarifications or corrections to your paraphrase. (There may not be any.)

Step 5: When it is clear you have correctly understood what the speaker said, continue the conversation either by (1) going back to Step 1 and listening for the next ideas, or (2) if it is your turn to speak, by contributing your own ideas.

Avoid Comparing Different Types of Hazards

Scientists and community members often define or perceive risks differently. For example, scientists tend to define and perceive risks from a purely objective standpoint. On the other hand, community members often are influenced by subjective factors, such as intuition, belief, rumor, emotions (mistrust, fear, anger, etc.), and whether the hazard has been imposed on them rather than assumed voluntarily. In some cases, scientists may be more concerned about the hazards at a site than the public; in other cases, the public may perceive hazards as being greater than scientists judge them to be. To ensure that community members feel their concerns are being addressed, avoid comparing risks related to the site to other types of risks—for example, risks that some community members may voluntarily expose themselves to, such as smoking cigarettes or driving a car. Because these types of comparisons do not take into account subjective aspects of risk perception, they can easily lead the community to feel that you do not understand or respect their concerns.

Be Aware of and Respect Diversity

To ensure you present information sensitively, you will need to be aware of and respect the diversity of people you will interact with at each site. A community includes many different

people with varying concerns, including people from different neighborhoods or towns, elected officials, environmental groups, health care providers, and others. Some people, including certain ethnic or racial groups, may be affected in unique ways by possible exposures to environmental contamination. Tribal communities, for example, may be uniquely affected because of their reliance on hunting of local game and consumption of local fish or use of plants for medicinal purposes. Certain neighborhoods in urban areas may have been exposed to a variety of contamination sources. Keep in mind that diversity also exists within any particular neighborhood, ethnic, or racial group. As discussed in Chapter 4, site team should use cultural contacts and interpreters as appropriate to ensure that communications are sensitive to the cultures and needs of different ethnic or racial groups within the community.

Avoid False Promises and Reassurances

To avoid losing credibility with the community, do not offer services, materials, or solutions that you may not be able to provide. If you do not know an answer, say so and get back to the person asking the question as soon as possible with an answer. Raising false expectations or hopes is generally worse than being able to offer nothing. Although residents may not like to hear that the agency's resources are limited, it is better to tell them the truth and try to figure out with them what might realistically be accomplished with available resources.

D.2 Communicating with Clarity and Accuracy

Following are some basic tips for communicating clearly and accurately in all of your written documents. For an example of a clearly written fact sheet that utilizes these tips to announce the findings of a public health assessment, see the attached fact sheet developed by ATSDR for a U.S. Air Force site.

Use "Plain English"

Environmental contamination, exposure, and health information are often highly complex. Your job is to boil down the science into a succinct, yet clear and accurate explanation. On the other hand, you do not want to oversimplify information. Although residents may not be familiar with regulatory jargon, they can understand complex concepts if explained adequately. Tips for conveying this information as clearly as possible to the public include:

- Avoid using scientific jargon, acronyms, and overly technical language. Use simpler terms where possible, such as "breathe" instead of "inhale," "eat" instead of "ingest," "child" or "adult" instead of "receptor," and "come in contact with" instead of "be exposed to." If you need to use technical terms, make sure you define them. For example,

  > Groundwater on the island is located in several distinct aquifers (an aquifer is a layer underground that contains water). One of these aquifers is contaminated. A separate aquifer is used to supply drinking water. The contaminated aquifer is not connected to the aquifer used for drinking water, therefore, island residents are not coming in contact with contaminated groundwater.

- In your sentences, use active rather than passive voice when possible. Active voice means putting the subject (the "doer") of your sentence *before* the verb rather than after. For example: "ATSDR conducted a public health assessment of the site" is active. "A public health assessment of the site was conducted by ATSDR" is passive. Active voice uses fewer words and is more direct and easier to understand than passive voice.

- Use shorter rather than longer sentences. Your material will be easier to understand if you use shorter sentences with simpler construction rather than more complex compound sentences. Check your writing for longer sentences that could be divided into two or more statements. For example:

  > "We do not expect that contamination in the shallow aquifer will migrate to the base water supply because a confining layer separates the shallow aquifer from the deeper aquifer, thus preventing the transfer of contaminants to the groundwater layer from which the base wells draw water."

  could be rewritten as:

  > "Wells at the Army base draw their water from an aquifer deep in the ground. The contaminated aquifer is nearer to the surface and separated from the deeper aquifer by a solid layer of bedrock. This layer prevents contaminants in the shallow aquifer from moving into the aquifer used for base water. For this reason, we do expect the base water to become contaminated."

- Relate information on a personal level and use examples, stories, and analogies as appropriate to establish a common understanding. This can also be particularly helpful when communicating orally.

- Make sure the reading level is appropriate for the intended audience. As appropriate, you can ask one or more community members to read your draft material and provide feedback on how clear and understandable it is.

- Include a user-friendly glossary that defines technical terms.

- Avoid minimizing risk. As you strive to communicate as simply and clearly as possible, make sure that the information you convey remains accurate, particularly the information about health hazards. State explicitly when a hazard does or does not exist and why or why not.

Tell the "Story"

Your information will be easiest to understand if you present it in a logical, well-organized manner and avoid irrelevant information. Try to focus on "telling the story" and omitting extraneous details that do not add to the story. Often, chronology provides an effective way to organize information, particularly when writing for the public. Following are two examples showing how information can be presented chronologically to tell the "story":

> Site X is an 8-acre facility that was used to store wastes and excess materials from 1956 to 1982. In the early 1980s, polychlorinated biphenyls (PCBs) were discovered in the facility's soil at unsafe levels. To

protect public health, the site was cleaned up several times in the 1980s and 1990s. Tests performed in 1996 showed that the extensive cleanup was successful in removing PCBs from the soil; following this, tests found no trace of PCBs in the soil. The town of Centerville is converting the site into a neighborhood park. Because of the extensive cleanup, visitors to the park will not come in contact with PCBs in soil.

The Pesticide Dump Site is a group of five formerly contaminated areas. EPA placed this site on its National Priorities List after discovering that soil and groundwater at the site were highly contaminated with pesticides. EPA and the potentially responsible parties (the organizations that may be responsible for the contamination) spent five years cleaning up the site. Even before this cleanup started, the contaminated groundwater stayed at the site, so local wells have not been contaminated and residents have not been exposed to contaminants in their drinking water. Tests in 1999 showed that the cleanup reduced pesticides in the soil to safe levels. EPA and the potentially responsible parties are now treating the groundwater and taking steps to help ensure that the water will not flow off the site and into public or private wells.

Acknowledge Uncertainties

Understandably, community members will want your statements and conclusions to be as definitive and certain as possible. Typically, however, the public health assessment process is fraught with uncertainties, such as whether and to what extent residents were exposed to contaminants; to what extent exposure to small concentrations of a substance may be a health hazard; and to what extent exposure to mixtures or multiple toxins influences the toxicity of the individual toxins. In your communications, clearly delineate what is known and not known; explain where and why there are uncertainties; and explain how you have accounted for these uncertainties in your conclusions. If there are uncertainties that could be resolved, let people know what you will do to resolve these uncertainties. For example,

The degree of health hazard that may be posed by drinking contaminated well water is related to how much contaminated water was consumed. Unfortunately, we do not know how long the well water has been contaminated, so we do not know how long residents may have been drinking this water. To compensate for this information gap, we made a very conservative assumption in our calculations that residents had drunk the contaminated well water over their entire lifetimes (which we assumed to be 70 years, on average). This is a worst-case scenario. Making this conservative assumption means that our calculations are likely to be, if anything, more protective of health for most people than they would be if we had actual exposure information.

Be Honest and Objective

Be objective (i.e., your tone should be neutral) and make a clear distinction between facts and other information (e.g., judgments and opinions). If information is unavailable and, as a result, no conclusions can be drawn, simply state so. For example,

ATSDR has gathered and reviewed all available information related to respiratory health concerns expressed by residents near the site. At this time, not enough information exists for the agency to draw conclusions about whether respiratory health effects are related to site contaminants. ATSDR will re-evaluate this concern if additional information becomes available.

If, after you have released results and conclusions to the public, new data become available that cause you to revise your conclusions, then you should clearly explain how and why the new information has led to different conclusions.

Also, if you realize you have provided inaccurate or misleading information, or there has been a miscommunication that has led the community to misunderstand what you intended to communicate, then acknowledge the mistake or miscommunication and correct it as soon as possible.

Put Health Information into its Proper Context

You do not want to unnecessarily alarm the community. Make sure dose and exposure conditions drive your discussions. Avoid making general statements like, "chemical 'x' causes cancer," without discussing under what conditions such health impacts could occur. In addition, to help community members understand how technical information ultimately affects them, you will want to put available environmental and health outcome data into meaningful perspective for them, as illustrated in the example below.

> Trichloroethylene (TCE), a volatile organic compound, is present in the groundwater at the site. However, base personnel and residents in the vicinity use public water, not groundwater, in their homes. As a result, no one is coming in contact with the TCE in groundwater. This means that no one is affected by the TCE.[1]

Avoid Conflicting Messages

When different agencies and groups provide conflicting information to the community, it undermines the credibility of all agencies, erodes trust, and generates confusion. To avoid this, you should be sure to communicate with other agencies at the beginning of and throughout the public health assessment process, and you should coordinate, as appropriate, to ensure that all agencies are presenting consistent messages and information. If conflicting information has already been presented, then you should attempt to reconcile the messages as soon as possible, taking care not to compromise the validity of what is being said. Consistency is also important in the draft and final public health assessment documents. When preparing the documents, make sure that the document is internally consistent—for example, that the conclusions are based on the information presented in earlier sections of the document, and that the recommendations parallel the conclusions.

[1] Although TCE is a possible human carcinogen, the important message is that no exposure is occurring. In other cases, should exposures be occurring, be sure to clearly explain whether the *levels to which people are being exposed* are expected to result in adverse health outcomes (or illness).

Appendix E

Chemical- and Site-Specific Factors That May Affect Contaminant Transport

Chemical- and Site-Specific Factors That May Affect Contaminant Transport

Transport Mechanism	Factors Affecting Transport	
	Chemical-specific considerations	**Site-specific considerations**
Groundwater		
Movement within and across aquifers and to surface water	• Density (more or less dense than water) • Water solubility • K_{OC} (organic carbon partition coefficient)	• Site hydrogeology • Precipitation • Infiltration rate • Porosity • Hydraulic conductivity • Groundwater flow direction • Depth to aquifer • Groundwater/surface water recharge and discharge zones • Presence of other compounds • Soil type • Geochemistry of site soils and aquifers • Presence and condition of wells (well location, depth, and use; casing material and construction; pumping rate) • Conduits, sewers
Volatilization (to soil gas, ambient air, and indoor air)	• Water solubility • Vapor pressure • Henry's Law Constant • Diffusivity	• Depth to water table • Soil type and cover • Climatologic conditions • Contaminant concentrations • Properties of buildings • Porosity and permeability of soils and shallow geologic materials
Adsorption to soil or precipitation out of solution	• Water solubility • K_{OW} (octanol/water partition coefficient) • K_{OC}	• Presence of natural carbon compounds • Soil type, temperature, and chemistry • Presence of other compounds
Biologic uptake	• K_{OW}	• Groundwater use for irrigation and livestock watering

Chemical- and Site-Specific Factors That May Affect Contaminant Transport

Soil (Surface and Subsurface), Sediment, Sludge, Waste Materials (Site-specific factors for Waste Materials are at the conclusion of this table)		
Runoff (soil erosion)	• Water solubility • K_{OC}	• Presence of plants • Soil type and chemistry • Precipitation rate • Configuration of land and surface condition
Leaching	• Water solubility • K_{OC}	• Soil type • Soil porosity and permeability • Soil chemistry (especially acid/base) • Cation exchange capacity • Organic carbon content
Volatilization	• Vapor pressure • Henry's Law Constant	• Physical properties of soil • Chemical properties of soil • Climatologic conditions
Biologic uptake	• Bioconcentration factor • Bioavailability	• Soil properties • Contaminant concentration

Chemical- and Site-Specific Factors That May Affect Contaminant Transport

Transport Mechanism	Factors Affecting Transport	
	Chemical-specific considerations	**Site-specific considerations**
Surface Water		
Overland flow (via natural drainage or man-made channels)	• Water solubility • K_{OC}	• Precipitation (amount, frequency, duration) • Infiltration rate • Topography (especially gradients and sink holes) • Vegetative cover and land use • Soil/sediment type and chemistry • Use as water supply intake areas • Location, width, and depth of channel; velocity; dilution factors; direction of flow • Floodplains • Point and nonpoint source discharge areas
Volatilization	• Water solubility • Vapor pressure • Henry's law constant	• Climatic conditions • Surface area • Contaminant concentration
Hydrologic connection between surface water and groundwater	• Density	• Groundwater/surface water recharge and discharge • Stream bed permeability • Soil type and chemistry • Geology (especially Karst conditions)
Adsorption to soil particles and sedimentation (of suspended and precipitated particles)	• Water solubility • K_{OW} • K_{OC} • Density	• Particle size and density • Geochemistry of soils/sediments • Organic carbon content of soils/sediment
Biologic uptake	• K_{OW} • Bioconcentration factor	• Chemical concentration • Presence of fish, plants, and other animals

Chemical- and Site-Specific Factors That May Affect Contaminant Transport

Air		
Aerosolization	• Water solubility	• Chemicals stored under pressure
Atmospheric deposition	• Particle size	• Rainfall/wind
Volatilization	• Henry's law constant	• Presence of open containers, exposed surfaces, or leaking equipment
Wind	NA	• Speed, direction, atmospheric stability
Biota		
Bioaccumulation	• K_{OW} • Persistence/half-life	• Presence of plants and animals • Consumption rate
Migration	NA	• Commercial activities (farming, aquaculture, livestock, dairies) • Sport activities (hunting, fishing) • Migratory species
Vapor sorption	NA	• Soil type • Plant species
Root uptake	NA	• Contaminant depth • Soil moisture • Plant species

Chemical- and Site-Specific Factors That May Affect Contaminant Transport

Waste Materials (Site-Specific Factors only)		
Surface water runoff	NA	• Waste type • Integrity of contaminant • Integrity of containers, impoundments, and other structures • Climatic conditions
Leaching		
Groundwater movement		
Volatilization		

Appendix F

Derivation of Comparison Values

DERIVATION AND DESCRIPTION OF COMPARISON VALUES

ATSDR has developed health guidelines and environmental guidelines to use when conducting the screening analysis and evaluating exposures to substances found at sites under investigation. *Health guidelines* are substance-specific doses or concentrations derived using toxicologic information. Where adequate dose-response data exist, health guidelines are derived for both the ingestion or inhalation routes of exposure. Health guidelines include ATSDR's minimal risk levels (MRLs). No health guidelines have been developed by ATSDR for dermal exposures. *Environmental guidelines* are media-specific substance concentrations derived from health guidelines using default exposure assumptions. ATSDR environmental guidelines include environmental media evaluation guides (EMEGs), reference dose media evaluation guides (RMEGs), and cancer risk evaluation guides (CREGs) that are available for contact with substances in water, soil, and air. No environmental guidelines have been developed by ATSDR for contact with contaminants in food or biota.

