Guidance Document

Decision Making at Contaminated Sites

Issues and Options in Human Health Risk Assessment

January 2015

Prepared by
The Interstate Technology & Regulatory Council
Risk Assessment Team

ABOUT ITRC

The Interstate Technology and Regulatory Council (ITRC) is a public-private coalition working to reduce barriers to the use of innovative environmental technologies and approaches so that compliance costs are reduced and cleanup efficacy is maximized. ITRC produces documents and training that broaden and deepen technical knowledge and expedite quality regulatory decision making while protecting human health and the environment. With private and public sector members from all 50 states and the District of Columbia, ITRC truly provides a national perspective. More information on ITRC is available at www.itrcweb.org. ITRC is a program of the Environmental Research Institute of the States (ERIS), a 501(c)(3) organization incorporated in the District of Columbia and managed by the Environmental Council of the States (ECOS). ECOS is the national, nonprofit, nonpartisan association representing the state and territorial environmental commissioners. Its mission is to serve as a champion for states; to provide a clearinghouse of information for state environmental commissioners; to promote coordination in environmental management; and to articulate state positions on environmental issues to Congress, federal agencies, and the public.

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DEDICATION

This document is dedicated in memory of our friend, mentor, and colleague

Steve DiZio, PhD

EXECUTIVE SUMMARY

Many regulatory agencies responsible for the cleanup of chemicals released to the environment use risk assessment within their site cleanup programs. These agencies develop and adopt regulations, guidance, and policies that define the use of risk assessment in the decision-making process for site cleanups. The regulations, guidance, and policies often incorporate risk management decisions that define default approaches, scenarios, and parameters as a starting point for risk assessment and the development of risk-based screening values. Project managers and decision makers, however, must rely on professional judgment when alternative approaches, scenarios and parameters are used for site-specific risk assessments. In these instances, despite the abundance of resources and experience available, project managers and decision makers are often faced with difficult technical issues.

While much of the science of risk assessment is the same across regulatory programs, the approaches to risk assessment and the risk management decisions related to risk assessment vary among regulatory programs (for example, regulatory programs differ in how they define target risk, default exposure scenarios, and exposure parameters). Additionally, the variability in default parameters, assumptions, and recommended methodologies among regulatory programs can cause risk assessment results to vary by orders of magnitude. Regulatory programs also differ on a particular approach to defining key risk assessment parameters (for example, using a maximum concentration versus a mean concentration as an exposure concentration) and processes (for example, eliminating exposure pathways from consideration in a risk assessment due to current or proposed future institutional controls, engineering controls, or both) when default parameters and assumptions do not apply.

This guidance document addresses a series of topic areas for five subjects associated with conducting and reviewing risk assessments for the cleanup of contaminated sites: planning, data evaluation, toxicity, exposure assessment, and risk characterization. In addition, this document views risk assessment, risk management, and risk communication as integral parts of the same decision process. Consequently, this document also addresses risk management and risk communication as they relate to risk assessment. The document identifies key issues, options, and additional helpful resources for each topic area addressed.

This document will assist project managers and decision makers tasked with developing or reviewing risk assessments for contaminated sites. It is also a useful tool, however, for community members, and other stakeholders who must understand and use risk assessment information to make environmental decisions. The document may be used to support the planning of a risk assessment, and it may be used to review the elements of a risk assessment, once tasks have been completed.

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1.0 INTRODUCTION

Evaluating site-specific modifications to default approaches, scenarios and parameters for risk assessment relies on the professional judgment and technical experience of the project managers and others producing, reviewing, and using risk assessments to support decisions regarding site cleanup. While many regulatory agencies responsible for the cleanup of chemicals released to the environment have adopted regulations, guidance and policies that define default approaches, scenarios and parameters as a starting point for risk assessment, project managers and decision makers are often faced with difficult technical issues when evaluating site-specific risk assessments. This document provides resources for project managers and decision makers to use when evaluating site-specific approaches, scenarios and parameters for risk assessment.

Two ITRC studies (ITRC 2005; ITRC 2008) examined state site cleanup programs that incorporated risk assessment, the differences in these programs, and the effect of the differences on site cleanup decisions. The first study, *Examination of Risk-Based Screening Values and Approaches of Selected States* (ITRC 2005), found that "variability in each state's basis and intended use of screening values" exists and that transparency is needed in the rationale for calculation and intended uses of the screening values. The study noted that in some cases the differences in screening values among states was minimal (with differences likely the result of rounding of values or other small differences in the input parameters), while in others the difference was greater than an order of magnitude, with differences not always apparent. The study further noted that some screening values are not risk based, but rather are based on other criteria such as background concentrations, laboratory detection limits, nuisance issues, historical values, or technology limits. The second study, *Use of Risk Assessment in Management of Contaminated Sites* (ITRC 2008), found that "the implementation of risk-based numerical criteria—the way in which the criteria are used in the field and in the management of contaminated sites via risk assessment—introduces orders of magnitude of variation in decision outcomes" (ITRC 2008). The study found that differences in sampling requirements, treatment of background concentrations, application of tiered approaches, site characterization requirements, and data interpretation and use all contributed to variability in the outcome of risk assessments and related decisions.

The variability in regulatory approaches may present difficulties for project managers and others associated with the site cleanup—especially when the risk assessment extends beyond default parameters and processes. These individuals must have sufficient background in and knowledge of the various default scenarios, input parameters, calculation processes, and alternatives in order to make informed decisions about site-specific risk assessments and site cleanup.

While many guidance documents and training programs related to risk assessment are available, project managers still face challenges when making decisions that involve site-specific risk assessment conclusions. This document provides project managers and others producing, reviewing, or relying on risk assessments with guidance to support consistent and effective site-specific risk assessment decisions for the cleanup of chemical contaminated sites.

This chapter provides an overview of the risk assessment process and touches on risk management, stakeholder engagement, risk communication, uncertainty, and ecological risk assessment. Chapter 2 discusses the use of risk assessment in site cleanup and explains different types of risk assessments such as forward and backward risk assessment calculations, tiered approaches, baseline risk assessments and deterministic/probabilistic risk assessments. Chapter 10 touches on tribal and public stakeholder perspectives and all references cited are included in Chapter 11.

The remainder of this document focuses on the following seven subjects:

1. Planning (Chapter 3)
2. Data Evaluation (Chapter 4)
3. Toxicity (Chapter 5)
4. Exposure Assessment (Chapter 6)
5. Risk Characterization (Chapter 7)
6. Risk Management (Chapter 8)
7. Risk Communication (Chapter 9)

Key issues for using human health risk assessment to support risk management decisions about site cleanup are highlighted throughout this document. Each key issue is briefly defined, and one or more potential options for addressing the issue are provided. References to additional relevant information and tools are also provided. The options are not all inclusive; other options not listed here may also be available. The options are not listed in order of priority. In some instances, combining options may be applicable for a site.

This document is intended for state, local, and federal project managers and others producing, reviewing, or relying on risk assessments to support decisions regarding site cleanup. This document is also a useful tool for environmental practitioners, community members, and other stakeholders (see Section 3.1) in understanding and using risk assessment information to make better environmental decisions. While this document is written for a broad audience of stakeholders with varying knowledge of risk assessment, it is assumed that readers are generally familiar with the risk assessment process.

1.1 Overview of Risk Assessment

Human health risk assessment is the process of characterizing the nature and magnitude of health risks (for example, cancer, birth defects, or liver disease) to humans from chemicals and other stressors that may be present in the environment (USEPA 2012c). Risk assessment is an integral component of risk management (see Section 1.2) that provides a scientific and defensible rationale to support decisions for the protection of human health and the environment. Risk assessment is interconnected with risk communication (see Section 1.4) and other components within the interactive process for risk management decision making. This interconnected and iterative process, along with a typical framework for risk assessment, is shown in Figure 1-1.

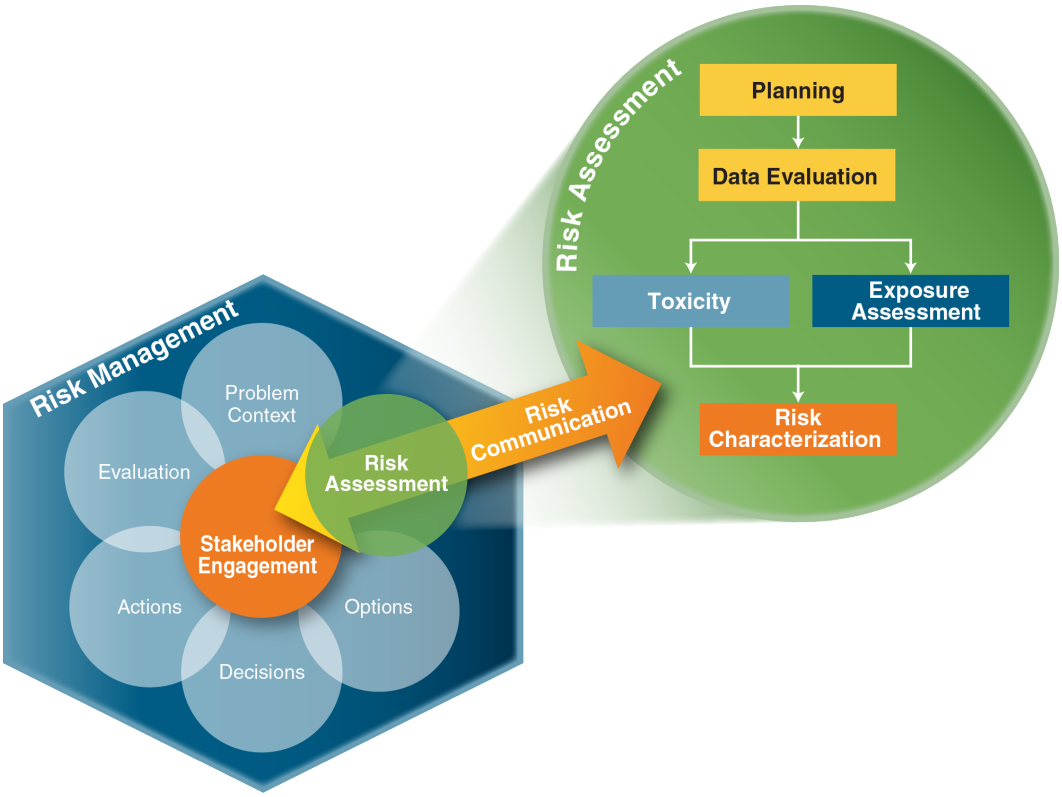

Figure 1-1. Typical framework for risk assessment.

Source: Adapted from Commission 1997a.

A human health risk assessment addresses four questions:

1. What are the potential adverse effects on human health (cancer and noncancer) from exposure to a chemical present in environmental media?
2. What is the concentration of a chemical in environmental media to which a person will be exposed?
3. How much contact will a person have with a chemical in environmental media?
4. What is the relationship between concentrations of a chemical in environmental media and the incidence or severity of potential adverse human health effects?

Note that these four questions do not assume that the presence alone of a chemical in environmental media necessarily poses a risk to human health. The risk assessment seeks to quantify whether concentrations present in the environment have the potential to pose an unacceptable risk to human health and to provide information to support decisions to mitigate, reduce, or eliminate unacceptable risk.

The complexity of a risk assessment may vary, and a detailed, site-specific risk assessment may not always be warranted. In some cases, a screening-level risk assessment using regulatory default

information (for example, default exposure scenarios and exposure factors) may be sufficient. In either case, incorporating risk assessment into a cleanup project requires proper planning (Chapter 3) to define the scope, the technical approach (Chapter 2), and the conceptual site model (CSM) for the risk assessment. The plan should be based on an understanding of the risk management goals (Chapter 8) and the need for communication (Chapter 9) with and between those involved in or affected by the risk assessment. The plan includes the development of a data collection program (Chapter 3) to identify the data to be collected and the quantity and quality of data appropriate for the risk assessment. The goal of data collection is to characterize the current or reasonably anticipated future exposures to support risk management decisions (Chapter 4).

The process of estimating risk consists of three primary steps: toxicity assessment (both hazard identification and dose-response assessment), exposure assessment, and risk characterization (Figure 1-2). Based on data analysis, a toxicity assessment (Chapter 5) is conducted to identify the potential hazard and toxicity associated with chemicals in environmental media. An exposure assessment (Chapter 6) is conducted to evaluate the mobility and exposure point concentration (EPC) of chemicals in environmental media and identify exposure pathways and receptors. Information from the toxicity assessment and exposure assessment are combined in the risk characterization (Chapter 7) to estimate and describe the potential human health risk associated with exposure to chemicals in environmental media. These steps are discussed in more detail in Section 1.1.1, Section 1.1.2, and Section 1.1.3. The results of the risk assessment support risk management decisions that protect human health (Chapter 8).

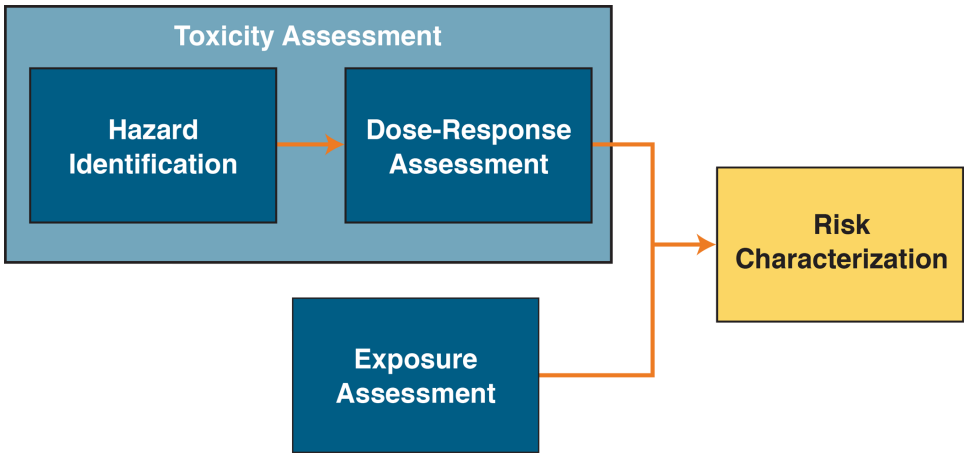

Figure 1-2. The process of estimating risk.

Source: Adapted from USEPA Human Health Risk Assessment (USEPA 2012c).

1.1.1 Toxicity Assessment

Toxicity assessment (Chapter 5) involves two steps: hazard identification and dose-response assessment. Hazard identification is the process of determining whether exposures to a chemical can cause an increase in the incidence of an adverse human health effect (for example, cancer, birth defects, or liver disease). Dose-response assessment is the process of quantifying the relationship between the degree of exposure to the chemical and incidence or severity of adverse human health

effects (USEPA 1989a). Toxicity assessment considers types of adverse human health effects associated with exposure to a chemical, relationships between the magnitude of exposure and adverse human health effects, and related uncertainties (USEPA 1989a).

The toxicity assessment results in a list of chemicals and toxicity values (for example, a reference dose [RfD] or cancer slope factor) that express the toxicity of a specific chemical. The toxicity value incorporates the findings of the hazard and dose-response assessments with safety factors to address uncertainties. This value also provides information about data quality, such as the weight of evidence of a particular chemical's carcinogenicity in humans. Toxicity assessments may conclude that a toxicity value cannot be developed because of inadequate or insufficient data.

1.1.2 Exposure Assessment

Exposure assessment (Chapter 6) quantifies the magnitude, frequency, and duration of actual or potential human exposure to chemicals in environmental media, as well as associated variability and uncertainty (USEPA 1989a). The objective is to provide a supported, quantitative estimate of exposure that is protective of human health based on site characterization data, CSMs, and receptor activity patterns. This information is used to estimate potential risks for receptors and subsequent risk management decisions.

Exposure assessment includes the following activities (see Figure 1-3):

- Characterizing exposure setting. The exposure setting is characterized with respect to physical aspects of the site including topography, climate, vegetation, and groundwater hydrology. Current and potential receptors are also identified and characteristics that influence their exposure are described, such as their location relative to the site, activity patterns, presence of sensitive subpopulations, and reasonably anticipated activities and land uses (USEPA 1989a; USEPA 1995e). This process begins during the planning stage of the risk assessment with the development of the CSM.
- Identifying exposure pathways. The exposure pathways (see Section 3.2) describe specific mechanisms by which humans could be exposed to chemicals at or originating from a site. Identifying the exposure pathways considers information that includes sources, releases, types and locations of chemicals, environmental media, chemical fate and transport, as well as location, proximity, and activities of receptor populations. Routes of exposure (ingestion, dermal contact, and inhalation) and exposure areas are identified for each exposure pathway. This process also begins during the planning stage of the risk assessment with the development of the CSM.
- Quantifying exposure. Exposure is quantified (see Section 6.2) by estimating magnitude, frequency, and duration of exposure for each pathway (estimating exposure concentrations and quantifying intakes). These estimates are conservative but within a realistic range of exposure for each exposure pathway for each receptor.