In addition to comparison values derived by ATSDR, other federal and some state agencies have developed similar types of health-based guidelines for concentrations of substances in water, soil, air, and food. You also may use these comparison values, when appropriate, to evaluate exposures to substances detected in various site media.

This appendix provides a description of comparison values available from ATSDR, as well as other sources. Sections 1.0 and 3.0 describe the health and environmental guidelines derived by ATSDR, respectively. ATSDR comparison values include MRLs, EMEGs, RMEGs, and CREGs. These values should receive priority when selecting comparison values. Sections 2.0 and 4.0 describe the health and environmental guidelines derived by other agencies, respectively. These values should be selected as comparison values only when appropriate ATSDR values are not available. Non-ATSDR comparison values discussed in this appendix include: EPA's RfDs, RfCs, CSFs, IURs, RBCs, MCLs, MCLGs, DWELs, HAs, SSLs, NAAQS; FDA's action levels; the National Council on Radiation Protection and Measurements (NCRP) radiation guidelines and (NCRP) soil screening limits; OSHA's PELs; NIOSH's RELs; and ACGIH's TLVs.

For each guideline discussed, a definition and description of the derivation and applicability or intended use are provided to enable you to determine if a comparison value is appropriate to use for evaluating site-specific conditions. For comparison values derived by agencies other than ATSDR, the referenced source(s) is also provided. Because comparison values are frequently revised and updated, any published table of values would soon be outdated. Therefore, numerical values are not presented in this appendix, instead sources in which values can be found are provided.

1.0 ATSDR's HEALTH GUIDELINES

1.1 Minimal Risk Levels (MRLs)

Definition/Derivation. ATSDR in cooperation with EPA has developed a priority list of hazardous substances found at hazardous waste sites, as directed under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the Superfund Amendment and Reauthorization Act of 1986 (SARA). For those substances most commonly found, ATSDR has prepared toxicological profiles that include an examination, summary, and interpretation of available toxicologic and epidemiologic data.

Based on the review of the available data, ATSDR has derived MRLs when reliable and sufficient data exist to identify the target organ(s) of effect or the most sensitive health effects(s) for a specific duration for a given route of exposure. MRLs are an estimate of the daily human exposure to a substance that is likely to be without appreciable risk of adverse health effects during a specified duration of exposure. MRLs are based only on noncarcinogenic effects. MRLs are screening values only and are not indicators of health effects. Exposures to substances at doses above MRLs will not necessarily cause adverse health effects and should be further evaluated.

Exhibit 1. Oral MRL Equation

An oral MRL is determined by the following equation:

MRL = NOAEL / UF

where,

MRL	=	minimal risk level (mg/kg/day)
NOAEL	=	no-observed-adverse-effect level (mg/kg/day)
UF	=	uncertainty factor (unitless)

MRLs are set below levels that might cause adverse health effects in most people, including sensitive populations. MRLs are derived for acute (1-14 days), intermediate (15-365 days), and chronic (365 days and longer) durations for the oral and inhalation routes of exposure. Currently, MRLs for dermal exposure are not derived because ATSDR has not yet identified a method suitable for developing MRLs for this route of exposure. MRLs are generally based on the most sensitive chemical-induced endpoint considered to be relevant to humans. Serious health endpoints (e.g., irreparable damage to the liver or kidneys, or birth defects) are not used as a basis for establishing MRLs.

MRLs are derived for substances by factoring the most relevant documented no-observed-adverse-effects level (NOAEL) or lowest-observed-adverse-effects level (LOAEL) and an uncertainty factor. Exhibit 1 demonstrates the derivation of an oral MRL using a NOAEL.

Inhalation MRLs are exposure concentrations expressed in units of parts per billion (ppb) for gases and volatiles, or micrograms per cubic meter ($\mu g/m^3$) for particles. Inhalation MRLs are derived for continuous, 24-hour a day exposures. The specific approach used to derive MRLs for individual substances are detailed in ATSDR's Toxicological Profile for each substance.

Most MRLs contain a degree of uncertainty because of the lack of precise toxicologic information about the people who might be most sensitive (e.g., children, elderly, those with pre-existing illnesses) to the effects of environmental contamination. ATSDR uses a conservative (i.e., protective) approach to address this uncertainty. This is consistent with the public health principle of prevention. Although human data are preferred, MRLs often must be based on animal studies because relevant human studies are lacking. In the absence of evidence to the contrary, ATSDR assumes that humans are more sensitive to the effects of hazardous substances than animals and that certain persons may be particularly sensitive. Uncertainties are accounted for by applying "uncertainty" factors to the NOAEL. For example, an uncertainty factor of between 1 and 10 may be applied for extrapolation from animal doses to human doses and/or a factor between 1 and 10 may be applied to account for sensitive individuals. When more than one uncertainty factor is applied, the uncertainty factors are multiplied. In this example, the uncertainty factor would be 100—10 for the extrapolation to humans and 10 to account for sensitive individuals.

For example, the MRL for chronic exposures through ingestion of pentachlorophenol is based on a reproductive study of female mink. Mink were exposed to a dose of 1 mg/kg/day from 3 weeks prior to mating until weaning of first-generation offspring. As a result of this exposure, no overt signs of toxicity were observed and no reproductive end points were altered, but serum thryoxine concentrations were reported in first generation males and in males and females in the second generation, along with significantly-decreased relative thyroid weight in females in the second generation. A dose of 1 mg/kg/day was identified as the LOAEL for pentachlorophenol. ATSDR divided the LOAEL by an uncertainty factor of 1,000 when deriving the MRL for pentachlorophenol. The uncertainty factor was based on factors of 10 to extrapolate from a LOAEL to a NOAEL, 10 to extrapolate from animal to human doses, and 10 to account for sensitive individuals, to result in an MRL of 0.001 mg/kg/day. (*Note that MRLs are rounded to one significant digit*.)

Applicability/Intended Use. MRLs are intended to serve only as a screening tool to help you decide if you should more closely evaluate exposures to a substance found at a site. MRLs are not intended to define cleanup or action levels. Exposure doses above the MRL does not necessarily mean that adverse health effects will occur.

When using MRLs, you should be aware that ATSDR derives MRLs assuming that exposures are occurring to a single substance and that only noncarcinogenic health effects will occur. At hazardous waste sites, people are usually exposed to a mixture of substances. Current scientific evidence indicates that substances can and do interact with each other to alter the substances' toxicities. Interactions may be additive, antagonistic, or synergistic. Because there are an infinite number of possible substance combinations and resulting interactions, only limited information is available to assess these interactions. With the lack of data on interactions, health assessors typically assume toxic effects are additive. You should be aware of the limitations that MRLs have in assessing chemical mixtures and seek information about possible substance interactions. This information can be gathered during the in-depth evaluation described in Chapter 8 of this manual.

MRLs also account only for noncarcinogenic toxic effects of substances. For carcinogenic substances, you follow the steps described in Chapter 8 of this manual, which involves a balanced review and integration of relevant exposure, toxicologic, epidemiologic, and medical data.

2.0 NON-ATSDR HEALTH GUIDELINES

2.1 Subchronic and Chronic Reference Doses (RfDs) and Reference Concentrations (RfCs)

Definition/Derivation. EPA developed chronic RfDs for ingestion and RfCs for inhalation as estimates of daily exposures to a substance that are likely to be without a discernable risk of deleterious effects to the general human population (including sensitive subgroups) during a lifetime of exposure. RfDs and RfCs are doses derived from the NOAEL or LOAEL by application of uncertainty factors and an additional modifying factor, which is based on a professional judgment of the entire database of the chemical. EPA includes uncertainties sometimes spanning orders of magnitude to ensure that the potential for health effects is overestimated. Exhibit 2 demonstrates the derivation of a RfD using a NOAEL.

The subchronic RfD or RfC is an estimate of an exposure level that would not be expected to cause adverse effects when exposure occurs during a limited time interval. Subchronic values are determined from animal studies with exposure durations of 30 to 90 days. Subchronic human exposure information is usually derived from occupational exposures and accidental acute exposures.

Exhibit 2. Oral RfD Equation

An oral RfD is determined by the following equation:

RfD = NOAEL / (UF x MF)

where,

RfD	= reference dose (mg/kg/day)
NOAEL	= no-observed-adverse-effect level (mg/kg/day)
UF	= uncertainty factor (unitless)
MF	= modifying factor (unitless)

Applicability/Intended Use. RfDs and RfCs are based on the assumption that thresholds exist for certain toxic effects such as cell death or organ damage. RfDs and RfCs are derived for the noncarcinogenic health effects of compounds that are also carcinogens. Therefore, it is essential to refer to other sources of information concerning the carcinogenicity of this substance. RfDs and RfCs are also derived assuming exposure to a single substance in a single media. Doses less than the RfD or RfC are not expected to be associated with health risks, but doses less than the RfD or RfC are not necessarily "acceptable," and doses in excess of the RfD or RfC are not necessarily "unacceptable."

References. EPA. 1993. Background Document 1A—Reference Dose (RfD): Description and Use in Health Risk Assessments. http://www.epa.gov/iris/rfd.htm. March 15, 1993.

EPA. 2001. Integrated Risk Information System (IRIS). Office of Research and Development, National Center for Environmental Assessment. http://www.epa.gov/iris/index.html. September 28, 2001.

2.2 Cancer Slope Factor (CSF) and Inhalation Unit Risk (IUR)

Definition/Derivation.

EPA evaluates the potential carcinogenicity of a substance using a two-step process—a qualitative weight-of-evidence approach and a quantitative assessment to define the relationship between dose and the likelihood of a theoretical increase in cancer cases in a population.

Based on the rationale and methods described in EPA's 2003 draft carcinogen risk assessment guidelines, EPA conducts a qualitative weight-of-evidence evaluation of human and animal toxicity studies of a substance. EPA provides weight-of-evidence narratives and presents the following descriptors to describe the carcinogenicity of a given substance:

- Carcinogenic to Humans
- Likely to Be Carcinogenic to Humans
- Suggestive Evidence for Carcinogenic Potential
- Inadequate Evidence to Assess Carcinogenic Potential
- Not Likely to Be Carcinogenic to Humans

Earlier EPA guidelines (1986) used a slightly different cancer classification scheme, which is still in place for many substances. Under that scheme potential carcinogens are classified as follows:

A	Human carcinogen (sufficient human data)
B1	Probable human carcinogen (limited human data, sufficient animal data)
B2	Probable human carcinogen (inadequate human data, sufficient animal data)
C	Possible human carcinogen (inadequate or no human data, sufficient animal data)
D	Not classifiable as to human carcinogenicity (inadequate or no human and animal data)
E	Evidence of noncarcinogenicity in humans (adequate human and animal data)

For known or possible carcinogens, CSFs and IURs are used as a quantitative indication of the carcinogenicity of a substance. A CSF is an estimate of possible increases in cancer cases in a population. A CSF is expressed in dose units $[(mg/kg/day)^{-1}]$ to allow for comparison with calculated oral doses, described in Appendix G of this manual. An IUR is an estimate of theoretical increases in cancer cases in a population expressed in concentration units $[(\mu g/m^3)^{-1}]$ to allow for comparison with site-specific air concentrations. Because there can be differences in the carcinogenicity of a substance depending on the route of exposure, a CSF for ingestion exposures or IUR for inhalation exposures should not be applied to a different route of exposure unless there is adequate justification for this assumption.

CSFs and IURs are usually derived from animal experiments that involve exposures to a single substance by a single route of exposure (i.e., ingestion or inhalation). EPA extrapolates CSFs and IURs from experimental data of increased tumor incidences at high doses to estimate theoretical cancer rate increases at low doses. The experimental data often represent exposures to chemicals at concentrations orders of magnitude higher than concentrations found in the environment.

Historically, EPA has used mathematical models, which apply a number of uncertainties and conservative assumptions, to manipulate the experimental data and extrapolate possible health outcomes from high doses to low doses. These mathematical models assume that there are no thresholds for cancer effects (or low dose linearity)—a single molecule of a carcinogen is assumed to be able to cause cancer.