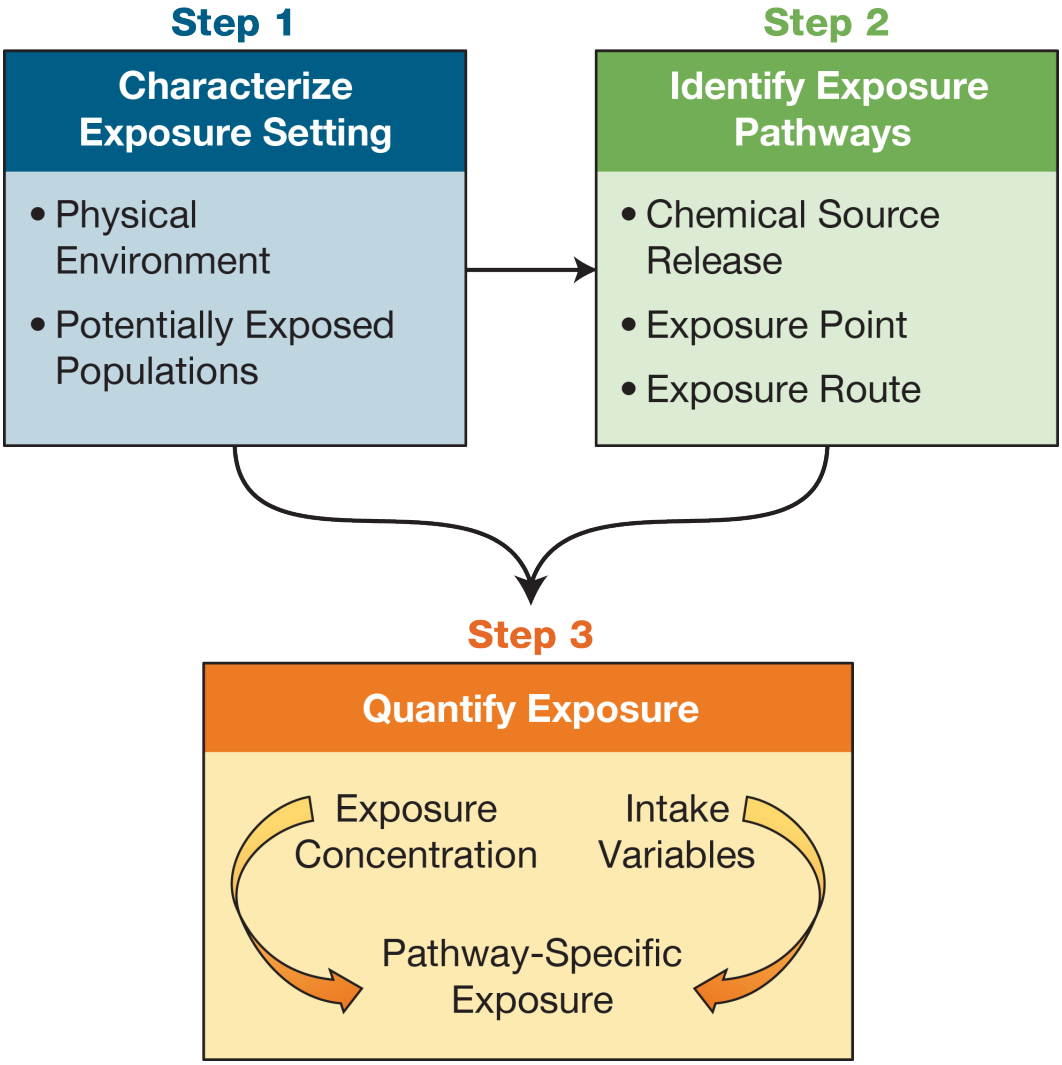

Figure 1-3. The exposure assessment process.

Source: USEPA 1989a.

Exposure assessments are usually performed for two sets of conditions: (1) conditions based on current chemical concentrations and chemical distribution in environmental media along with current on-site and off-site land use; and (2) conditions based on predicted future concentrations and distribution along with reasonably anticipated future land use. Exposure estimates for the current land uses are used to determine whether immediate action or interim measures are needed to mitigate existing and ongoing exposures. Exposure estimates for the reasonably anticipated future land use are used to determine whether remedial action is needed for long-term protection at a site (USEPA 1989a).

1.1.3 Risk Characterization

Risk characterization (Chapter 7) is the final step of the human health risk assessment process. This step combines the results of the exposure assessment (magnitude, frequency, and duration of

exposure) and toxicity assessment (toxicity value) to provide a quantitative estimate of risk (for example, incremental excess lifetime cancer risk). Along with the quantitative estimate of risk, a qualitative narrative is produced (for example, a description of potentially sensitive populations). The narrative describes the key assumptions, professional judgments, estimates of uncertainties, and other issues and questions that were identified and resolved during the risk assessment. This discussion also provides information that can be used to communicate potential risks and remedial action decisions to interested parties.

The following resources offer additional information on risk characterization:

- *Risk Characterization Handbook* (USEPA 2000b)
- *Guidance for Risk Characterization* (USEPA 1995c)
- *Elements to Consider When Drafting USEPA Risk Characterizations* (USEPA 1995b)
- *Risk Assessment Guidance for Superfund (RAGS)* (USEPA 1989a; USEPA 1991c; USEPA 1991b; USEPA 2004b; USEPA 2009a)

Chapter 7 provides guidance on key issues associated with risk characterization.

1.2 Risk Management

The Presidential/Congressional Commission on Risk Assessment and Risk Management (Commission 1997a) described an iterative and interactive framework for risk management consisting of six stages, with risk communication as an important component of all stages. This framework is shown in Figure 1-1 with the concepts summarized below:

- Problem Context - Define the problem and put it into context.
- Risk Assessment - Analyze risks associated with the problem.
- Options - Examine the options available to address the risks.
- Decisions - Decide which options will reduce or prevent risks.
- Actions - Act on the decisions.
- Evaluation - Evaluate the action taken.
- Risk Communication - Collaborate with and involve stakeholders early.

Essentially, risk management (Chapter 8) defines the problem to be addressed by the risk assessment, provides guidance for the risk assessment, and selects and implements scientific and defensible actions to protect human health in compliance with applicable laws. These actions rely on an understanding and consideration of the potential for people to be harmed as identified in the risk assessment (Commission 1997a), along with other issues that may be relevant to stakeholders (for example, environmental, social, cultural, political, and economic issues).

In the context of contaminated site cleanup, the risk management process is implemented through various mechanisms that may include statutes, regulations, policies, guidelines, and regulatory decision making. These mechanisms can define the objectives, processes, and parameters that affect a risk assessment and the decision criteria affecting actions to be taken as a result of the risk

assessment. Approaches to risk management for the cleanup of contaminated sites vary by state due to differences among the states that include the legal basis and framework for risk management, regulatory policy structure, technical approaches, decision making practices, and political factors (ITRC 2008). Given these differences, the specific regulatory framework within which the project is being conducted and its effect on the risk assessment, particularly at the beginning of the project, must be understood so that both the investigation and the risk assessment meet the risk management goals and expectations of the stakeholders (NRC 1983).

Risk management decisions should consider the views of those stakeholders affected by the decision along with the following factors (Commission 1997a; Commission 1997b):

- best available technical information, including an "analysis of the weight of scientific evidence that supports conclusions about a problem's potential risks to human health" (Commission 1997a)
- sensitivity to political, social, legal, and cultural considerations
- examination of a range of legal, regulatory, and nonregulatory risk management options
- feasibility, with benefits reasonably related to their costs
- alternatives to command-and-control regulation, including incentives for innovation, evaluation, and research
- ability to be implemented effectively, expeditiously, flexibly, and with stakeholder support

Overall, risk management involves making choices in regard to overall risks associated with chemicals in environmental media to determine appropriate actions considering environmental, social, cultural, political, and economic factors (Commission 1997a). Chapter 8 identifies key issues associated with risk management and provides insight on some of the challenges faced by project managers and others associated with risk assessment.

1.3 Stakeholder Engagement

A stakeholder is anyone who is affected by or can affect the development, outcome, or decisions made as a result of a risk assessment. Stakeholders can include individuals or organizations who conduct or oversee cleanup activities as well as those who may be affected by or who may influence the decisions. Depending on the site, stakeholders may include state regulatory agencies, federal regulatory agencies, Native American tribes, individuals, elected officials, or organizations representing local communities, and regulated parties.

Stakeholder engagement is the practice of involving stakeholders throughout a risk assessment project. Stakeholders can offer expertise, expectations, and requirements important to the development and oversight of the risk assessment and the decisions making process. Engagement of the stakeholders can be critical to the acceptance of a risk assessment, particularly since lack of communication often increases stakeholder concerns. An example of potential stakeholders is shown in Figure 1-4. In some cases, an individual or a group may represent multiple stakeholders (for example, the regulatory agency may also be the project manager or the responsible party may also be the property owner).

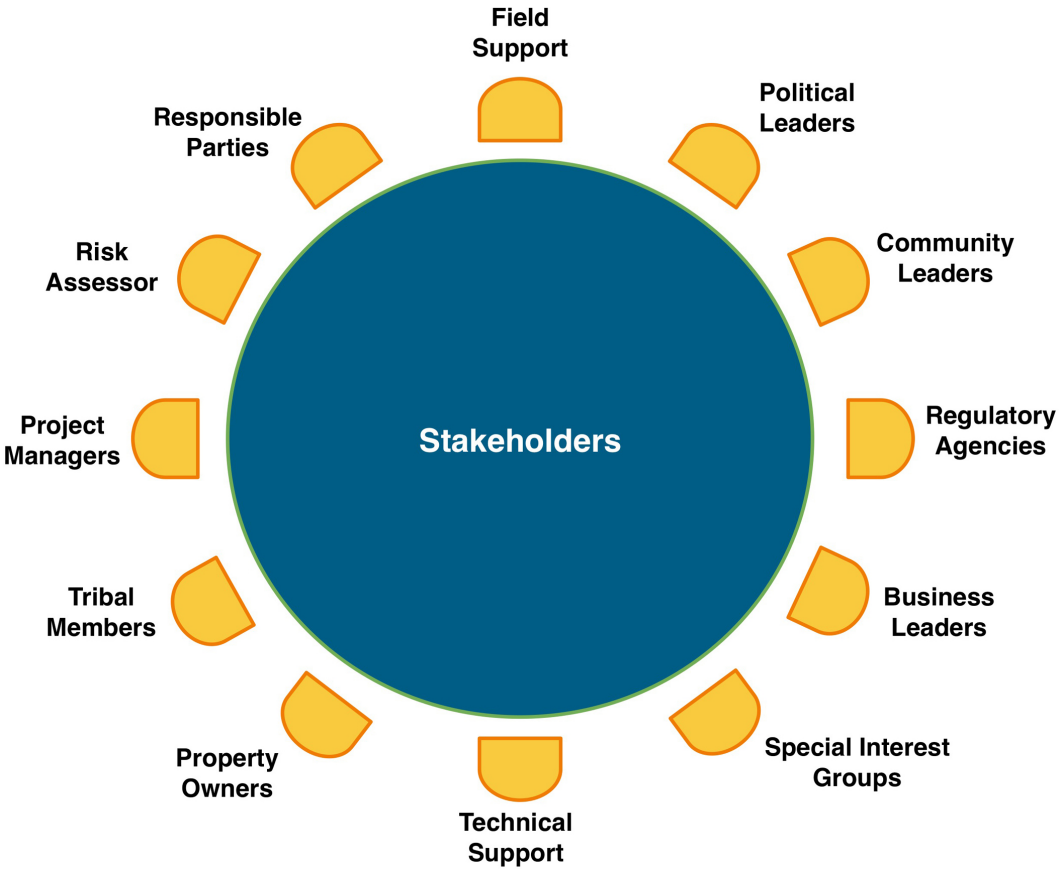

Figure 1-4. Example stakeholders in the risk communication process.