As scientists learn more about how carcinogens produce tumorogenic responses in animals and humans (i.e., the mechanism of action), they are finding that some carcinogens exhibit thresholds.[1] In light of the evolving science, EPA's more recent guidelines call for more emphasis on analyzing the dose-response data before invoking low-dose linear defaults as described above. The new guidelines call for closer examination of substance-specific modes and mechanisms of action. This procedure "weighs" the available evidence, invoking a two-step dose-response process: (1) modeling the observed data to the "point of departure" and (2) extrapolating to lower doses. When data are sufficient, nonlinear extrapolation may be considered.[2] In the absence of adequate data showing nonlinear dose-response, the guidelines call for defaulting to linear assumptions. The concepts described in the guidelines are consistent with ATSDR's approach to assessing carcinogenic substances, as described in Chapter 8 of this manual.

Applicability/Intended Use. EPA assesses the carcinogenicity of a substance both qualitatively and quantitatively. As a result of a qualitative evaluation of information relevant to carcinogenicity and the quality of this information, EPA assigns cancer classifications to suspected carcinogenic substances. The cancer classifications should be discussed when discussing carcinogens in your public health assessment.

EPA develops CSFs and IURs as a result of a quantitative evaluation of a suspected carcinogenic substance. CSFs and IURs are combined with information about exposure doses to estimate a theoretical increase in cancer cases in a population. Risk assessors conducting human health risk assessment using EPA's Risk Assessment Guidance for Superfund (RAGS) (1989), use the following equation to estimate possible excess cancer risks in a population:

[1]Likewise, some noncarcinogens may have no threshold (e.g., lead). To reflect new findings, scientists are now considering a more harmonized approach in assessing effects of substance exposures.

[2]The framework for evaluating the evidence for nonlinear dose-response include asking questions such as: Is the hypothesized mode of action (MOA) sufficiently supported by test animals? Is the hypothesized MOA relevant to humans? Which populations or life stages can be particularly susceptible to the hypothesized MOA?

Exhibit 3. Derivation of a Population Cancer Estimate

ER = CSF (or IUR) x dose (or air concentration)

where,

ER	= estimated theoretical risk (unitless)
CSF/IUR	= cancer slope factor [$(mg/kg/day)^{-1}$] or inhalation unit risk [$(Fg/m^3)^{-1}$]
dose	= estimated exposure dose (mg/kg/day) [or (Fg/m^3)]

Under the quantitative risk assessment method, site-specific cancer doses and concentrations are multiplied by EPA's CSFs or IURs, respectively. This exercise estimates a theoretical excess cancer risk expressed as the proportion of a population that may be affected by a carcinogen during a lifetime of exposure. For example, an estimated cancer risk of 2×10^{-6} represents a possible 2 excess cancer cases in a population of 1 million. Because of the uncertainties and conservatism inherent in deriving the CSFs and IURs, this is only an estimate of risk; the true risk is unknown and could be as low as zero (EPA 2003).

Although ATSDR recognizes the utility of numerical risk estimates in risk analysis, the agency considers such estimates in the context of the variables and assumptions involved in their derivation and in the broader context of biomedical opinion, host factors, and actual exposure conditions. The actual parameters of environmental exposures must be given carefully considered in evaluating the assumptions and variables relating to both toxicity and exposure (ATSDR 1993).

References. ATSDR. 1993. Cancer Policy Framework. U.S. Department of Health and Human Services. January 1993.

EPA. 1989. Risk assessment guidance for Superfund. Volume I. Human health evaluation manual. Interim final. EPA/540/1-89/002.
http://www.epa.gov/oerrpage/superfund/programs/risk/ragsa/index.htm

EPA. 2003. Draft final guidelines for carcinogen risk assessment final (external review draft). U.S. Environmental Protection Agency, Risk Assessment Forum, Washington, DC, NCEA-F-0644A. March 2003.

EPA. 2001. What is IRIS? Office of Research and Development, National Center for Environmental Assessment. http://www.epa.gov/iris/intro.htm. August 13, 2001.

3.0 ATSDR'S ENVIRONMENTAL GUIDELINES

3.1 Environmental Media Evaluation Guides (EMEGs)

Definition/Derivation. EMEGs represent concentrations of substances in water, soil, and air to which humans may be exposed during a specified period of time (acute, intermediate or chronic) without experiencing adverse health effects. Acute exposures are defined as those of 14 days or less; intermediate exposures are those lasting 15 days to 1 year; and chronic exposures are those lasting longer than 1 year. EMEGs have been calculated for substances for which ATSDR has developed Toxicological Profiles using information about the substance toxicity (MRLs) and default exposure assumptions. The default exposure assumptions account for variations in water and soil ingestion between adults and children. For exposure to substances in the air, EMEGs are expressed as air concentrations and are the same for adults and children. The derivation of EMEGs is discussed separately under each media section (water, soil, and air), below.

Applicability/Intended Use. EMEGs are used when conducting an environmental guideline comparison during a screening analysis to quickly evaluate large quantities of data for a site under investigation. Substances found at concentrations below EMEGs are not expected to pose public health hazards. Substances found at concentrations above EMEGs require further evaluation before drawing a public health conclusion. When conducting an environmental guideline comparison, you must remember that EMEGs are screening values only, and not indicators of adverse public health effects. Substances found at concentrations above EMEGs will not necessarily cause adverse health effects and should be further evaluated.

In using EMEGs for a environmental guideline comparison, you have several choices of EMEGs based on chronic and intermediate duration exposures for adults and children. For health assessment purposes, you typically assume that chronic exposures to children are possible and use the corresponding EMEG to conduct an environmental guideline comparison. The chronic EMEG for children is usually the lowest EMEG concentration available for a substance and represents the most conservative, or protective, assumptions when conducting a screening analysis. When chronic exposures or child exposures can be excluded, the intermediate EMEGs or adult EMEGs may be the most appropriate values for conducting screening. You can also derive an EMEG from an acute MRL, as described later in this section of the appendix, when only short-term exposures are occurring. You are encouraged to consider all available site-specific conditions about the possible exposure durations and possibly exposed populations when selecting the most appropriate EMEG.

You should, however, recognize the limitations of EMEGs. ATSDR makes three assumptions when deriving EMEGs: 1) exposures are occurring through contact to a single medium, 2) exposures are occurring to a single substance, and 3) only noncarcinogenic health effects will occur.

Although EMEGs assume exposures are occurring through contact with a substance in a single medium, a person could be concurrently exposed to the substance in multiple media (e.g., water, soil, air, or food). The relative contribution of a particular exposure pathway to the total amount

of a substance that a person contacts can vary dramatically depending on site-specific circumstances. Because of site-to-site variability, it is infeasible for ATSDR to develop EMEGs that account for possible exposures from multiple pathways. Therefore, if exposure to a substance is occurring by multiple exposure pathways, you should consider conducting a health guideline comparison during the screening process, as described in Chapter 7 and Appendix G of this guidance manual.

EMEGs are derived assuming that exposures are occurring from a single substance. More often than not, hazardous waste sites contain a mixture of substances to which people will be exposed. A growing body of scientific information exists documenting the occurrence of interactive effects from simultaneous exposures to two or more substances. Such interactions may be additive, antagonistic, or synergistic. Most studies that have documented interactions have resulted from exposures where mixture components are in the observable effects range, *not* at concentrations at or below NOAELs—the dose levels from which EMEGs are derived. Studies that have examined exposures to lower concentrations suggest that exposure to a mixture of chemicals is unlikely to produce adverse health effects as long as components of that mixture are detected at levels well below NOAEL for individual contaminants. While no set of environmental guidelines could account for the infinite array of substances in varying proportions that may be found at sites, it is reasonable to conclude that if detected levels of chemicals are individually below health-based screening values described in this appendix, then exposure to these chemicals collectively is not expected to be of health concern.

EMEGs are based on toxicity information (MRLs), which consider noncarcinogenic toxic effects of chemicals, including their developmental and reproductive toxicity. MRLs do not consider potential genotoxic or carcinogenic effects of a substance. Because some substances have both noncarcinogenic and carcinogenic effects, ATSDR has derived CREGs to consider potential carcinogenic effects of a substance. CREGs are discussed in more detail in Section 3.3 of this appendix.

Water EMEGs. Water EMEGs are derived for potable water used in homes. Potable water includes water used for drinking, cooking, and food preparation. Exposures to substances that volatilize from potable water and are inhaled, such as volatile organic compounds (VOCs) released during showering, are *not* considered when deriving EMEGs. More information about exposures to substances from volatilization is discussed in Appendix G. For potable water exposures, an EMEG is derived from the following equation:

Exhibit 4. Derivation of an EMEG for Drinking Water

$$EMEG_W = (MRL \times BW) / IR$$

where,

$EMEG_W$	= water evaluation guide (mg/L)
MRL	= minimal risk level (mg/kg/day)
BW	= body weight (kg)
IR	= ingestion rate (L/day)

To derive the water EMEGs, ATSDR uses the chronic oral MRLs from the Toxicological Profiles. Ideally, the MRL is based on an experiment in which the chemical was administered in water. However, in the absence of such data, an MRL based on an experiment in which the chemical was administered by gavage or in food may have been used. The Toxicological Profiles for individual substances provide detailed information about the MRL and the experiment on which it was based.

Children are usually assumed to constitute the most sensitive segment of the population for water ingestion because their ingestion rate per unit of body weight is greater than the adults' rate. An EMEG for a child is calculated assuming a daily water ingestion rate of 1 liter per day (L/day) for a 10-kilogram (kg) child. For adults, a water EMEG is calculated assuming a daily water ingestion rate of 2 liters per day and a body weight of 70 kg. According to the U.S. Environmental Protection Agency's (EPA's) Exposure Factor's Handbook (EPA 1997), the average adult and child (ages 1 through 10 years) water intake rates are 1.4 L/day and 0.74 L/day, respectively. The 90th percentile drinking water intake rates for an adult and child are 2.3 L/day and 1.3 L/day, respectively. The body weights are based on an average infant (6 to 11 months) body weight of 9.1 kg and an average adult body weight of 71.8 kg (EPA 1997). Concentrations of substances in water are expressed as milligrams per liter (mg/L) or parts per million (ppm).

For example, ATSDR derived the EMEG for a child and adult exposed to 1,1-dichloroethene in drinking water as follows.

Reference Child (chronic exposures)

$EMEG_W$ = (MRL x BW) / IR
$EMEG_W$ = (0.009 milligrams per kilogram per day [mg/kg/day][3] x 10 kg) / (1 L/day)
$EMEG_W$ = 0.09 mg/L[4]

Reference Adult (chronic exposures)

$EMEG_W$ = (MRL x BW) / IR
$EMEG_W$ = (0.009 mg/kg/day[1] x 70 kg) / (2 L/day)
$EMEG_W$ = 0.3 mg/L

Soil EMEG. Soil EMEGs are calculated using the following equation. As noted below, these EMEGs apply only to soil that is ingested.

[3]Because MRLs are subject to change, you should ensure that you are using EMEGs derived using the most up-to-date MRLs. The most current MRLs are available in the HazDat database or by reviewing the most current Toxicological Profile for a substance. For each example presented in this appendix, ATSDR has presented the most-up-to-date MRL at the time of publication.

[4]ATSDR reports comparison values to one significant figure. Throughout this appendix, examples are reported to one significant figure.

Exhibit 5. Derivation of an EMEG for Soil Ingestion

$$EMEG_S = (MRL \times BW) / (IR \times CF)$$

where,

$EMEG_S$	= soil evaluation guide (mg/kg)
MRL	= minimal risk level (mg/kg/day)
BW	= body weight (kg)
IR	= soil ingestion rate (mg/day)
CF	= conversion factor of 10^{-6} (kg/mg)

To derive the soil EMEGs, ATSDR uses the chronic oral MRLs from its Toxicological Profiles. Many chemicals bind tightly to organic matter or silicates in the soil. Therefore, the bioavailability of a chemical is dependent on the media in which it is administered. Ideally, an MRL for deriving a soil EMEG should be based on an experiment in which the chemical was administered in soil. However, data from this type of study is seldom available. Therefore, often ATSDR derives soil EMEGs from MRLs based on studies in which the chemical was administered in drinking water, food, or by gavage using oil or water as the vehicle. The Toxicological Profiles for individual substances provide detailed information about the MRL and the experiment on which it was based.

Children are usually assumed to be the most highly exposed segment of the population because their soil ingestion rate is greater than adults' rate. Experimental studies have reported soil ingestion rates for children ranging from approximately 40 to 270 milligrams per day (mg/day), with 100 mg/day representing the best estimate of the average intake rate (EPA 1997). ATSDR calculates an EMEG for a child using a daily soil ingestion rate of 200 mg/day for a 10-kg child.

For sites where the only receptors for soil ingestion are adults, an EMEG is calculated using an adult body weight of 70 kilograms and an assumed daily soil ingestion rate of 100 mg/day. There are very few data on soil ingestion by adults, but limited experimental studies suggest a soil ingestion rate in adults of up to 100 mg/day, with an average intake of 50 mg/kg (EPA 1997). Concentrations of substances in soil are expressed as milligrams per kilogram (mg/kg) or ppm.

For example, ATSDR derived the EMEG for a child and adult exposed to 1,1-dichloroethene in soil as follows:

Reference Child (chronic exposure)

$EMEG_S = (MRL \times BW) / (IR \times CF)$

$EMEG_S = (0.009 \text{ mg/kg/day} \times 10 \text{ kg}) / (200 \text{ mg/day} \times 10^{-6} \text{ kg/mg})$

$EMEG_S = 500 \text{ mg/kg}$

Reference Adult (chronic exposure)

$EMEG_S$ = (MRL x BW) / (IR x CF)

$EMEG_S$ = (0.009 mg/kg/day x 70 kg) / (100 mg/day x 10^{-6} kg/mg)

$EMEG_S$ = 6000 mg/kg

ATSDR also develops EMEGs for soil-pica exposures. Soil-pica involves ingestion of soils at unusually high rates that greatly exceed most of the population (1,000–5,000 mg/day) (ATSDR 2001). The distribution of soil-pica ingestion rates has not been well-characterized. Most exposure data related to soil-pica behavior is based on observations of only a few children conducted during a short period (2 weeks or shorter), not accounting for frequency of or variations in this behavior. These studies report daily ingestion rates ranging up to 50,000 mg, with a 95th percentile soil ingestion rate reported at 208 mg/day (ATSDR 2001; Calabrese and Stanek, 1998; EPA 1997). Based on available data, ATSDR uses a soil ingestion rate of 5,000 mg/day for a 10-kg child in developing child pica EMEGs. This is considered a conservative default value (ATSDR 2001). ATSDR does not develop child pica EMEGs for chronic exposures because exposures are expected to be more intermittent (i.e., of an acute or intermediate nature).