1.4 Risk Communication

To effectively engage stakeholders in the decision-making process, there must be a common understanding of what potential risks are associated with exposure to chemical releases and the assumptions made to calculate the potential risks (for example, who are the receptors? what is the use of the land considered?). This common understanding is the basis of the conversations that will eventually lead to reaching transparent risk management decisions.

Risk communication includes formal and informal communication among organizations responsible for site cleanup, as well as among the parties potentially at risk from or otherwise interested in the site. Project managers and others associated with risk assessment must communicate with various audiences about risks in order to learn about patterns of exposure, gain an understanding of the different perceptions about risk, and describe risks and uncertainties openly and clearly (Commission 1997a). Risk communication, therefore, is an ongoing interaction in all phases of risk management (see Figure 1-1) to solicit and exchange information and share results among stakeholders. With good risk communication, all those involved or affected by the decisions share a common understanding of the processes and assumptions used in risk assessment and of the objective and scope of alternatives for risk management decisions. With this understanding, stakeholders can develop a scientifically informed opinion and participate in site decisions (USEPA 2007e).

Chapter 9 highlights common problems and issues encountered in risk communication for risk assessments. Although Chapter 9 provides some examples on how to communicate the results of a risk assessment, the examples are intended to be illustrative and should be modified as necessary. This chapter also provides sources for guidance on the "how to" of risk communication.

1.5 Variability and Uncertainty

Variability and uncertainty are inherent in the risk assessment process. "Variability and uncertainty have the potential to result in overestimates or underestimates of the predicted risk" (USEPA 2014j). It is important to specify the key variabilities and uncertainties in the risk assessment in order to place the risk estimates in proper perspective for the risk manager and for risk communication. The level of effort needed for the evaluation of variability and uncertainty will vary by project depending on the scope of the assessment and the resources available (USEPA 1995c).

Variability arises from true heterogeneity in characteristics such as dose-response differences within a population, or differences in concentrations of chemicals in the environment (USEPA 1995c). The USEPA lists four types of variability (USEPA 2011c):

- *Spatial or variability across locations*. For example, fish intakes rates may vary depending on the region of the country, and exposure may vary depending on proximity to a source.
- *Temporal or variability over time, including both short-term and long-term time frames*. For example, personal activities vary daily, and some chemicals degrade or break down over time.
- *Intra-individual or variability within an individual*. For example, water ingestion rates for a single person may vary day by day and height and weight may change over time.
- *Inter-individual or variability among individuals*. For example, inhalation rates vary both by age and level of activity and individuals vary on factors such as predisposition to diseases and other medical conditions.

Agencies often address variability by use of central tendency and reasonable maximum exposure (RME) assumptions (for example, default exposure parameters and upper confidence limits [UCLs] on average exposure concentrations). Probabilistic risk assessment, which evaluates data distributions rather than using a single value for each input parameter, can also be used to address variability.

Uncertainty represents lack of knowledge about factors such as adverse effects or concentrations of chemicals in environmental media (USEPA 1995c). The difference between uncertainty and variability is that uncertainty can be reduced with additional study. Variability is inherent among individuals; it cannot be reduced with additional investigation, only better understood or characterized.

Common sources of uncertainty in risk assessment include:

- scientific measurements
- environmental sampling

- dose-response models
- exposure assumptions
- models of environmental fate and transport
- data gaps

A sensitivity analysis can be used to determine which parameters/assumptions have the most influence on the risk assessment conclusion and whether further information would sufficiently decrease the uncertainty in the outcome (see Appendix A of USEPA's guidance [2001c] for additional information on sensitivity analysis). Examples of measures that can be taken to reduce uncertainty include an unbiased sampling design or use of a more sophisticated modeling tool. Probabilistic techniques can also be used to address uncertainty. Since it is difficult to eliminate uncertainty, professional judgment must be used.

Variability and uncertainty can both be present in some of the risk assessment parameters/assumptions. For example, soil ingestion rate varies with age and individual, but estimates of soil ingestion are also inherently uncertain because it is a difficult exposure parameter to measure.

Variability and uncertainty associated with any decision-making process can be a source of concern among public and tribal stakeholders. All risk assessments incorporate variability and uncertainty and it is important to understand whether these result in estimates of risk that meet the overall risk management goals. The risk assessment should also provide sufficient information so that the stakeholders can understand and accept the variability and uncertainty in the risk assessment. Variability and uncertainty associated with risk assessment is discussed in the related topics presented in this document.

Further discussion of variability and uncertainty in risk assessment can be found in the following documents:

- *Probabilistic Risk Assessment to Inform Decision Making: Frequently Asked Questions* (USEPA 2014j)
- *Exposure Factor Handbook: 2011 Version. Chapter 2, Variability and Uncertainty* (USEPA 2011c)
- *Risk Assessment Principles and Practices. Office of Science Advisor Staff Paper* (USEPA 2004a)
- *Guidance for Risk Characterization* (USEPA 1995c)

1.6 Ecological Risk Assessment

Ecological risk assessment is a scientific evaluation of the potential for harm to occur to ecological receptors as a result of exposure to some stressor such as a chemical in environmental media. Human health and ecological risk assessments are distinct processes; however, they share some commonality and interconnection. This document focuses on human health risk assessment, but ecological risk assessment is also a consideration within the overall risk assessment process.

Information concerning ecological risk assessment can be found in the following guidance documents:

- *Risk Assessment Guidance for Superfund, Volume 2: Environmental Evaluation Manual* (USEPA 1989b).
- *Framework for Ecological Risk Assessment* (USEPA 1992b).
- *Guidelines for Ecological Risk Assessment* (USEPA 1995d).
- *ECO Update: Ecological Assessment of Superfund Sites: An Overview*, Vol. 1, Number 2 (USEPA 1991a)
- *Guidance for Ecological Risk Assessments at Hazardous Waste Sites and Permitted Facilities* (DTSC 1996).
- *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments – Interim Final* (USEPA 1997a)

1.7 Resources and Tools

The following resources and tools were not cited in the sections above and are included here for further information.

Human Health Risk Assessment Web Page (USEPA 2012c)

Public Health Assessment Guidance Manual (Update) (ATSDR 2005)

Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part A) (USEPA 1989a).

Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals) (USEPA 1991b).

Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part C, Risk Evaluation of Remedial Alternatives) (USEPA 1991c).

Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments) (USEPA 2001d).

Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment (Final) (USEPA 2004b).

Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment (Final) (USEPA 2009a).

Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual Supplemental Guidance Standard Default Exposure Factors (USEPA 1991d)

Risk Assessment Guidance for Superfund: Volume III – Part A. Process for Conducting Probabilistic Risk Assessment (USEPA 2001c)

Supplemental Guidance to RAGS: Calculating the Concentration Term (USEPA 1992d).

Exposure Factor Handbook: 2011 Version (USEPA 2011c).

2.0 USE OF RISK ASSESSMENT IN SITE CLEANUP

The use of risk assessment in the cleanup process depends on the regulatory agency, regulatory program, purpose of the risk assessment, and phase of the project. In some cases, risk assessment may be used to estimate an incremental excess lifetime cancer risk (cancer risk) or hazard quotient (noncancer hazard) from a chemical in one or more environmental media (forward risk assessment). In other cases, risk assessment may be used to back-calculate a chemical concentration in a single environmental medium that corresponds to a specified risk or hazard (backward risk assessment), as discussed in Section 2.1. Some regulatory programs use a tiered approach for risk assessment that requires the use of published screening criteria or simplifying and protective assumptions (or both) as an initial evaluation. This conservative risk assessment can be refined using more site-specific assumptions as the site investigation progresses, as discussed in Section 2.2. A baseline risk assessment, assuming no action and unrestricted land use, is discussed in Section 2.3. Risk assessments can also be based on deterministic approaches using reasonable maximum input parameters or on more complex probabilistic approaches to determine input parameters, as discussed in Section 2.4.

In many cases, a screening-level risk assessment may effectively and efficiently support risk-based decisions. In other cases, a more detailed site-specific risk assessment may be needed. The scope, type, and complexity of the human health risk assessment that would best serve risk management decision making depends upon a number of factors, including the specifics of the project or site, the complexity of the issues at hand, and the types of risk management decisions that must be supported. The following sections provide a brief description of different types of risk assessments, their potential benefits, and their limitations.

2.1 Forward and Backward Risk Assessment Calculations

Risk assessment can be conducted using a forward or backward calculation. The forward and backward calculations use the same equations and assumptions but vary in the direction in which the risk assessment proceeds. The forward calculation starts with a concentration of a chemical in environmental media (exposure concentration), defines exposure assumptions, calculates dose, identifies toxicity values, and estimates a cancer risk or noncancer hazard (see Figure 2-1).