Air EMEG. EMEGs for inhalation exposures to airborne contaminants are derived from the chronic inhalation MRLs presented in the ATSDR Toxicological Profiles or ATSDR's HazDat database. The inhalation MRLs are expressed in concentration units of micrograms/cubic meter (Fg/m^3) or parts per billion (ppb). Therefore, the air EMEG for a chemical is the same as its MRL, and no mathematical calculation is required. The same air EMEG value is used for all segments of the population. For chemical substances that exist in a vapor form at standard temperature and pressure (STP), the value is given in ppb (volume basis); for substances that are solids at STP, the value is given in Fg/m^3.

ATSDR MRLs are derived for continuous, 24-hour a day exposures. In many instances, inhalation exposures from a site may be for less than 24 hours per day. Therefore, the use of air EMEGs based on MRLs to assess these situations would provide a conservative approach for identifying air contaminants of potential health concern.

Conversion Factor for Air

To change Fg/m^3 to ppb, use the following equation:

$$C_{Fg/m3} = C_{ppb} \times (MW/24.45)$$

where,

C_{Fg/m^3} = concentration in Fg/m^3

C_{ppb} = concentration in ppb

MW = molecular weight of substance in grams/mole

For some chemicals, there may be experimental toxicity data in which the chemical was administered orally, but no data in which the chemical was administered by inhalation. Significant differences may exist in the toxicity of the chemical for oral ingestion as compared to inhalation exposure because of differences in the absorption, metabolism, distribution, and site-specific toxicity of the chemical. Therefore, an air EMEG is derived only from a MRL that is based on an inhalation study.

3.2 Reference Dose Media Evaluation Guides (RMEG)

Definition/Derivation. If no MRL is available to derive an EMEG, ATSDR develops RMEGs using EPA's reference doses (RfDs) and default exposure assumptions, which account for variations in intake rates between adults and children. EPA's reference concentrations (RfCs) serve as RMEGs for air exposures. Like EMEGs, RMEGs represent concentrations of substances (in water, soil, and air) to which humans may be exposed without experiencing adverse health effects. RfDs and RfCs consider lifetime exposures, therefore, RMEGs apply to chronic exposures.

Like EMEGs, RMEGs are developed assuming: 1) exposures are occurring through contact to a single medium, 2) exposures are occurring to a single substance, and 3) only non-carcinogenic health effects will occur. As such, you should be aware of the limitations associated with using RMEGs, which are the same as the limitations of using EMEGs described in Section 1.1 of this appendix.

Applicability/Intended Use. When no EMEGs are available, RMEGs serve as a screening tool to be used when conducting an environmental guideline comparison. Like EMEGs, substances found at concentrations below RMEGs are not expected to pose public health hazards and substances found at concentrations above RMEGs require further evaluation before drawing a public health conclusion. RMEGs also serve only as screening values and not indicators of public health hazards.

In selecting the RMEG that represents the possibly exposed population, you typically assume that exposures to children are possible. The RMEG derived for childhood exposures, therefore, should be used for assessing substance concentrations unless childhood exposures can be excluded. Because RMEGs are derived assuming chronic exposures, they should be used only for long-term (greater than a year) exposures.

3.3 Cancer Risk Evaluation Guides (CREGs)

Definition/Derivation. CREGs are media-specific comparison values that are used to identify concentrations of cancer-causing substances that are unlikely to result in an increase of cancer rates in an exposed population. ATSDR develops CREGs using EPA's cancer slope factor (CSF) or inhalation unit risk (IUR), a target risk level (10^{-6}), and default exposure assumptions. The target risk level of 10^{-6} represents a theoretical risk of 1 excess cancer cases in a population of 1 million[5]. The default exposure assumptions account for ingestion rates and body weights. CREGs are only available for adult exposures—no CREGs specific to childhood exposures are available.
In developing the CREGs, ATSDR assumes that 1) exposures occur through contact to a single medium, 2) exposures occur to a single substance, and 3) only cancer health effects will occur.

[5] A theoretical risk level is used to calculate CREGs because scientists employee a number of assumptions about the relative potency of a carcinogen at low doses. As such, the true risk is unknown and may be as low as zero (EPA 2003).

As such, you should be aware of the limitations associated with using CREGs, which are similar to the limitations of using EMEGs described in Section 3.1 of this appendix. More information about the derivation of CREGs are included in the discussion of each media (water, soil, and air), below.

Applicability/Intended Use. CREGs serve as a screening tool for evaluating concentrations of carcinogens during an environmental guideline comparison. CREGs should be used only when assessing exposures to adults; CREGs for children have not yet been developed. You should also remember that CREGs are based on theoretical estimates of cancer risk. CREGs should, therefore, serve only as a screening tool and not as an indication that cancer is expected or predicted.

Water and Soil CREGs. Like EMEGs, water CREGs are derived for potable water used in homes, including water used for drinking, cooking, and food preparation. Soil CREGs apply only to soil that is ingested. Water and soil CREGs are derived from the following equation:

Exhibit 6. Derivation of a CREG for Drinking Water or Soil Ingestion

$$CREG_{W/S} = (TR \times BW) / (IR \times CSF)$$

where,

$CREG_{W/S}$	= cancer risk evaluation guide (mg/L or mg/kg)
TR	= target risk level (10^{-6})
BW	= body weight (kg)
IR	= ingestion rate (L/day or mg/day)
CSF	= cancer slope factor [$(mg/kg/day)^{-1}$]

To derive the CREG for soil, a conversion factor (CF) of 10^{-6} mg/kg is included in the denominator to convert from milligrams of soil ingested to milligrams of substance per kilogram of soil.

In understanding this equation, remember that a theoretical risk is calculated by multiplying the dose and the CSF, as described in Appendix G. When developing the CREG, the target risk level (10^{-6}), which represents a theoretical risk of 1 excess cancer case in a population of 1 million, and the CSF are known. The calculation seeks to find the substance concentration and dose associated with this target risk level.

To derive the water and soil CREGs, ATSDR uses CSFs developed by EPA and reported in the Integrated Risk Information System (IRIS). The IRIS summaries, available at http://www.epa.gov/iris/, provide detailed information about the derivation and basis of the CSFs for individual substances. ATSDR derives CREGs for lifetime exposures, and therefore uses exposure parameters that represent exposures as an adult. An adult is assumed to ingest 2 L/day of water and weigh 70 kg. For soil ingestion, ATSDR assumes a soil ingestion rate of 100 mg/day.

For example, ATSDR derived CREGs for lifetime exposures to vinyl chloride through ingestion of drinking water or soil as follows:

Lifetime Drinking Water Exposure

$CREG_W = (TR \times BW) / (IR \times CSF)$
$CREG_W = (10^{-6} \times 70\ kg) / (2\ L/day \times 1.4\ (mg/kg/day)^{-1})$
$CREG_W = 0.00003\ mg/L$

Lifetime Soil Ingestion Exposure

$CREG_S = (TR \times BW) / (IR \times CF \times CSF)$
$CREG_S = (10^{-6} \times 70\ kg) / (100\ mg/day \times 10^{-6}\ kg/mg \times 1.4\ (mg/kg/day)^{-1})$
$CREG_S = 0.5\ mg/kg$

Air CREG. A CREG for inhalation to a substance in the air is derived from the following equation:

Exhibit 7. Derivation of a CREG for Inhalation

$$CREG_A = TR / IUR$$

where,

$CREG_A$ = cancer risk evaluation guide ($\mu g/m^3$)
TR = target risk level (10^{-6})
IUR = inhalation unit risk [$(\mu g/m^3)^{-1}$]

To derive the air CREGs, ATSDR uses IURs developed by EPA and reported in IRIS. Because toxicity studies of inhalation exposures express doses as concentrations, the IURs are estimates of the theoretical risk of cancer associated with a carcinogen expressed in concentration units. As such, no exposure parameters for intake rate or body weight are needed to derive CREGs for inhalation exposure. ATSDR assumes, however, that exposure is continuous—occurring for 24 hours a day.

For example, the CREG for lifetime exposures to vinyl chloride through inhalation is as follows:

Lifetime Inhalation Exposures

$CREG_A = TR / IUR$
$CREG_A = 10^{-6} / 0.000009\ \mu g/m^3$
$CREG_A = 0.1\ \mu g/m^3$

4.0 NON-ATSDR ENVIRONMENTAL GUIDELINES

When ATSDR values are not available, environmental guideline from other sources, such as those described below can be considered. Before using non-ATSDR derived guidelines, however, it is important to understand the derivation and underlying use of that guideline to ensure that screening a substance against it is appropriate. Generally, only human health-based values should be considered.

4.1 EPA Region 3 Risk-Based Concentrations (RBCs)

Definition/Derivation. EPA Region 3 Risk Based Concentrations (RBCs) are guidelines used to assess the potential for harm from chemicals found at a hazardous waste site. They are developed by combining a substance's toxicologic properties with "standard" scenarios for encountering the substance. EPA's measures of a substance's toxicologic properties are the RfD and CSF. The RfD is the dose of a chemical not expected to result in noncarcinogenic health effects, and the CSF is the cancer risk per unit dose. Exposure scenarios are taken from RAGS or Superfund supplemental guidance. The exposure parameters are generic and are intended to be overly conservative and protective of most populations. EPA uses these standard exposures to determine the exposure dose equivalent of the RfD or target cancer risk level. EPA Region 3 has compiled RBCs for 400 to 500 substances in soil, air, water, and fish. RBCs are presented by EPA Region 3 in the RBC Table, which is generally updated every 6 months.

Applicability/Intended Use. EPA Region 3 developed the RBC Table as a tool to aid Superfund risk assessors in screening substances at hazardous waste sites. RBCs are also used for responding to citizen inquiries and spot-checking baseline risk assessments.

RBCs have some important limitations. Each RBC is estimated assuming a person is exposed to a single substance in a single media. They do not consider the transfer of substances from soil to air or dermal contact with a substance. Toxicity information in the RBC Table was calculated by hand, and though the Table has been checked several times, it may contain errors. Therefore, EPA Region 3 emphasizes that RBCs are not intended to be used as regulatory cleanup goals. RBCs do not consider site-specific exposure scenarios because they are derived from generic exposure parameters. However, they can be used as an initial screening of substances found in site media.

References. EPA. 1989. Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A). Office of Solid Waste and Emergency Response, Toxics Integration Branch. Publication No.: EPA/540/1-89/002. December 1989.

EPA Region 3 Hazardous Site Cleanup Division. Risk Assessment. EPA Region III Risk-Based Concentration Table. http://www.epa.gov/reg3hwmd/risk/riskmenu.htm.

4.2 EPA Maximum Contaminant Levels (MCLs)

Definition/Derivation. The Safe Drinking Water Act (SDWA) establishes national primary drinking water regulations in the form of maximum contaminant levels (MCLs). MCLs are enforceable drinking water regulations that are protective of public health, but also consider economic and technological constraints. Consideration of economic and technological constraints does *not* imply that MCLs are set above levels harmful to human health. Rather, MCLs represent more realistic assumptions about toxicity and contain fewer uncertainty factors than the very conservative ATSDR environmental guidelines. National primary drinking water regulations apply to all public water systems including community water systems and transient and nontransient noncommunity water systems.

An MCL is the maximum permissible level of a contaminant in water that is delivered to the free-flowing outlet of the ultimate user of a public water system. Contaminants added to the water by the user, except those resulting from corrosion of piping and plumbing caused by water quality, are exempt from meeting MCLs. In setting MCLs, EPA considers health implications from possible exposures, as well as available technology, treatment techniques, and other means to reduce contaminant concentrations. Cost of implementing technologies is also considered.

MCLs are deemed protective of public health during a lifetime (70 years) at an exposure rate of 2 L/day. MCLs are dynamic values, subject to change as water treatment technologies and economics evolve and/or as new toxicologic information becomes available.

Applicability/Intended Use. MCLs are the heart of the national primary drinking water regulations, and have been issued by EPA under the authority of the SDWA. Drinking water standards in the United States were originally promulgated in 1914; they were reissued or revised in 1925, 1942, 1946, and 1962. While the 1914 drinking water standards were concerned solely with bacteriologic quality, the 1925 standards and those of following years include maximum permissible limits for chemical substances. Although the 1962 U.S. Public Health Service Drinking Water Standards were replaced in 1975 (effective in 1977) by national interim primary drinking water regulations, many of the original maximum permissible limits from 1962 were adopted as MCLs. MCLs are now periodically proposed or re-evaluated.

By law, MCLs are monitored on a prescribed schedule (frequency) and by using a specified analytical method. Legal violation of a MCL is not determined or based on the results of a single sample; it is based on a series of samples taken during the prescribed monitoring period.

Besides their primary use as regulatory standards for public water supplies, MCLs are useful in evaluating water quality data from private water supplies for determining potability. When applying MCLs to private water supplies, however, it is important to remember that they were developed considering more than just health concerns. MCLs are not intended to apply to single sample results, or to results from source water samples. To reasonably apply MCLs, data should originate from the MCL-specified analytical procedures.