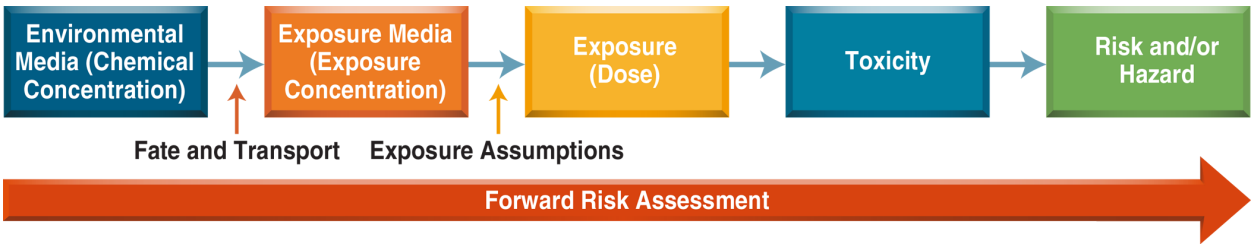

Figure 2-1. Forward risk assessment process.

The forward calculation is used to determine whether chemicals in environmental media present a risk to human health and to guide remedial action selection. This calculation requires well-defined exposure concentrations and is easier for calculating cumulative risks (see Section 7.1.2) for complicated exposure pathways (for example, homegrown produce).

The backward calculation uses the same steps as the forward calculation, but reverses the order of the steps. The backward calculation begins with the selection of a target cancer risk or noncancer hazard, identifies a potential chemical in environmental media, defines the exposure assumptions, calculates a factor representing dose, identifies toxicity values, and determines the concentration of a chemical in environmental media that is protective of human health based on the acceptable cancer risk or hazard quotient (see Figure 2-2).

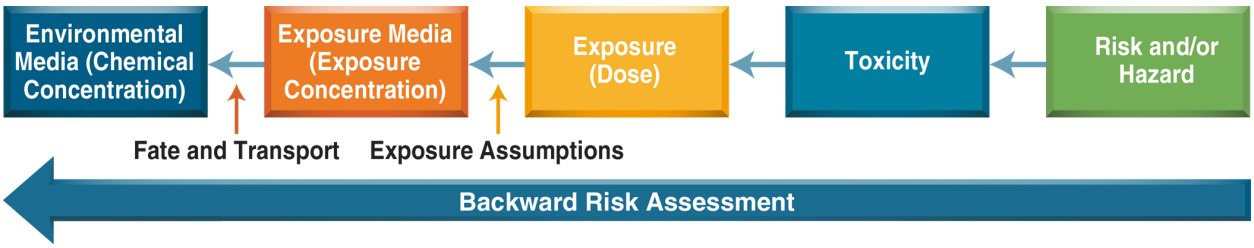

Figure 2-2. Backward risk assessment process.

The backward calculation is used in developing most health-based screening values such as the USEPA Regional Screening Levels (USEPA 2014e) or state program screening values. Assuming all applicable exposure routes/pathways are included, the backward calculation can provide a simple way to screen concentrations of a chemical in environmental media, particularly for large sites where the exact exposure areas are not yet defined. This calculation can also be used to develop chemical and environmental media-specific target levels for remedial action. For sites with multiple chemicals, the cumulative risks can also be estimated through this approach, as discussed in Section 5.14.2 of the USEPA's Regional Screening Levels Users Guide (USEPA 2014e). It may be difficult, however, to identify contributing pathways, and screening values can become outdated as parameters and assumptions change (for example, if newer toxicity values become available or agency exposure assumptions change). When previously existing, health-based screening values are used, the user should understand the input parameters that were used to calculate the screening values.

With a backward calculation, it may be difficult to identify contributing pathways, and screening values can become outdated as parameters and assumptions change.

2.2 Tiered Risk Assessment Approach

A tiered approach for risk assessment is a systematic progression that starts with a high degree of conservatism (but low complexity) and progresses to decreasing conservatism and increasing complexity in the values and information used to estimate risk. The tiered approach offers a balance between the benefits of conducting more complex site investigations and the cost of additional

time, resources, and risk communication challenges. Each tier provides an opportunity to review and communicate results of the risk assessment and make decisions on subsequent actions or tiers in the risk assessment process.

The tiered approach can be applied using either a forward or backward risk assessment calculation. This approach typically begins with a qualitative assessment to identify chemicals of concern and determine whether potentially complete exposure pathways are present (Tier 1). For potentially complete exposure pathways under Tier 1, concentrations of chemicals in environmental media are compared to the applicable predetermined screening values, or a conservative risk assessment calculation may be performed. The Tier 1 evaluation is generally based on default exposure scenarios, conservative parameters, and conservative exposure concentrations (for example, a maximum reported concentration of a chemical in an environmental medium). Subsequent tiers replace the conservative assumptions used in Tier 1 with more site-specific data and information to better represent the actual exposures/risks at a site. Further evaluation may involve more intensive investigation of chemicals present, exposure pathways, and receptor characteristics. Additionally, the site may require more complex modeling, statistical analysis (including probabilistic evaluations), and introduction of alternative toxicity values (based on new information).

If a Tier 1 screening-level assessment indicates potential risk to human receptors, then managers must decide whether to move to the next tier or to conduct appropriate remedial actions. Some considerations for this decision may include:

- Are the conservative assumptions and exposure pathways used in the Tier 1 risk assessment representative of the conditions at the site?
- Were all appropriate exposure pathways considered in the Tier 1 risk assessment?
- Will a site-specific risk assessment result in a significantly different outcome for the risk assessment?
- Will a site-specific risk assessment conducted in Tier 2 or Tier 3 result in a significantly different or less extensive remedial action?
- Are resources and time available to support more study?

Many state underground storage tank programs use a risk-based corrective action (RBCA) approach to evaluate risks posed by underground storage tank sites. The ASTM published its first RBCA standard (ASTM E1739) to assist at petroleum cleanup sites (ASTM 2010b) and its second RBCA standard (ASTM E2081) for all corrective action sites (ASTM 2010a). RBCA incorporates a tiered evaluation process to classify and evaluate sites based on risk. Evaluations under the initial tier typically rely on screening values developed through a risk assessment and based on conservative scenarios and assumptions (see backward risk assessment calculation in Section 2.1). Subsequent tiers allow site-specific scenarios and assumptions to be incorporated into the risk assessment.

Other examples of tiered approaches include state voluntary action programs and corrective action programs. Many of these programs rely on screening values, developed using risk assessment based on conservative scenarios and assumptions, as an initial screening tool followed by site-

specific risk assessments to develop remedial action target levels. For example, the Illinois Tiered Approach to Corrective Action Objectives (TACO) program is the Illinois Environmental Protection Agency's (IEPA's) risk-based method for developing remedial action objectives for soil and groundwater that take into account site conditions and land use (IEPA 2007). TACO is a three-tiered approach that uses risk-based screening values for the Tier 1 evaluation provided in tables in the appendix of the regulations and allows cleanup criteria to be developed by applying site-specific data to preestablished modeling equations in Tier 2. Tier 3 allows other fate and transport models and any modifications to exposure and toxicity criteria to be used.

2.3 Baseline Human Health Risk Assessment

The baseline risk assessment, commonly associated with the USEPA's Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and Resource Conservation and Recovery Act (RCRA) programs, is an analysis of the risks for potential adverse human health effects caused by a release from a site in the absence of any actions to control or mitigate the exposure (USEPA 1989a). Baseline risk assessments commonly assume the most conservative land-use scenario in the absence of institutional or engineering controls (for example, a residential land use). A baseline risk assessment is conducted when chemicals have been identified in environmental media during initial data collection for the remedial investigation. Baseline risk assessments quantify potential risks posed by chemicals in environmental media and assist in determining if these risks require action.

2.4 Deterministic and Probabilistic Risk Assessments

The type of risk assessment to be used is determined by site-specific conditions and the regulatory program under which the risk assessment is being conducted. There are two types of risk assessments methods:

- Deterministic risk assessments are the most common type of risk assessment and are conducted using a single value for each input parameter to calculate an estimate of the risk. Deterministic risk assessments can use established default assumptions (such as RME) as input parameters or use site-specific information, where available. The output of the deterministic risk assessment is usually a single point risk estimate (for example, 1×10^{-6}) or hazard quotient/index, with a qualitative discussion of variability and uncertainty.
- Probabilistic risk assessments use statistically derived distributions of input values to calculate a range of risk. The probabilistic risk assessment can address both variability and uncertainty, with the output of the assessment being a distribution of risk that identifies individual risks at the mean or 95th percentile, for example. As a result, these assessments can provide a more detailed understanding of the variability and uncertainty of potential risks and the sensitivity of the input parameters (identifying which parameters have the most effect on the risk results). A probabilistic risk assessment is typically conducted to support a quantitative uncertainty analysis. Because of the quantity and quality of data needed for a probabilistic risk assessment, the assessment is often conducted only for complex sites and for exposure pathways that contribute significantly to the risk estimate. The complexity

decreases with fewer exposure pathways evaluated and decreases if the distribution data needed have already been developed.

Each type of risk assessment can affect the site cleanup decision making. A deterministic risk assessment provides a single risk estimate that can be used as a basis for decisions. A probabilistic risk assessment provides a range of values for the risk estimate, which must be interpreted in order to determine the action warranted.

2.5 Resources and Tools

The following resources and tools were not cited in the sections above and are included here for further information.

Probabilistic Risk Assessment to Inform Decision Making: Frequently Asked Questions (USEPA 2014j).

Risk Assessment Forum White Paper: Probabilistic Risk Assessment Methods and Case Studies (USEPA 2014l).

Policy for Use of Probabilistic Analysis in Risk Assessment at the U.S. Environmental Protection Agency (USEPA 1997e).

Guiding Principles for Monte Carlo Analysis (USEPA 1997c).

Use of Risk Assessment in Management of Contaminated Sites (ITRC 2008)

Risk Assessment Guidance for Superfund (RAGS) Volume III - Part A: Process for Conducting Probabilistic Risk Assessment (USEPA 2001c).