References. EPA. 2000. Setting Standards for Safe Drinking Water. Office of Water. http://www.epa.gov/safewater/standard/setting.html. June 9, 2000.

EPA. 2001. Drinking Water Standards. Office of Water. http://www.epa.gov/safewater/creg.html. July 23, 2001.

National Primary Drinking Water Regulations, 40 C.F.R. Sect. 141.1B141.210.

4.3 EPA Maximum Contaminant Level Goals (MCLGs), Drinking Water Equivalent Levels (DWELs), and Health Advisories (HAs)

Definition/Derivation. EPA establishes several guidelines for permissible levels of a substance in a drinking water supply, including maximum contaminant level goals (MCLGs), drinking water equivalent levels (DWELs), and health advisories (HAs). MCLGs, formerly known as Recommended Maximum Contaminant Levels, are drinking water health goals. MCLGs are set at a level at which EPA has found that "no known or anticipated adverse effect on human health occurs and which allows an adequate margin of safety." EPA considers the possible impact of synergistic effects, long-term and multi-stage exposures, and the existence of more susceptible groups in the population when determining MCLGs. For carcinogens, the MCLG is set at zero, unless data indicate otherwise, based on the assumption that there is no threshold for possible carcinogenic effects.

The DWEL is a lifetime exposure level specific for drinking water (assuming that all exposure is from drinking water) at which adverse, noncarcinogenic health effects would not be expected.

EPA developed HAs as substance concentrations in drinking water at which adverse noncarcinogenic health effects would not be anticipated with a margin of safety. Drinking water concentrations are developed to establish acceptable 1-day and 10-day exposure levels for both adults and children when toxicologic data (NOAEL or LOAEL) exist from animal or human studies. Short-term HAs are intended to be used for short-term exposures such as spills and accidents. Lifetime HAs represent that portion of an individual's total exposure to a chemical that is attributed to drinking water. This is considered protective of noncarcinogenic health effects occurring during a lifetime (70 years) of exposure. Lifetime HAs are derived from DWELs. For organic compounds, lifetime HAs are 20 % of the DWEL; for inorganic compounds, lifetime HAs are 10 % of the DWEL. Typically, lifetime HAs are not determined for class A and B carcinogens. When sufficient information is available, however, the substance concentration corresponding to a target cancer risk of 10^{-4} (an increase of one cancer case in a population of one thousand) may be calculated. For Class C carcinogens, the lifetime HA is divided by an additional factor of 10.

Applicability/Intended Use. MCLGs and Proposed Maximum Contaminant Level Goals (PMCLGs) are not legally enforceable values. However, SARA now requires attaining MCLGs when relevant and appropriate. MCLGs and PMCLGs are commonly used for developing and re-evaluating health advisories and are used as screening parameters for determining potability of

private water supplies. MCLGs and PMCLGs may be more applicable than MCLs when identifying potable water supplies because they are strictly health-based.

DWELs are not legally enforceable, nor do they carry any legal authority under SDWA. However, they may be used as a source of information on noncarcinogenic health effects when developing or re-evaluating drinking water standards.

HAs are not legally enforceable standards, they are not issued as an official regulation, and they may or may not lead ultimately to the issuance of a national standard or MCL. Because MCLs consider occurrence, relative source contribution factors, treatment technologies, monitoring capability, costs, and health, it is more than likely that any resulting MCL would differ from the strictly health-based HA. The existence of an HA provides useful information to assist in setting control priorities in cases where contaminants in drinking water have been found.

References. Comprehensive Environmental Response, Compensation, and Liability Act of 1980, Pub. L. No. 95-510 (Dec 11, 1980), as amended by the Superfund Amendments and Reauthorization Act of 1986, Pub. L. No. 99-499 (Oct 17, 1986), codified together at 42 U.S.C. 9601, et seq.

EPA. 2000. Drinking Water Regulations and Health Advisories. Office of Water. Publication No.: EPA-822-B-00-001. http://www.epa.gov/ost/drinking/standards/. Summer 2000.

Note: Health advisory values may be re-evaluated and calculated without publishing new health advisory documents.

4.4 EPA Soil Screening Levels (SSLs)

Definition/Derivation. Soil screening levels (SSLs) are estimates of contaminant concentrations not expected to result in noncarcinogenic health effects during a specified duration of exposure (similar to EMEGs), or to be associated with no more than an estimated one excess cancer in a million (10^{-6}) persons exposed during a 70 year life span (similar to CREGs). SSLs are derived by calculating exposure equations and pathway models to estimate an “acceptable” level of a contaminant in soil via ingestion, dermal, and inhalation pathways. SSLs combine EPA toxicity criteria with generic exposure parameters and are intended to be overly conservative and protective of most populations. SSLs also consider the potential of contaminants to migrate to groundwater, and are calculated such that substance migration to groundwater would meet MCLGs or MCLs.

Applicability/Intended Use. SSLs are used by EPA to help standardize and accelerate the evaluation and cleanup of contaminated soils at NPL sites by screening out areas, exposure pathways, or chemicals from further consideration. When contaminant concentrations fall below SSLs, no further action or study is necessary. Therefore, SSLs provide a means to focus resources on exposure areas, contaminants, and exposure pathways of potential concern. However, SSLs are not cleanup standards, and exceeding a SSL does not necessarily indicate an unacceptable level of substance in soil or the need for action. Generally, where contaminant

concentrations exceed SSLs, EPA considers further study, not necessarily cleanup, to be necessary.

References. EPA. 1996. Soil Screening Guidance: Fact Sheet. Office of Emergency and Remedial Response. Publication No.: EPA/540/F-95/041. http://www.epa.gov/superfund/resources/soil/fact_sht.pdf. July 1996.

EPA. 1996. Soil Screening Guidance: User's Guide, Second Edition. Office of Emergency and Remedial Response. Publication No.: EPA/540/R-96/018. http://www.epa.gov/superfund/resources/soil/ssg496.pdf. July 1996.

4.5 EPA National Ambient Air Quality Standards (NAAQS)

Definition/Derivation. National Ambient Air Quality Standards (NAAQS) are set under Section 109 of the Clean Air Act (CAA) for any pollutants which, if present in air, might endanger the public health (primary standards) or public welfare (secondary standards). In developing primary standards, all sources of the pollutant that contribute to the health risk are considered. The standards must allow for an adequate margin of safety and must consider the nature and severity of the health effects of each contaminant, the most sensitive group of individuals at risk, and the degree of uncertainty of the scientific evidence. The CAA does not require EPA to consider economic or technical feasibility of implementing the standards.

Applicability/Intended Use. NAAQSs are not directly enforceable; they establish ceilings that should not be exceeded in an area where the source or sources of the pollutant are located. Thus, the standards determine restrictions on new sources and the degree of control to be imposed on existing sources. In effect, these controls determine if a new facility can be built in a given region and the type of pollution abatement systems that new and existing facilities must install. Standards can be promulgated as annual maximums, annual geometric means, annual arithmetic means, or for other time periods that vary from 1 hour to 1 year, depending on the pollutant.

References. Clean Air Act of 1970, as amended by the Clean Air Act Amendments of 1990, (November 15, 1990), 42 U.S.C. 7409. National ambient air quality standards. Sect. 109.

EPA. 2004. National Ambient Air Quality Standards (NAAQS). Office of Air Quality Planning and Standards. http://www.epa.gov/air/criteria.html. Last updated October 1, 2004.

4.6 National Council on Radiation Protection and Measurements (NCRP) Radiation Guidelines and NCRP Soil Screening Limits

Definition/Derivation. The National Council on Radiation Protection and Measurements (NCRP) developed the radiation guidelines and soil screening limits as tools to aid in the cleanup of surface soil radionuclide contamination. The radiation guidelines and soil screening limits are derived by first reviewing the current models for estimating dose, then using the estimation in eight different land-use scenarios to calculate the highest annual exposure from external dose, or the committed effective dose from inhalation or ingestion that would be delivered by the

radionuclide and its daughter products. Conservative values are selected to overestimate possible doses and to protect public health. This approach results in annual committed effective doses and screening limits that are realistic but still conservative.

Applicability/Intended Use. After ATSDR review, the Division of Health Assessment and Consultation (DHAC) adopted the use of NCRP Report 129 as a method of screening radiation levels in soil. Radiation guidelines and soil screening limits are used as a conservative method of relating an effective dose limit for an exposed critical population to a corresponding soil contamination level. Usually, these values are used for decision-making regarding the need for possible action based on present soil radionuclide levels. When radionuclide concentrations fall below the suggested limits, further action is generally not required. If the soil concentration exceeds the limit, then a site-specific dose assessment is recommended. The calculated doses are deliberately designed to conservatively represent the maximum dose to any individual. Therefore, these doses are inappropriate for use in calculating population exposures or for estimating health effects. The calculation of doses to actual individuals requires the use of site-specific and individual-specific parameters.

References. National Council on Radiation Protection and Measurements. 1999. Recommended Screening Limits for Contaminated Surface Soil and Review of Factors Relevant to Site-Specific Studies. NCRP Report No. 129. January 29, 1999.

4.7 Food and Drug Administration (FDA) Action Levels and Guidelines

Definition/Derivation. Action levels are enforceable regulatory limits of pesticides on or in human food, including fish, and animal feed. Food or feed may contain pesticide residues even if good agricultural or manufacturing practices were used. For example, some harmful substances persist in the environment. Action levels are derived considering the extent to which a pesticide cannot be avoided and existing analytical detection levels. In other words, action levels are not based exclusively on health considerations. The complete technical basis for the Food and Drug Administration (FDA) action levels is not publicly available. Action levels currently exist for approximately 23 toxic substances.

Tolerance levels were established by EPA as a measure of the maximum allowable levels of pesticide residues in or on raw agricultural products, including fish, and in processed food. If both a tolerance level and an action level exist for the same chemical or foodstuff, the tolerance level replaces the action level. Tolerance levels are derived by considering the possible toxic effects of a substance and the average daily intake of a food that contains the substance. A tolerance level is approved if the substance in a food is unlikely to result in an adverse health impact at the average daily intake rate.

Applicability/Intended Use. Action levels are used as legally enforceable guidance levels for pesticide residues when food additive regulations do not exist. If food, including fish, or feed exceeds the action level, the FDA has the discretion to take legal action to remove the product from the market.

Tolerance levels are used for testing food, including fish, and feed produce as soon as a food commodity is marketed so that any violations may be traced directly to the source. Tolerance levels are used to answer three questions: 1) what substance residues are in or on the foodstuff, 2) how much of the substance residues are in or on the foodstuff, and 3) is the level of dietary exposure to the substances acceptable. In other words, a tolerance level is the level at which no adverse effects would be expected to occur after a lifetime of dietary exposure to the substance under normal conditions.

References. FDA. 2000. Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed. Industry Activities Staff. http://vm.cfsan.fda.gov/~lrd/fdaact.html. August 2000.

Federal Insecticide, Fungicide, and Rodenticide Act of 1976, as amended by the Food Quality Protection Act of 1996, Pub .L. No. 104-170 (August 3, 1996), 7 U.S.C. 136 et seq.

Food, Drug, and Cosmetic Act of 1938, as amended by the FDA Modernization Act of 1997, 21 U.S.C. 346, et seq.

Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Food, 40 C.F.R. Sect. 180, et seq.

Unavoidable Contaminants in Food for Human Consumption and Food-packaging Material, 21 C.F.R. Sect. 109 (2000).

Unavoidable Contaminants in Animal Food and Food-packaging Material, 21 C.F.R. Sect. 509 (2000).

4.8 Occupational Safety and Health Administration (OSHA) Standards and Guidelines

Definition/Derivation. Permissible Exposure Limits (PELs) were developed by the Occupational Safety and Health Administration (OSHA) to provide safe and healthful working conditions, as mandated by Occupational Safety and Health Act of 1970. PELs are maximum exposure limits for certain airborne contaminants in the workplace, based on health criteria and technical feasibility. They are designed to ensure, to the extent feasible, that no employee suffers impairment of health or functional capacity even if regularly exposed to a substance throughout his/her working life.

PELs are usually listed as 8-hour time-weighted averages (TWA). The level may be exceeded at points in time, but the sum of the exposure levels averaged over 8 hours must not exceed the limit. In some cases, ceiling and peak levels are listed in place of, or in addition to, the 8-hour TWA. Ceiling values cannot be exceeded at any time. During a designated time period, substance concentrations may reach, but never exceed, a peak level.

The short-term exposure limit (STEL) is a 15-minute TWA which should not be exceeded at any time during a workday even if the 8-hour TWA is within the PEL. Exposures at the STEL should

not exceed 15 minutes and should not be repeated more than four times per day. There should be at least a 60-minute interval between successive exposures at the STEL. A STEL is recommended only in cases in which toxic effects have been reported from high short-term exposures in either animals or humans. It is not a separate, independent exposure limit, but rather a supplement to the PEL.

Applicability/Intended Use. PELs and STELs are enforceable regulatory standards for contaminants in the workplace and are revised as new information becomes available. If an employee is exposed to an OSHA-regulated substance at a level exceeding the PEL or STEL, the employer must comply with the substance-specific health standards listed in 29 CFR part 1910 to reduce the exposure.

It is important to understand that PELs and STELs apply to healthy adult employees working 40-hour weeks and not to the general population—including children, the elderly, and the sick—who may be subject to continuous environmental exposure.

References. Air Contaminants, 29 C.F.R. Sect. 1910.1000, et seq.
http://www.osha-slc.gov/SLTC/pel/index.html.

NIOSH. 2001. NIOSH Pocket Guide to Chemical Hazards and Other Databases. US Department of Health and Human Services. Publication No. 2001-145.
http://www.cdc.gov/niosh/npg/npg.html. August 2001.

4.9 National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limits (RELs)

Definition/Derivation. Under the authority of OSHA of 1970, the National Institute for Occupational Safety and Health (NIOSH) develops and periodically revises the recommended exposure limits (RELs), which are exposure limits for potentially hazardous substances or conditions in the workplace. NIOSH also publishes Immediately Dangerous to Life and Health (IDLH) levels, which represent the maximum concentration from which one could escape within 30 minutes without incurring impairing symptoms or irreversible health effects.

Applicability/Intended Use. RELs are available for airborne contaminants in the workplace. The RELs are developed as 8- or 10-hour TWAs or ceiling levels, as discussed under the definition and use of PELs. RELs are published and transmitted to OSHA and the Mine Safety and Health Administration for use in promulgating legal standards.

Similar to PELs and STELs, RELs apply to healthy adult employees working 40-hour weeks and not to the general population, who may be subject to continuous environmental exposure.

References. NIOSH. 2001. NIOSH Pocket Guide to Chemical Hazards and Other Databases. US Department of Health and Human Services. Publication No. 2001-145.
http://www.cdc.gov/niosh/npg/npg.html. August 2001.

4.10 American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs)

Definition/Derivation. The American Conference of Governmental Industrial Hygienists (ACGIH) is an organization concerned with industrial health and occupational health and safety. With these concerns in mind, ACGIH has developed threshold limit values (TLVs), which are airborne concentrations of substances that are not believed to cause harmful effects in workers exposed regularly. ACGIH develops and updates TLVs based on toxicity information from industrial exposures, animal studies, and human studies, if available. ACGIH stresses that TLVs for individual substances may be based on different toxicologic studies and endpoints.

Applicability/Intended Use. TLVs are developed as a TWA for exposures 8 hours a day during a 40 hour work week and as TWA for short-term (15 minute) exposures, and as ceiling levels that should never be exceeded. TLVs are intended only as guidelines for protecting worker safety and do not represent an enforceable standard or finite level of toxicity.

Similar to OSHA and NIOSH values, TLVs apply to healthy adult employees working 40-hour weeks and not to the general population, who may be subject to continuous environmental exposure.

References. American Conference of Governmental Industrial Hygienists. http://www.acgih.org/home.htm.

References

ATSDR. 1993. Cancer Policy Framework. U.S. Department of Health and Human Services. January 1993.

ATSDR. 2001. Summary Report for the ATSDR Soil Pica Workshop. June 2000. Atlanta, Georgia. March 20, 2001.

Calabrese EJ and Stanek.EJ. 1998. Soil Ingestion estimation in children and adults: a dominant influence in site-specific risk assessment. Environmental News Reporter 28 ELR 10660–71. November 1998.

EPA. 1997. Exposure Factors Handbook. Volumes 1, 2, and 3. http://www.epa.gov/ncea/pdfs/efh/front.pdf

EPA. 2003. Draft final guidelines for carcinogen risk assessment final (external review draft). U.S. Environmental Protection Agency, Risk Assessment Forum, Washington, DC, NCEA-F-0644A. March 2003.

Appendix G

Calculating Exposure Doses

CALCULATING EXPOSURE DOSES

The environmental guidelines (e.g., environmental media evaluation guides [EMEGs], reference dose media evaluation guides [RMEGs], and cancer risk evaluation guides [CREGs]), presented in Appendix F, provide one method for selecting contaminants that need to be further evaluated for their potential impact on public health. Applying the screening analysis, you conduct a direct comparison of substance concentrations detected at a site to environmental guidelines, as described in Chapter 7 of this manual.

Environmental guidelines, however, are derived using default exposure assumptions and may not represent site-specific conditions. To conduct screening using site-specific information, you estimate doses and compare these doses to appropriate health guidelines (e.g., minimal risk levels [MRLs] and reference doses [RfDs]). This appendix describes in detail the equations and methods used when estimating doses and conducting a health guideline comparison, as discussed in Chapter 7. Default exposure parameters (e.g., exposure rates and durations) are presented for illustrative purposes. However, depending on site-specific exposure conditions, alternate parameters may be selected to reflect more realistic exposure estimates.

This appendix addresses dose calculations for exposure to chemical substances, and not radiation or radionuclides. Many complex factors must be considered when estimating radiation doses, therefore, you should consult with a health physicist when radiation or radionuclides are a concern at a site.

The following generic equation in Exhibit 1 is used to estimate the exposure dose resulting from contact with a contaminated medium:

Exhibit 1. Generic Exposure Dose Equation

D = C x IR x AF x EF / BW

where,

D	=	exposure dose
C	=	contaminant concentration
IR	=	intake rate of contaminated medium
AF	=	bioavailability factor[1]
EF	=	exposure factor
BW	=	body weight.

[1]The bioavailability factor represents, as a percent, the total amount of a substance ingested, inhaled, or contacted that actually enters the bloodstream and is available to possibly harm a person. Typically, the bioavailability factor is assumed to be 1 (100%) for screening purposes—that is, all of a substance to which a person is exposed is assumed to be absorbed. The bioavailability factor may be revisited if you conduct a more refined analysis of exposures and substance toxicology, as described in Chapter 8.

In many instances, the exposure factor (EF) will equal 1—representing a daily exposure to the contaminant. However, some exposure may occur on an intermittent or irregular basis. For these kinds of exposures, an EF can be calculated to average the dose over the exposure interval. The EF is calculated by multiplying the exposure frequency by the exposure duration (ED) and dividing by the time period during which the dose is to be averaged (Exhibit 2).

Exhibit 2. Exposure Factor Equation

EF = (F x ED) / AT

where,

F	=	frequency of exposure (days/year)
ED	=	exposure duration (years)
AT	=	averaging time (ED x 365 days/year)

For example, if a child comes into contact with contaminated soil twice a week during a 5-year period, the exposure factor would be:

EF = (F x ED) / AT
EF = ([2 days/week x 52 weeks/year] x 5 years) / (5 years x 365 days/year)
EF = 0.28

The use of an exposure factor gives the dose averaged during the period of exposure. When daily exposures are occurring, the length of time used for the exposure duration (ED) in the numerator will be incorporated in the denominator. However, because some health effects may not depend on the average dose but rather on the peak dose or some other measure of the dose rate, the length of time in the denominator may change. For example, if exposure is being derived for a carcinogen, the time period during which the dose is averaged may be a lifetime (e.g., instead of 5 years, 70 years would be used in the denominator).

The site-specific exposure conditions will determine what values you should use in the exposure dose equation. The U.S. Environmental Protection Agency's (EPA's) Exposure Factors Handbook (1997) is a good source for locating ranges and percentiles for various exposure information that may be relevant to the site being evaluated. The key to calculating the most accurate exposure dose is to identify values that specifically relate to the exposure situation being assessed. If site-specific information is not available, several conservative exposure assumptions can be applied.

Some standard default values that may be useful in estimating exposures are shown in the text box to the right[2]. You should remember that, if a chemical concentration exceeds an EMEG, an RMEG, a CREG, or a dose calculated using the standard default values, it will also exceed the MRL, RfD, or target risk level.

Standard Default Values

Body Weight (BW):
70 kg - adult, approximate average
16 kg - children 1 through 6 years old, 50th percentile
10 kg - infant (6 to 11 months) approximate average

Exposure Duration (ED):
70 yrs - lifetime; by convention
30 yrs - national upper-bound time (90th percentile) at one residence
9 yrs - national median time (50th percentile) at one residence
6 yrs - children 1 through 6 years old

Note:
kg - kilogram
yrs - years

The following discussion provides an overview of the quantitative evaluation of human exposure through the following pathways: water ingestion, dermal contact, and inhalation (Section 1); soil ingestion, dermal contact, and dust inhalation (Section 2); air inhalation and dermal contact (Section 3); and food ingestion (Section 4).

Note that estimating an exposure or administered dose as described in the sections below does not take into account the relatively complex physiological and chemical processes that occur once a substance enters the body. Depending on the exposure situation being studied, you may need to qualitatively consider additional factors through the in-depth analysis discussed in Chapter 8. This additional evaluation is particularly appropriate when determining the public health significance of an estimated exposure dose that exceeds an existing health guideline. The in-depth analysis will allow you to gain a better understanding of what is known (and not known) about the likelihood that a particular exposure will result in a harmful effect.

1.0 DRINKING WATER (GROUNDWATER AND SURFACE WATER)

Ingestion of contaminated water is often the most significant source of exposure to hazardous substances from a site. However, various studies indicate that when certain chemicals, such as volatile organic compounds (VOCs), are present in the water, inhalation and dermal exposures can make a significant contribution to the total exposure dose. The magnitude of these exposures varies depending on the frequency of showering and bathing, time spent indoors, air exchange rates in the bathroom and house, and other factors. Although a precise estimate of exposures by these non-ingestion pathways will seldom be available, it may be estimated that non-ingestion exposures could yield a contaminant dose that is comparable to the ingestion dose.

[2]The standard default values shown in the box are exposure assumptions that ATSDR uses when calculating comparison values. According to EPA's Exposure Factor's Handbook (1997), the average adult body weight is 71.8 kilograms (kg), the average infant (6–11months) body weight is 9.1 kg, and the 90th percentile for the length of time a person lives at one residence is 33 years.

1.1 Ingestion

Ingesting contaminated water is one of the most significant exposure pathways at a site. To estimate exposure to a contaminant from the ingestion of potable water, analyzing contaminant concentrations in tap water samples from *individual homes* is preferred. Data collected from private wells or municipal wells may also be used. In the absence of data from drinking water supplies, you may consider using data from monitoring wells to estimate upper limits for exposures to contaminants.

Site-specific information, such as the climate in which the exposure is occurring, will enable you to calculate a more accurate exposure dose for the particular situation being evaluated. For example, if exposure doses are being calculated for a person in a more tropical climate, the intake rates may need to be increased because people in hotter climates tend to drink more water than the default value often used. More importantly, realize that the default intake rate of 2 L/day represents intake of fluids from all sources. As such, assuming the default intake rate suggests all fluids are from a single drinking water source.

Exhibit 3 illustrates how exposure doses via drinking water can be estimated and provides default values that may be used when site-specific information is not available[3].

Exhibit 3. Water Ingestion Exposure Dose Equation

Exposure doses from ingestion of water can be calculated as follows:

$$D = (C \times IR \times EF) / BW$$

where,

D = exposure dose (mg/kg/day)
C = contaminant concentration (mg/L)
IR = intake rate of contaminated water (L/day)
EF = exposure factor (unitless)
BW = body weight (kg)

Default Drinking Water Intake Rates[3]

2 L/day – adult
1 L/day – child

Note:
L/day – liters per day

For example, consider human exposure to a water supply contaminated with 35 milligrams per liter (mg/L) methylene chloride. To calculate an adult exposure dose using default values, you

[3]The default values are exposure assumptions that ATSDR uses when calculating drinking water comparison values. According to EPA's Exposure Factor's Handbook (EPA 1997), the average adult and child (1–10 years) water intake rates are 1.4 L/day and 0.74 L/day, respectively. The 90th percentile drinking water intake rates for an adult and child are 2.3 L/day and 1.3 L/day, respectively.

would assume a body weight of 70 kilograms (kg), a water intake rate of 2 liters per day (L/day), and daily exposure:

D = (C x IR x EF) / BW
D = (35 mg/L x 2 L/day x 1) / 70 kg
D = 1 milligrams of chemical per kilogram body weight per day (mg/kg/day)

For children, you could assume an average weight of 10 kg, a water intake rate of 1 L/day, and daily exposure:

D = (C x IR x EF) / BW
D = (35 mg/L x 1 L/day x 1) / 10 kg
D = 4 mg/kg/day

In some cases, you may be asked to evaluate exposures during swimming or recreational activities in swimming pools or surface water bodies. Generally, water intake under such scenarios is considered nominal. However, doses can be estimated by using the water ingestion exposure dose equation (Exhibit 3) and using an intake rate of 50 milliliters per hour or swimming event (EPA 1989).

1.2 Dermal Contact

Dermal absorption of contaminants in water occurs during bathing, showering, or swimming and may be a significant route of exposure depending on the substance-specific characteristics. The permeability of the skin to a chemical is influenced by the physicochemical properties of the substance, including its molecular weight (size and shape), electrostatic charge, hydrophobicity, and solubility in aqueous and lipid media. In general, chemicals that demonstrate high skin permeability are low in molecular weight, non-ionized, and lipid soluble.

Chemical-specific permeability coefficients should be used to estimate dermal absorption of a chemical from water. Values for dermal permeability coefficients may vary over a large range, depending on the chemical. Part E of the Risk Assessment Guidance for Superfund, Supplemental Guidance for Dermal Risk Assessment (EPA 2001) provides available dermal permeability coefficients for some chemical substances. When the permeability coefficient for a chemical is known, the dermal absorption of a chemical from water can be estimated.

Before using a dermal permeability coefficient, the original reference should be checked to ensure the applicability of the experimental study. For example, dermal permeability coefficients derived from animal studies may not be applicable for human assessment purposes because of substantial differences in skin permeability. In some studies, the permeability coefficients were determined using neat liquids (liquids that have not been mixed or diluted) or concentrated aqueous solutions; exposure of skin to high concentrations of organic solvents can damage the skin, which can profoundly alter the skin's permeability.

Another factor to consider when calculating exposure doses from dermal contact is the exposure frequency and duration. When calculating exposure doses from contact with surface waters, you should consider geographic factors, such as proximity or availability of surface waters for recreation, seasonal factors, and age.

Exhibit 4 illustrates how exposure doses via dermal contact with water can be estimated and provides default dermal exposure values that can be used when the entire body is exposed. Remember that when only parts of the body are exposed, surface areas for those specific body parts should be used. EPA's Exposure Factors Handbook (1997) is a good source for additional body part surface areas.