Best Practices for Risk-Informed Decision Making Regarding Contaminated Sites: Summary of a Workshop Series (NRC 2014)

3.0 PLANNING

As indicated in the Framework for Human Health Risk Assessment to Inform Decision Making (USEPA 2014f), the risk assessment should be "fit for purpose," should be tailored to the decisions at hand, and should inform the decision-making process (NRC 2009). A thoughtful and thorough planning process defines the scope and technical approach for the risk assessment, develops a CSM to guide the risk assessment, and defines a data collection program. The scope and technical approach of the risk assessment varies based on many factors including regulatory context, the size and setting of the site, the distribution of chemicals in environmental media, and information and data needs. The planning process should incorporate input from stakeholders so that the approach is understood and agreed upon before the site investigation and risk assessment begins.

This chapter provides guidance on key issues associated with planning a risk assessment. The key issues are organized around three general topic areas:

Scoping and Technical Approach

- Identifying Appropriate Support for the Risk Assessment
- Communicating During the Risk Assessment Planning and Implementation Process
- Determining the Regulatory Context

Conceptual Site Model

- Using a Generic or Inadequate CSM
- Incorporating Future Land Uses and Groundwater Uses into the CSM
- Determining Whether to Include Institutional and Engineering Controls or Planned Remedial Action in the CSM
- Identifying Which Sources, Receptors, and Exposure Pathways to Include in the CSM
- Developing the CSM When Limited Information is Known About Historical Site Sources

Data and Information

- Determining the Adequacy of Data and Information for the Risk Assessment
- Determining the Availability of Samples from Site-Specific Exposure Areas
- Assessing Hot Spots
- Determining Whether the Data Set is Representative of the Exposure Areas
- Recognizing Biases in the Data Set that Will Affect Risk Estimates
- Selecting Analytical Parameters
- Addressing Background Concentrations in the Risk Assessment

3.1 Scoping and Technical Approach

Project scoping is critical for risk assessment. During scoping, the appropriate project team should be identified (including agencies, risk assessors, other technical experts, and stakeholders), lines and methods of communication should be established, and the regulatory framework (from statutes through guidance) identified.

3.1.1 Issue – Identifying Appropriate Support for the Risk Assessment

During the planning stage, the appropriate individuals and organizations needed to support the risk assessment and to develop and work toward a common purpose, scope, and technical approach should be identified. This support varies by site and project, but usually includes:

- regulatory agencies (including the regulatory project manager overseeing the cleanup)
- responsible parties or remediating parties (including technical project managers representing the responsible parties)
- technical experts (risk assessors and others as needed, including engineers, geologists, chemists, and statisticians)
- risk communication experts
- community and other stakeholders (for example, affected community, tribes, public health agencies)

Stakeholders may hold differing views on both the definition of the problem and on the list of possible options or problem evaluation methods (Adler and Kranowitz 2005). It is better to discover these differences during project planning than after communicating the risk assessment results. These differences may result from an individual's risk perception on the basis of fear or feelings of inequality or distrust (see Section 9.2). Disagreements among stakeholders on critical aspects of the risk assessment may also pertain to issues not initially viewed as topics for discussion. Some examples include questions such as:

- Who sets the framework of the assessment? This question may include issues such as administrative site boundaries, sampling and assessment project time frames, and identifying appropriate regulation or guidance. For tribal stakeholders in particular, a parallel governmental structure exists with explicit or implicit rules.
- Who defines the time line for the project? The proposed schedule may not fit the time frame when some stakeholders are available to provide input. Stakeholders may also have a sense of urgency regarding their input that does not meet project management expectations. Where stakeholder involvement is key, deadlines should be set with sufficient time to allow stakeholder engagement and interaction.
- Whose has the power to make or influence decisions in risk management? Risk management decisions are a balance of costs and benefits of remedial actions. The weighting of costs versus benefits is strongly affected by cultural values and other factors—including whether a stakeholder bears the costs or receives the benefits. But the costs and benefit of a

remedial action may seem different to stakeholders who weigh prevention of ecological disturbance and prevention of potential human exposures differently.

Project managers must be aware of issues outside the perceived scope of the risk assessment that may derail project planning and risk communication.

3.1.1.1 Option – Clarify the Primary Regulatory Agency Jurisdiction

For many sites, one regulatory agency clearly has jurisdiction over a particular contaminated site cleanup. In some cases, however, multiple agencies and regulatory programs may have jurisdiction. Where multiple agencies or regulatory programs affect the planning and implementation of the risk assessment, appropriate jurisdiction and regulatory context (applicable statutes, regulations, policies, guidance, and project-specific approaches for a given risk assessment) should be determined and the roles and hierarchy for these agencies be identified. For example, in California, any one of several local, regional, or federal agencies may have jurisdiction on a given site, including USEPA, various California EPA agencies (such as DTSC, OEHHA, Air Resources Board, or RWQCB), county or city health departments, county or city fire departments, and other agencies. Many of these jurisdictions have their own risk assessment guidance, policies, or regulations, or a given jurisdiction may apply federal or state approaches. In some cases, a given governmental entity may not have jurisdiction in a strictly legal sense but may have the ability to influence the approach, methods, and interpretation of the risk assessment. Regardless of the number of agencies and regulatory programs, agree on an agency to take the lead in the oversight of the risk assessment and on the roles and hierarchy for other agencies.

3.1.1.2 Option – Identify Technical Expert and Resource Availability

Risk-based programs may require access to technical experts (for example, risk assessors) and appropriate technical resources (for example, modeling software and training). If the appropriate technical expertise or resources are not readily available in-house or readily accessible to a project manager, then outsourcing may be required to adequately staff the project. Private contractors, academia, and USEPA regional and state technical experts may be brought in to support the risk assessment. Many states may lack financial resources necessary to bring in contracted technical experts, but may find support from their USEPA regional offices, a state or federal (for example, ATSDR) public health agency, or other technical resources such as ITRC. Similar technical experts may be brought in representing the different agencies or organizations with varying levels of experience. This diversity of expertise can sometimes lead to power struggles. Identifying roles and responsibilities that include a hierarchy of technical experts helps to reduce power struggles.

3.1.1.3 Option – Engage all Appropriate Stakeholders

Community and other stakeholder input are important throughout the risk assessment process.

Early involvement of stakeholders often improves the quality of the risk assessment, expedites the risk assessment review, shortens the risk assessment schedule, and lowers the overall level of effort for finalizing the risk assessment. For example, Native American cultural/tribal exposure scenarios and issues are often different than those for the general public, vary by site, and may include unanticipated exposure media (for example, specific plants), exposure rates, and exposure pathways (for example, ceremonial use). Early involvement helps to identify site-specific exposure media, exposure points, receptor groups, exposure pathways, and data gaps that can be addressed during data collection and risk assessment. Stakeholders are also more engaged when they are part of the planning and review stages of the risk assessment. Community engagement during the planning stage demonstrates the commitment to addressing their interests and potential exposures.

Experience shows that decisions that are made during the risk assessment process in collaboration with stakeholders are more effective and durable. Stakeholders bring to the table important information, expertise, and knowledge that may increase the accuracy of the risk estimates (for example, a hill in the study area is often used by children for games). Additionally, stakeholders are more likely to accept the implementation of a risk management decision that they participated in shaping (Commission 1997a; Commission 1997b).

3.1.2 Issue – Communicating During the Risk Assessment Planning and Implementation Process

Risk assessment requires ongoing communication between all key players (regulators, responsible parties, environmental consultants, and other stakeholders) to achieve a common goal. Failure to properly communicate can result in incomplete or inappropriate data collection, misinterpretation of results, disagreement over the conclusions of the risk assessment, or rejection of the risk assessment by the regulatory agency.

3.1.2.1 Option – Establish a Defined and Clear Communication Process

A clear process of communication and information sharing should include intra- and inter-disciplinary communications, technical to management communications, and communications to decision makers. Communicating with the community and other stakeholders throughout the process allows their input to be solicited and considered (see Chapter 9 for a discussion of risk communication).

3.1.2.2 Option – Engage Stakeholders

Keeping stakeholders engaged throughout the risk assessment process helps achieve a consensus outcome for the risk assessment. Communication between stakeholders supports clarity, transparency, and ultimately acceptance of the risk assessment outcome. Engagement begins with involving all stakeholders prior to initiating the risk assessment (and ideally before any field work is conducted) in defining roles and responsibilities and developing the purpose, scope, and technical approach of the risk assessment.

Inadequate coordination and communications among the disciplines involved in site cleanup can result in a rift between risk assessment and risk management because of the common perception that risk assessment should be completely separated from risk management. Agencies, however, often achieve successful integration between risk assessment and risk management. (Sedman, Reynolds, and Hadley 1992) present several examples of the successful integration of risk assessment and risk management functions. In addition to establishing clearer understandings and agreements about quantitative sampling objectives, which is where site characterization and risk assessment may overlap, risk assessors must be involved throughout the site cleanup process. Previous ITRC guidance recommends that all key players be identified up front, that they communicate and agree upon a common framework, and that the risk assessment process be iterative and modified as appropriate as new information becomes available. This process is necessary in order to achieve the best risk assessment and risk management possible (ITRC 2008).

3.1.3 Issue – Determining the Regulatory Context

In any particular regulatory jurisdiction, regulatory direction may range from a clear authoritative direction to none at all, with many projects falling somewhere in between. Sometimes the applicable requirements are clearly spelled out in statutes or regulations so that closely following these requirements achieves the needed risk assessment. In jurisdictions where the requirements are less clear, professional judgment must be used to achieve a risk assessment that is technically sound, coherent, and consistent with requirements.