Exhibit 4. Water Dermal Contact Dose Equation

Doses from dermal contact with water can be calculated as follows:

D = (C x P x SA x ET x CF) / BW

where,

D = dose (mg/kg/day)
C = contaminant concentration (mg/L)
P = permeability coefficient (cm/hr)
SA = exposed body surface area (cm^2)
ET = exposure time (hours/day)
CF = conversion factor (1 L/1,000 cm^3)
BW = body weight (kg)

Default Dermal Exposure Values
50^{th} percentile total body surface area (square centimeters [cm^2])

Age (years)	Male	Female
3 < 6	7,280	7,110
6 < 9	9,310	9,190
9 < 12	11,600	11,600
12 < 15	14,900	14,800
15 < 18	17,500	16,000
18 – 70	19,400	16,900

Source: EPA 1997

1.3 Inhalation

As a health assessor, you should also recognize the potential for inhalation of volatile organic compounds (VOCs) that escape from water used in the home. Experimental studies have demonstrated that VOCs can be efficiently transferred from water to air, especially in showers where the water is heated and there is a large water-air interface.

Experimental studies have demonstrated that the internal dose of chloroform from showering (inhalation plus dermal) can be comparable to the exposure dose resulting from drinking the water (Jo et al. 1990a and b).

VOCs released to the air can equilibrate with the air in the bathroom and eventually with the rest of the house. Modeling has been used to calculate the concentration of VOCs in air in various parts of the house as a result of VOC release during indoor water use. These data, in combination with time-activity profiles of residents, have been used to estimate indoor air exposures to VOCs.

The models and studies applied to predict exposures expected to result from inhalation of VOCs have reported varying results, based on chemical-specific properties and exposure conditions. The varied findings across experimental studies underscores the difficulty in characterizing this exposure pathway. Remember that actual exposures depend on number of factors, such as chemical concentration, extent of ventilation, length of shower, among others. A few examples follow.

In some model shower experiments, about 40–60% of tricholoroethylene (TCE) in water was volatilized to the air, depending on water temperature and other factors (Andelman 1985). A one-compartment exposure model used by Maslia et al. (1996) indicated that exposure to TCE by inhalation during shower is nearly identical to that of ingesting water contaminated with TCE. Xu and Weisel (2003) found that inhalation exposures to the particulate phase of disinfection byproducts during showering are less than 1% of the ingestion dose, whereas vapor-phase haloketonic exposures under the same scenario represent more than 10% of the ingestion dose. The ratio of 3:4:3 for ingestion, inhalation, and skin absorption exposures to chloroform during a 10-minute shower has been shown to change to a ratio of 1:7:2 when the shower duration is increased to 20 minutes (Kuo et al. 1998). Lin and Hoang (2000) reported that the combined inhalation exposure to trihalomethanes during showering and cooking was comparable to the exposure dose from direct ingestion. McKone (1989) applied three-compartment model to estimate concentrations of VOCs in a shower, bathroom, and remainder of a house. Applying modeling results, household-inhalation uptake were shown to be 1 to 6 times higher than ingestion uptake for VOCs (McKone 1989). *Regardless of the variation in their findings, most researchers indicate that inhalation to volatile chemicals can be an important exposure route.*

In addition to using modeling as a method to determine indoor air concentrations of chemicals, researchers have also conducted field studies measuring tap water concentrations and resulting airborne concentrations. For example, Jo et al. (1990a and b) provide measured shower air data associated with water contaminated with chloroform—their measurements showing an equal risk associated with ingestion and inhalation exposures. Be aware that application of a conservative screening model using comparable water concentrations could predict air concentrations more than10 times greater than those measured in these particular studies.

Air concentrations of VOCs released from the water can be estimated by applying models or by searching available literature to identify chemical-specific field studies. Using either method, however, requires an understanding of the model and/or study limitations, as discussed in Chapter 5. Once a concentration is estimated, the air inhalation Exposure Dose Equation (Exhibit 7) in Section 3.1 can be used to calculate exposure doses.

VOCs, after being inhaled, can be absorbed by the respiratory epithelium and transported throughout the body by systemic blood circulation. Respiratory absorption of VOCs is influenced by the concentration in the air, breathing rate, and the duration of exposure.

2.0 SOIL (SURFACE SOIL AND SEDIMENT)

2.1 Ingestion

Soil ingestion can occur by the inadvertent consumption of soil on hands or food items, mouthing of objects, the ingestion of nusually high amounts of soil (i.e., soil-pica)[4], or through the intentional ingestion of earths as part of certain cultural practices (i.e., geophagy). All children mouth or ingest non-food items to some extent.

Soil-pica behavior is the recurrent ingestion of unusually high amounts of soil (i.e., 1,000–5,000 mg/day) (ATSDR 2001).

Both use of and accessibility to the site and surrounding areas must be considered when evaluating a site's soil exposure pathways. Sites with abandoned buildings, standing water, or streams may attract children, and exposures may occur at sites near playgrounds or school yards despite fencing and other efforts to restrict access. Both residential and recreational areas are likely to provide access for exposure. Contaminated soil can be brought into homes on the feet of family members and pets. Suspended soil particulates in outdoor air can also enter a house through indoor-outdoor air exchange. A young child playing on the floor will have the maximum opportunity both for ingestion and for dermal exposure to soil and dust accumulated on the floor.

Exhibit 5 illustrates how exposure doses via ingestion of soil can be estimated and provides some default soil intake rates for various age groups.

[4]The degree of soil-pica behavior varies widely in the population, and is influenced by nutritional status and the quality of care and supervision. Groups at risk of exhibiting soil-pica behavior include children 6 years old and younger and developmentally delayed individuals. ATSDR generally uses an intake rate of 5,000 mg/kg when evaluating soil-pica exposures. This value is believed to represent a conservative estimate based on available studies (ATSDR 2001).

Exhibit 5. Soil Ingestion Exposure Dose Equation

Exposure doses from ingestion of soil can be calculated as follows:

D = (C x IR x EF x CF) / BW

where,

D	=	exposure dose (mg/kg/day)
C	=	contaminant concentration (mg/kg)
IR	=	intake rate of contaminated soil (mg/day)
EF	=	exposure factor (unitless)
CF	=	conversion factor (10^{-6} kg/mg)
BW	=	body weight (kg)

Default Soil Intake Rates

100 mg/day -	adult, average soil ingestion rate
200 mg/day -	child, average soil ingestion rate
5,000 mg/day -	pica child, average soil ingestion rate *(to be used when assessing acute exposure situations only)*

Note:
mg/day - milligrams per day

For example, consider adult ingestion of soil with a non-carcinogenic contaminant concentration of 100 milligrams per kilogram (mg/kg) and a daily soil ingestion rate of 100 milligrams per day (mg/day). Assume the person is on site 5 days per week, 50 weeks per year, for 30 years. First calculate the exposure factor:

EF = (F x ED) / AT
EF = ([5 days/week x 50 weeks/year] x 30 years) / (30 years x 365 days/year)
EF = 0.68

Next calculate the exposure dose:

D = (C x IR x EF x CF) / BW
D = (100 mg/kg x 100 mg/day x 0.68 x 10^{-6} kg/mg) / 70 kg
D = 9.7 x 10^{-5} mg/kg/day

2.2 Dermal Contact

As a health assessor, you must acknowledge the potential for exposure by dermal absorption of chemicals from contaminated soil[5]. Dermal absorption of contaminants from soil or dust depends on the area of contact, the duration of contact, the chemical and physical attraction between the contaminant and the soil, and the ability of the contaminant to penetrate the skin. Chemical-specific factors, such as lipophilicity, polarity, volatility, molecular weight, and solubility also affect dermal absorption.[6]

For most exposure scenarios, ATSDR generally considers dermal exposure to be a minor contributor to the overall exposure dose relative to contributors from ingestion and inhalation. Many organic chemicals bind to organic matter in soil, and are therefore not readily available for absorption by the skin. In addition, only the fraction of the contaminant that is in direct contact with the skin is amenable to absorption. Therefore, the ability of a soil contaminant to be dermally absorbed depends on the diffusion of the contaminant through the soil matrix.

A soil-specific factor involved in dermal absorption is adherence. Many uncertainties exist for estimating the amount of soil that will adhere to the skin, making it very difficult to recommend a default value. Adherence depends on soil properties, the part of the body exposed to the soil, and the type of activity being performed during soil contact (EPA 2001). Site- and exposure-specific conditions should therefore be considered where possible. Default soil adherence values may be found in the following text box.

Adherence is the amount, in milligrams per square centimeter (mg/cm^2), of soil that adheres to the skin.

Another factor to consider when calculating exposure doses from dermal contact is the exposure frequency and duration. Young children (2.5 years), older children, and adults are expected to have different exposure frequency and duration. Young children would have an increased exposure frequency because they tend to retain soil on their skin after coming indoors. Adults would have a decreased exposure frequency because they tend to have less time to be exposed to outdoor soil (EPA 1997).

Exhibit 6 illustrates how soil dermal absorbed doses can be estimated and provides default dermal exposure values.

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[5]Direct dermal contact with soil contaminants may provoke dermal sensitization reactions based on chemical reactivity or allergic sensitivity. These types of sensitivity reactions result from direct skin contact with the chemical sensitizer and are not dependent on dermal absorption of the contaminant. There is large intra-individual variability in dermal sensitization reactions. Therefore, this type of sensitization reaction is not considered in the comparison values for soil or other environmental media.

[6]In addition to the multiple factors one needs to consider when evaluating the extent of dermal absorption, health assessors should also recognize the limitations of applying dermal toxicologic data to site-specific scenarios. While informative to the process, much of the data depend on animal studies with repeated applications of relatively high doses of pure substance directly on the skin of the test animal. This information needs to be put into the context of site-specific exposures. The data may not be directly applicable to short periods of human contact with soil, for example.

Exhibit 6. Soil Dermal Contact Dose Equation

Doses from dermal contact with soil can be calculated as follows:

D = (C x A x AF x EF x CF) / BW

where,

D = dose (mg/kg/day)
C = contaminant concentration (mg/kg)
A = total soil adhered (mg)
AF = bioavailability factor (unitless)
EF = exposure factor (unitless)
CF = conversion factor (10^{-6} kg/mg)
BW = body weight (kg)

Default Dermal Exposure Values

Age (yrs)	Body Weight (kg)	Total Surface (cm^2)	% Area Exposed	Exposed Area (cm^2)	Total Soil Adhered (mg)
0–1	10	3,500	30	1,050	210
1–11	30	8,750	30	2,625	525
12–17	50	15,235	28	4,266	299
18–70	70	19,400	24	4,656	326

Total soil adhered (A) is estimated by multiplying the exposed area by the default soil adherence concentration of 0.07 mg/cm^2 for adults and 0.2 mg/cm^2 for children.

Source: EPA 2001; EPA 1997

For example, one can calculate the estimated average daily exposure dose for a child that has been exposed to a soil contaminant at a concentration of 100 mg/kg every day from birth through 11 years of age. Assume that the average exposed skin surface area during this time is 30% and the bioavailability for the contaminant is 0.1.

First calculate the exposure factor for age 0–1:

EF = (F x ED) / AT
EF = (365 days/year x 1 year) / (11 years x 365 days/year)
EF = 0.09

Then calculate the exposure factor for age 1–11:

EF = (F x ED) / AT
EF = (365 days/year x 10 years) / (11 years x 365 days/year)
EF = 0.91

Next calculate the dose:

D = [exposure for age 0–1] + [exposure for age 1–11]
D = [(C x A x AF x EF x CF) / BW] + [(C x A x AF x EF x CF) / BW]
D = [(100 mg/kg x 210 mg x 0.1 x 0.09 x 10^{-6} kg/mg) /10 kg] + [(100 mg/kg x 525 mg x 0.1 x 0.91 x 10^{-6} kg/mg) / 30 kg]
D = (0.00002 mg/kg/day) + (0.00016 mg/kg/day)
D = 0.00018 mg/kg/day

2.3 Dust Inhalation

As the health assessor, you should also consider the inhalation of dusts from contaminated soils. In both children and adults, the dose of a soil contaminant that results from oral ingestion is likely to exceed the dose resulting from dust inhalation (Hawley 1985). However, for contaminated dusts, chemicals that have specific toxic effects on the respiratory tract (e.g., chromium and lung cancer) may require special concern. When there is a special concern about a contaminant in dust, the air inhalation Exposure Dose Equation (Exhibit 7) in Section 3.1 can be used to calculate exposure doses.

3.0 AIR

3.1 Inhalation

Inhalation is an important pathway for human exposure to contaminants that exist as atmospheric gases or are adsorbed to airborne particles or fibers. Inhalation exposure to contaminants from hazardous waste sites can occur as a result of direct release of gases and particles from an on-site facility, volatilization of gases from contaminated soils or water bodies, or resuspension of dust and particles from contaminated soil surfaces. When assessing exposure to atmospheric gases, generally, the estimation of inhaled dose is not necessary. The doses in the toxicological literature are reported as concentrations that can be directly compared to concentrations measured at a site. Inhalation rates are taken into account when studying dose-response relationships and in developing the screening values.[7] A dose calculation may be necessary when considering exposure to contaminants adhered to dust and inhaled.

[7]Note that IRIS employs a default inhalation rate of 20 m^3/day, which is greater than the recommended default in EPA's Exposure Factor Handbook and presented in PHAGM.

Exhibit 7 illustrates how inhalation exposure doses can be estimated and provides default air intake rates. A person's activity level, physical condition, gender, and age are a few factors that will influence the air intake rate.