Typically there are hierarchies of requirements on any project. Risk assessment generally follows the hierarchy triangle presented in Figure 3-1.

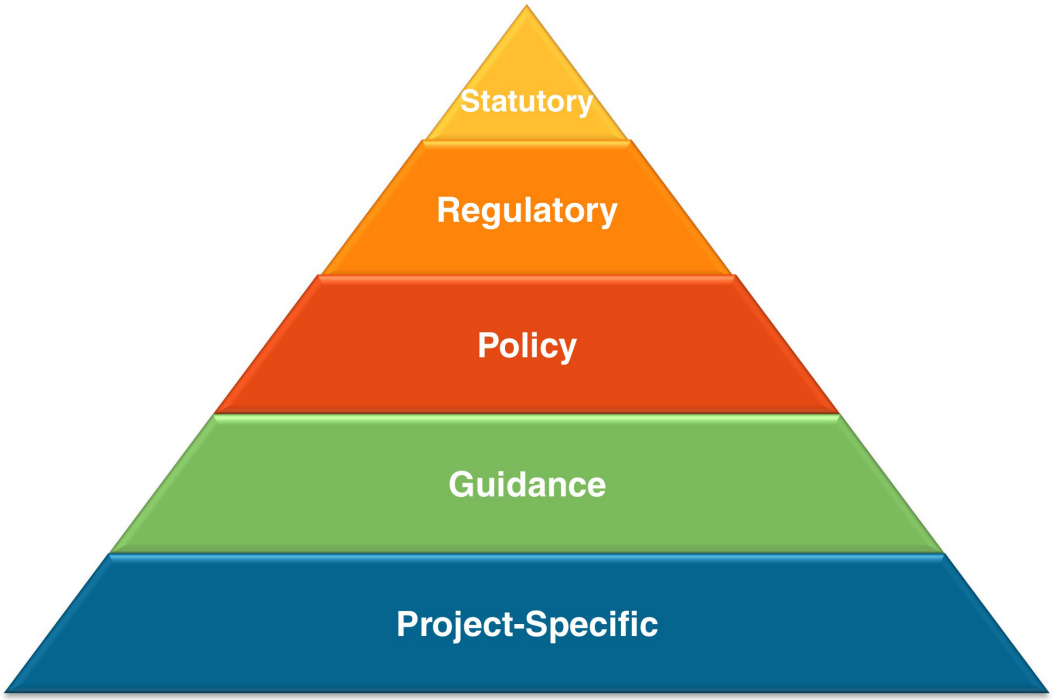

Figure 3-1. Regulatory context hierarchy.

In addition to the various levels of hierarchy that may be associated with a particular risk assessment, there may also be multiple jurisdictions (federal, state, local) each applying their hierarchy separately. Within this often complex set of requirements, multiple stakeholders may want additional social, environmental, or economic issues to be addressed in the risk assessment. A project manager should consider all of these issues in performing the risk assessment.

The laws, statutes, and regulations have the force of law, whereas policies and guidance are recommendations. Regulations may be the key driver in the risk process and can be either generic or specific (for example, specific exposure scenarios to consider, the toxicity values to be used). Although legislative statutes and regulations carry more authority, they often lack the detail necessary to prepare a risk assessment.

Project-specific judgment (at the bottom of the pyramid) is generated as a result of the regulatory project manager's decisions on a specific site. The project manager may or may not have specific directives from legislation, regulation, and guidance that should be followed. Even if specific requirements are in place, there is often room for interpretation or site-specific conditions present that allow project-specific adjustments. If no requirements or only vague requirements exist, then project managers may need to use professional judgment on what may be allowed on a project. When using professional judgment, decisions should be based on data pertinent to the specific circumstances, rather than on personal opinions.

3.1.3.1 Option – Review Agency-Approved Work Plan, if Available

In some cases, regulatory requirements define the scope and contents that must be included in a work plan for the risk assessment; in other cases, a project-specific work plan is prepared and approved by the regulatory agency prior to preparation of the risk assessment. Where a project -specific work plan is prepared and approved, the scope and contents of the risk assessment should be compared to the agency-approved work plan in order to determine whether the risk assessment meets agency requirements. This approach, however, assumes that the agency staff that reviewed and approved the work plan were aware of the correct agency requirements, that agency requirements have not changed since the work plan was approved, and that the work plan was adequately detailed. The scope and level of detail presented in a risk assessment work plan can vary widely depending on the agency and can range from a brief overview of the major steps of the risk assessment process to detailed information on data groupings, exposure scenarios, models, input assumptions, and toxicity values to be used. In the absence of state-specific requirements for risk assessment content and reporting format, one resource to use is *Risk Assessment Guidance for Superfund Part D* (USEPA 2001b).

An iterative process can be used to modify/update the risk assessment scope presented in the work plan. When the risk assessment scope is prepared prior to data collection, it may be appropriate to later modify the scope based on findings of the site investigation and updates to the CSM.

3.2 Conceptual Site Model

The CSM describes the potential chemical sources, release mechanisms, fate and transport pathways, affected environmental media, receptors, and exposure pathways for current and reasonably anticipated activities and land uses. This model documents current site conditions and conceptualizes the relationship between sources and receptors by considering potential or actual migration and exposure pathways (ITRC 2013). The CSM assists in organizing the risk assessment, identifying uncertainties and data gaps, and focusing data collection efforts.

The CSM is a working model that is refined and updated throughout the risk assessment as additional information and data are obtained that changes the understanding of site conditions or exposure scenarios. Changes may be based on information such as previously unidentified chemicals in environmental media or exposure media, screening results using risk-based concentrations and background data, and new information concerning potential activities and land uses. In addition, the CSM should be finalized during preparation of the risk assessment and included in the "Exposure Assessment" discussion of the risk assessment.

The presentation of the CSM is the basis for understanding the risk assessment process. A CSM presented in text format and accompanied by supporting diagrams or flow charts is generally the most useful. An example diagram from ITRC (2012a) is presented in Figure 3-2 and a flowchart CSM in Figure 3-3. In addition, the U.S. Navy offers guidance (2014a) that can be used for CSM development. Other example CSMs are provided in the USEPA *RSL User's Guide* (USEPA 2014e) and USACE's *Conceptual Site Models* (USACE 2012).

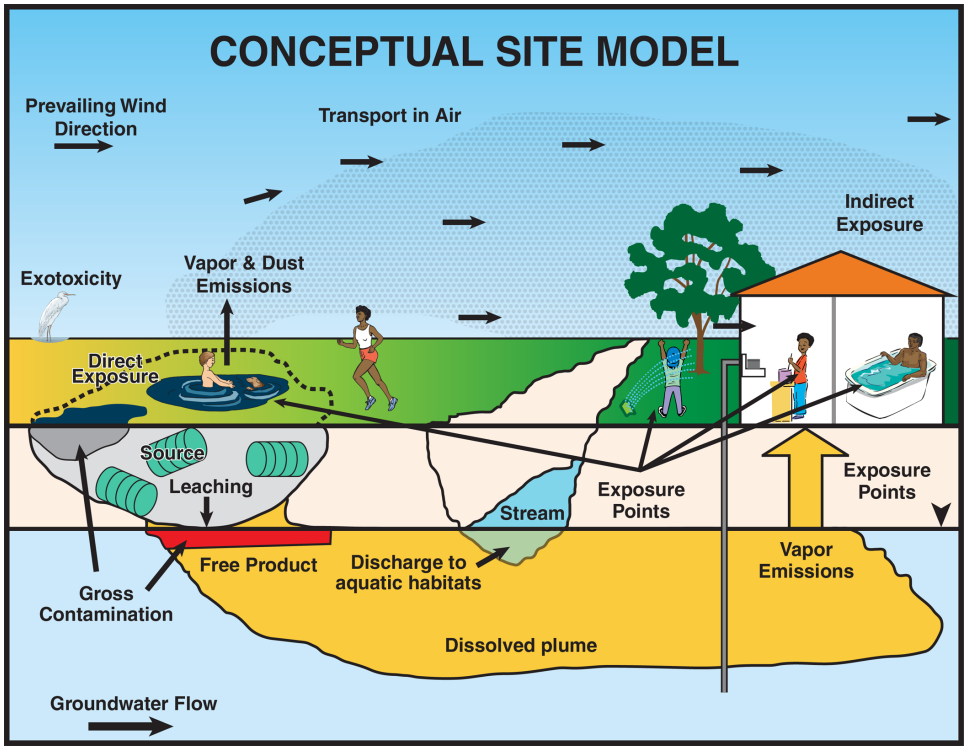

Figure 3-2. Example CSM.