Exhibit 7. Inhalation Exposure Dose Equation

Exposure doses from inhalation of air can be calculated as follows:

D = (C x IR x EF) / BW

where,

D = exposure dose (mg/kg/day)
C = contaminant concentration (mg/m^3)
IR = intake rate (m^3/day)
EF = exposure factor (unitless)
BW = body weight (kg)

Default Air Intake Rates
(approximate mean)

4.5 m^3/day - infant, less than 1 year
10 m^3/day - child, 6–8 years
12 m^3/day - girl, 12–14 years
15 m^3/day - boy, 12–14 years
11.3 m^3/day - female, 19–65+ years
15.2 m^3/day - male, 19–65+ years

Source: EPA 1997

3.2 Dermal Contact

Dermal exposure to some air contaminants could also result in absorption through the skin. However, data are not likely to be available to quantitatively estimate exposures from this pathway. Nevertheless, you should acknowledge potential exposure pathway for air contaminants that can be readily absorbed through the skin.

4.0 FOOD CHAIN (BIOTA)

4.1 Ingestion

Assessment of the human health risk from ingestion of contaminated food requires information on the quantities of contaminated foodstuffs consumed and the extent of contamination present in foodstuffs. The most reliable method of assessing the extent of human exposure to contaminants in food is direct measurement of concentrations in foodstuffs. Such measurements should be conducted on foodstuffs prepared for consumption or portions of contaminated plants and animals that are representative of those portions used as food.

If the food chain appears to be a significant pathway for human exposure and the appropriate information on contaminant levels is not available, that lack of information should be explicitly identified in the public health assessment and a recommendation should be made that the appropriate information be obtained. When making this recommendation, consider the substances found at the site and understand the substances' tendencies to bioaccumulate in animals or plants so that you may recommend the most appropriate strategy for obtaining necessary information.

Estimation of exposure dose through food chains requires knowledge of the consumption rate of specific food items in the human diet. EPA's Exposure Factors Handbook (1997) provides intake rates for a variety of foodstuffs. You should be aware that consumption rates of the population in the vicinity of a hazardous waste site may differ considerably from national average consumption rates. For example, regional consumption rates of beef may vary widely from national averages. Consumption rates of subpopulations within the contaminated area may also vary significantly from the national averages. For example, people such as American Indian or Alaska Natives who subsist on fish from a primary source would likely have an increased consumption rate. When local consumption patterns are available and are different from national averages, they should be used in the calculations to determine exposure doses.

Most commonly, as a health assessor, you are concerned about exposures from consuming fish that have bioaccumulated a substance found in surface water or sediment. Typically, you will assume that all fish consumed are caught from one contaminated water body. Exhibit 8 illustrates how fish ingestion exposure doses can be estimated. If the exposed population is consuming fish from multiple sources, however, the equation presented in Exhibit 9 should be used.

As a conservative estimate, this example does not consider contaminant reduction due to cooking. Cooking fish prior to eating can reduce the levels of some substances. You can review scientific literature to identify how cooking may affect the substance under evaluation. For example, studies have shown a 20-70% reduction of some lipophilic substances (e.g., polychlorinated biphenyls [PCBs]) in fish as a result of cooking (Sherer and Price 1993; Wilson et al. 1998).

Exhibit 8. Fish Ingestion Exposure Dose Equation

Exposure doses from ingestion of fish can be calculated as follows:

$D = C \times IR \times AF \times EF \times CF) / BW$
where,

D	=	exposure dose (mg/kg/day)
C	=	contaminant concentration (mg/kg)
IR	=	intake rate of contaminated medium (mg/day)
AF	=	bioavailability factor (unitless)
EF	=	exposure factor (unitless)
CF	=	conversion factor (10^{-6} kg/mg)
BW	=	body weight (kg)

Fish Intake Rates

20,100 mg/day	general population (all fish) nationwide average
25,000 mg/day	recreational fishers (freshwater fish), 95th percentile nationwide
26,000 mg/day	recreational fishers (marine fish), 95th percentile for Gulf region
170,000 mg/day	subsistence fishers (all fish), 95th percentile nationwide

Source: EPA 1997

For example, consider an adult who is a recreational fisher at a nearby lake and ingests 25,000 mg/day of fish with a non-carcinogenic contaminant concentration of 100 mg/kg. The fish intake rate is a daily average, so the exposure factor is equal to 1. To calculate the exposure dose:

D = C x IR x EF x CF) / BW
D = (100 mg/kg x 25,000 mg/day x 1 x 10^{-6} kg/mg) / 70 kg
D = 3.57 x 10^{-2} mg/kg/day

In the case of residential soil contamination, the consumption rate of homegrown foods and local wild plants is also of interest. To estimate the total daily intake of a particular contaminant that may bioaccumulate in multiple foodstuff, daily intakes of contaminants from all affected foodstuffs should be considered. Exhibit 9 illustrates how food ingestion exposure doses can be estimated.

Exhibit 9. Food Ingestion Exposure Dose Equation

Exposure doses from ingestion of food can be calculated as follows:

$$D = \sum_{i=1}^{n} (CL \times CRi \times EF) / BW$$

where,

D = exposure dose (mg/kg/day);
CL = contaminant concentration (mg/g);
CRi = consumption rate of food group (g/day);
EF = exposure factor (unitless);
BW = body weight (kg);
n = total number of food groups.

Exposure doses from ingestion of homegrown food is calculated similarly:

$$D = \sum_{i=1}^{n} (CL \times CRi \times EF \times PHi) / BW$$

where,

PHi = percentage of food that is homegrown.

The following example illustrates the calculation of the food ingestion exposure dose for cadmium through garden crop contamination. The consumption rates and percentage of foods that are homegrown were obtained from EPA's Exposure Factors Handbook (1997).

Food	CL (mg/g)	CR[8] (g/day)	PH (%)	EF	BW (kg)	Exposure dose (mg/kg/day)
Potatoes	0.02	65.6	3.8	1	70	0.0007
Dark green vegetables	0.01	10.8	4.4	1	70	0.00007
Deep yellow vegetables	0.51	8.8	6.5	1	70	0.004
Tomatoes	0.24	52.6	18.4	1	70	0.03
Other vegetables	0.01	79.0	6.9	1	70	0.0008
Total						0.036

Thus, the daily human exposure dose of cadmium from contaminated garden produce in this example is estimated to be 0.036 mg/kg/day. Estimates should be confirmed, as necessary, by a local consumption survey.

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[8]CR was converted to g/day from g/kg-day by multiplying by 60 kg (EPA 1997).

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Appendix H

Public Health Conclusion Categories

ATSDR CONCLUSION CATEGORIES

Analyses conducted throughout the public health assessment process provide the basis for conclusions regarding the level of public health hazard a site or hazardous substance release might pose. As described in Chapter 9, conclusions are dependent on the extent and magnitude of exposures resulting from completed or potential exposure pathways. To help ensure a consistent approach in drawing conclusions across sites and to assist the public health assessment team in determining the type of follow-up actions that might be warranted, ATSDR has established distinct descriptive conclusion categories that are assigned to every site. The conclusion categories are assigned depending on whether your site:

- Poses a hazard
  - Category 1: Urgent public health hazard or
  - Category 2: Public health hazard

- Poses no hazard
  - Category 4: No apparent public health hazard or
  - Category 5: No public health hazard

- Cannot be fully evaluated because *critical* information is missing
  - Category 3: Indeterminate public health hazard

The definitions for each of the five conclusion categories are presented in detail below. In addition, the specific criteria that should be used in selecting a category are presented along with possible follow-up activities associated with each of ATSDR's conclusion categories.

CATEGORY 1 : URGENT PUBLIC HEALTH HAZARD

This category is used for sites where short-term exposures (< 1 yr) to hazardous substances or conditions could result in adverse health effects that require rapid intervention.

This determination represents a professional judgement based on critical data which ATSDR has judged sufficient to support a decision. The assignment of this category does not necessarily imply that the available data are complete; in some cases additional data may be required to confirm or further support the decision made.

Criteria

Evaluation of available relevant information* indicates that site-specific conditions or likely exposures have had, are having, or are likely to have in the future, an adverse impact on human health that requires immediate action or intervention. Such site-specific conditions or exposures may include the presence of serious physical or safety hazards, such as open mine shafts, poorly stored or maintained flammable/explosive substances, or medical devices which, upon rupture, could release radioactive materials.

**** Such as environmental and demographic data; health outcome data; exposure data; community health concerns information; toxicologic, medical, and epidemiologic data.***

ATSDR Actions

ATSDR will expeditiously issue a health advisory that includes strong recommendations to immediately stop or reduce exposure to mitigate the health risks posed by the site. The recommendations issued in the health advisory and/or public health assessment should be consistent with the degree of hazard and temporal concerns posed by exposures to hazardous substances at the site.

Based on the degree of hazard posed by the site and the presence of sufficiently defined current, past, or future completed exposure pathways, one or more of the following public health actions *also* may be recommended:

- biologic monitoring
- biomedical testing
- case study
- epidemiologic study
- community health investigations
- registries
- public health surveillance
- cluster investigation
- health statistics review
- health professional education
- community health/stress education
- substance-specific applied research

CATEGORY 2: PUBLIC HEALTH HAZARD

This category is used for sites that pose a public health hazard due to the existence of long-term exposures (> 1 yr) to hazardous substances or conditions that could result in adverse health effects.

This determination represents a professional judgement based on critical data that ATSDR has judged sufficient to support a decision. The assignment of this category does not necessarily imply that the available data are complete; in some cases additional data may be required to confirm or further support the decision made.

Criteria

Evaluation of available relevant information* suggests that, under site-specific conditions of exposure, long-term exposures to site-specific contaminants have had, are having, or are likely to have in the future, an adverse impact on human health that requires one or more public health interventions. Such site-specific exposures may include the presence of serious physical hazards, such as open mine shafts, poorly stored or maintained flammable/explosive substances, or medical devices which, upon rupture, could release radioactive materials.

*****Such as environmental and demographic data; health outcome data; exposure data; community health concerns information; toxicologic, medical, and epidemiologic data.***

ATSDR Actions

ATSDR will make recommendations to stop or reduce exposure in a timely manner to mitigate the health risks posed by the site. The recommendations issued in the public health assessment should be consistent with the degree of hazard and temporal concerns posed by exposures to hazardous substances at the site. Actions related to the recommendations may have occurred before the actual completion of the public health assessment.

Based on the degree of hazard posed by the site and the presence of sufficiently defined current, past, or future completed exposure pathways, one or more of the following public health actions *also* may be recommended:

- biologic monitoring
- biomedical testing
- case study
- epidemiologic study
- community health investigations
- registries
- public health surveillance
- cluster investigation
- health statistics review
- health professional education
- community health/stress education
- substance-specific applied research

CATEGORY 3: INDETERMINATE PUBLIC HEALTH HAZARD

This category is used for sites when a professional judgement on the level of health hazard cannot be made because information critical to such a decision is lacking.

Criteria

This category is used for sites in which "*critical*" data are *insufficient* with regard to extent of exposure and/or toxicologic properties at estimated exposure levels. The health assessor must determine, using professional judgement, the "criticality" of such data and the likelihood that the data can be obtained and will be obtained in a timely manner. Where some data are available, even limited data, the health assessor is encouraged to the extent possible to select other hazard categories and to support their decision with clear narrative that explains the limits of the data and the rationale for the decision.

ATSDR Actions

ATSDR will make recommendations in the public health assessment to identify the data or information needed to adequately assess the public health risks posed by the site.

Public health actions recommended in this category will depend on the hazard potential of the site, specifically as it relates to the potential for human exposure of public health concern. Actions related to the recommendations may have occurred before the actual completion of the public health assessment.

If the potential for exposure is high, initial public health actions aimed at determining the population with the greatest risk of exposure can be recommended. Such public health actions may include:

- community health investigation
- health statistics review
- biologic monitoring
- environmental sampling
- cluster investigation
- epidemiologic study

If the population of concern can be determined through these or other actions, any of the remaining follow-up health actions listed under categories 1 and 2 may be recommended.

In addition, if data become available suggesting that human exposure to hazardous substances at levels of public health concern is occurring or has occurred in the past, ATSDR will reevaluate the need for any follow-up actions or activities.

CATEGORY 4: NO APPARENT PUBLIC HEALTH HAZARD

This category is used for sites where human exposure to contaminated media may be occurring, may have occurred in the past, and/or may occur in the future, but the exposure is not expected to cause adverse health effects.

This determination represents a professional judgement based on critical data that ATSDR considers sufficient to support a decision. The assignment of this category does not necessarily imply that the available data are complete, in some cases additional data may be required to confirm or further support the decision made.

Criteria

Evaluation of available relevant information* indicates that, under site-specific conditions of exposure, exposures to site-specific contaminants in the past, present, or future are not likely to result in adverse impact to human health.

*****Such as environmental and demographic data; health outcome data; exposure data; community health concerns information; toxicologic, medical, and epidemiologic data; monitoring and management plans.***

ATSDR Actions

The following public health actions may be recommended for sites in this category:

- cease or further reduce exposure*
- community health/stress education
- health professional education
- community health investigation

*This conclusion category is based on information indicating that no human exposure is occurring or has occurred in the past to hazardous substances at levels of public health concern. Therefore, recommendations to reduce exposure are not needed to reduce risk, but may be considered prudent public health practice centered on prevention or may be deemed appropriate to minimize potential future impacts.

If additional data become available suggesting that human exposure to hazardous substances at levels of public health concern is occurring, or has occurred in the past, ATSDR will reevaluate the need for any follow-up actions or activities.

CATEGORY 5: NO PUBLIC HEALTH HAZARD

This category is used for sites that, because of the absence of exposure, do NOT pose a public health hazard.

Criteria

Sufficient evidence indicates that no human exposures to contaminated media have occurred, no exposures are currently occurring, and exposures are not likely to occur in the future.

ATSDR Actions

The following public health actions may be recommended for sites in this category:

- community health education
- no recommendation at this time