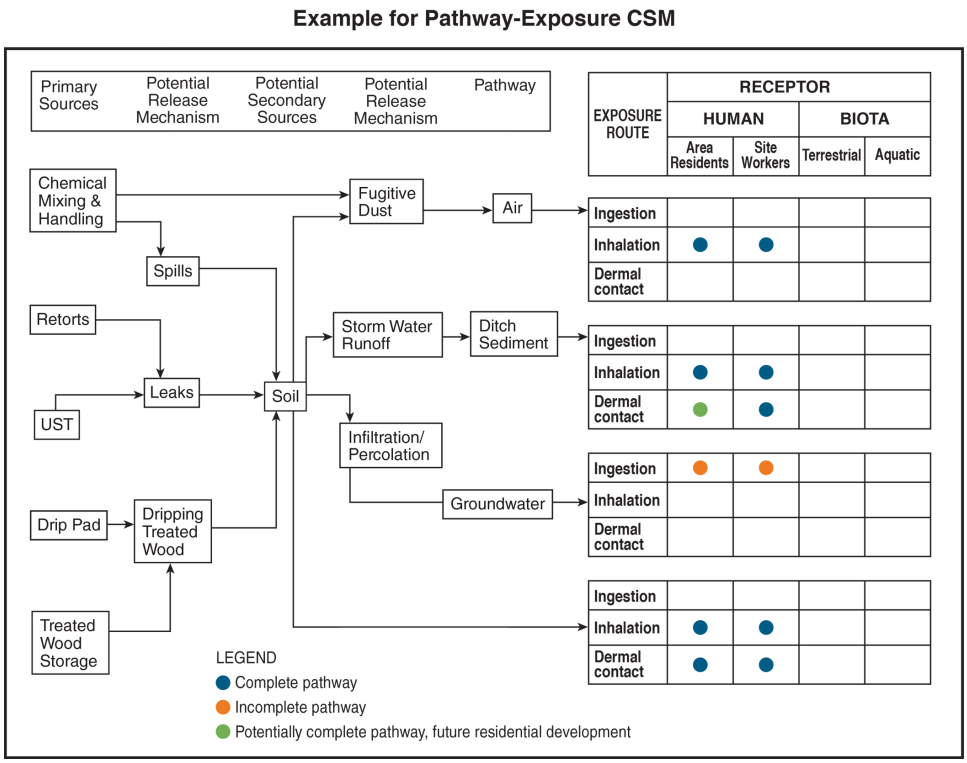

Figure 3-3. Example pathway-exposure CSM.

Source: Appendix A1, DTSC 2008.

3.2.1 Issue – Using a Generic or Inadequate CSM

An inadequate CSM can result in collecting unnecessary or inadequate data or can have a negative effect on the risk assessments by not evaluating potential risks for all relevant receptors and exposure pathways.

3.2.1.1 Option – Prepare and Refine a Site-Specific CSM

The CSM is a dynamic element of the site investigation and the risk assessment process. The CSM may start out with a generic framework; however, as more information becomes available the CSM can be refined so as to better support decision making. In order to best support the development of an effective risk assessment, the CSM should be tailored to the circumstances and conditions at each particular site, rather than to a generic site or based on boilerplate language copied from other reports. An effective CSM can help to define overall project objectives and establish stakeholder agreement on key issues (including risk assessment scope and data needs), thus minimizing significant revisions or significant data gaps during stakeholder review of the risk assessment. All stakeholders should agree on the CSM before the project moves forward. In some cases, dis-

cussions with technical experts may be necessary to explain certain aspects of the CSM so that the entire team can reach consensus.

The CSM includes known and suspected sources of chemicals in environmental media, types of chemicals, affected environmental media, known and potential routes of migration, and known or potential human receptors (USEPA 1988a). The model incorporates available information regarding current and historical activities at the site, known or suspected chemicals in environmental media, current and reasonably anticipated future on-site and nearby off-site activity and land use, resources and their locations (for example, wetlands, water supply wells), populations (for example, residents, schools, hospitals), and physical and geological features (for example, groundwater hydrology, soil type, vegetation).

3.2.2 Issue – Incorporating Future Land Uses and Groundwater Uses into the CSM

Current and potential future exposure pathways are important components of the risk assessment. A site and its surroundings may be used for specific purposes today (such as commercial/industrial land use), but could change to other more sensitive land uses (such as residential) in the future. For example, groundwater may not be used for municipal, industrial, or agricultural uses today, but it may be designated for such uses in the future.

3.2.2.1 Option – Consider Unrestricted Use

An unrestricted use exposure scenario (for example, residential) may be evaluated when the future site use is uncertain and a residential scenario is reasonably anticipated. This scenario can also be used to provide the scientific basis for possible restrictions on the land and groundwater use even when the future use is known. In this case, an unrestricted use evaluation can identify the chemicals and media warranting remedial action, in addition to those warranted for a reasonably anticipated alternative (other than residential) future land use and groundwater use. This information can be used to identify the incremental effort and investment needed to provide protection of human health for alternate future land uses. An unrestricted use scenario is not always a reasonable assumption. In some situations residential land use is not possible or not a realistic future site use (for example, at Department of Defense munitions sites with exclusions zones, within wetlands, and where physical features such as steep hillsides practically eliminate the likelihood).

In some cases, residential land use is not the most conservative land use evaluation for a risk assessment. For example, if bioaccumulative chemicals are present in soil and agricultural use of the land is possible, then an agricultural scenario may yield more conservative results than a residential scenario.

3.2.2.2 Option – Consider Reasonably Anticipated Future Land Use and Groundwater Use

When the current or reasonably anticipated future land use is other than residential, known existing exposure scenarios (for example, for workers who are currently employed at the property) and

reasonably anticipated future exposure scenarios may be evaluated. Consider future land and groundwater use to determine the types of exposures that should be evaluated in a risk assessment and the frequency of exposures to any residual chemical concentrations that may occur. The evaluation of future land and groundwater use may be based on specific knowledge of the future use, such as when a property owner intends to maintain the current use or when future use decisions have been made and documented (for example, municipal zoning and planning ordinances).

Developing assumptions regarding reasonably anticipated future land and groundwater use can be challenging. A systematic process can be used to identify the reasonably anticipated future land and groundwater use for the site and adjacent properties. In some cases, the future land use may be determined by conducting a reuse assessment, which includes collecting and evaluating information to develop assumptions about reasonably anticipated future land use (USEPA 2001b).

Determining reasonably anticipated future land use should not be an "extensive, independent research project" (USEPA 1995c). Existing information can be used, much of which is available from local land use and land planning authorities (USEPA 1995c). The USEPA guidance can be used as a framework for identifying future land use (USEPA 1995c) and (USEPA 2001b). Sources of helpful information may include:

- current land use
- zoning laws and maps
- community master plans or development plans
- relevant chemical data
- population growth patterns and projections
- existing institutional controls
- current land use in close proximity to the site
- wellhead protection information
- comprehensive groundwater protection plans
- historical or recent development patterns
- cultural factors (for example, Native American religious sites and historic sites)

This information, combined with interaction with stakeholders, increases the certainty of assumptions about reasonably anticipated future activity and land use, and thus increases the usefulness of the risk assessment.

3.2.3 Issue – Determining Whether to Include Institutional and Engineering Controls or Planned Remedial Action in the CSM

Typically, a baseline risk assessment is prepared for a site. Baseline risks are defined in *Risk Assessment Guidance for Superfund* (USEPA 1989a) as "risks that might exist if no remediation or institutional controls were applied at a site." Risk assessment, however, is often used as a tool to evaluate situations beyond baseline risks, such as residual exposure scenarios and concentrations remaining after a planned remedial action, or residual risks remaining after implementing a specific institutional control (for example, prohibiting residential land use).

When a baseline risk assessment is not prepared, an issue that is often encountered during the risk assessment planning process is whether to incorporate existing or planned institutional controls, engineering controls, or planned remedial action into the risk assessment as part of the development of the CSM.

USEPA defines institutional controls as non-engineered instruments, such as administrative and legal controls, that minimize the potential for exposure to chemicals in environmental media or protect the integrity of a response action (USEPA 2012d). The USEPA's *Institutional Controls: A Guide to Planning, Implementing, Maintaining, and Enforcing Institutional Controls at Contaminated Sites* (USEPA 2012d) provides detailed information on the key activities of the life cycle for institutional controls, including planning, implementation, maintenance, enforcement, and termination. Regardless of whether or not institutional controls, engineering controls, or planned remedial action are incorporated as part of the risk assessment, the mechanism for how they are maintained and enforced after the corrective action is complete is crucial for long-term protectiveness of the site.

Effective Engineering and Institutional Controls: The Love Canal Site

From 1942 to 1953, the Hooker Chemical company drained a former canal, lined it with clay, and used it to dispose of over 21,000 tons of toxic waste in capped cells. In 1953, the site was sold to the local school district, which had insisted on buying the property to build a school even though Hooker Chemical had warned the district about the buried waste.

Over the next several years, an elementary school and several single-family homes were built around the site. During the installation of sewers for these neighborhoods, the clay walls and cap that had contained the toxic waste were damaged, allowing groundwater and rainwater to move the waste into the neighborhood (for example, seeping into basements). The lack of clear communication about the presence of institutional and engineering controls at this site resulted in the evacuation of over 900 families, prompting the 1980 Superfund law.

Sources: USEPA 2015d and USEPA 2012f

3.2.3.1 Option – Incorporate Institutional Controls, Engineering Controls, and Planned Remedial Action in the CSM

Incorporating existing or planned institutional controls, engineering controls, or planned remedial action allows streamlining of the risk assessment effort. This practice maintains focus on evaluating current and future exposure scenarios to assess whether additional actions are needed (on the basis of risk) beyond the controls already in place or planned. The USEPA guidance notes that a risk assessment should address current and reasonably foreseeable exposure scenarios rather than worst-case exposure scenarios. By doing so, the level of effort for the risk assessment is tailored to

the site-specific issues and questions to be answered using risk assessment as a decision-making tool. The institutional and engineering controls can be used as a single action or part of a group of actions to render the exposure pathway incomplete.

During the risk assessment planning process, incorporation of existing or planned institutional controls, engineering controls, or planned remedial action into the risk assessment should be confirmed with stakeholders. While planned institutional or engineering controls are important in determining reasonably anticipated future land use, the risk assessment should clearly communicate assumptions that rely on planned engineering controls, institutional controls, or remedial actions to eliminate certain land or groundwater use scenarios. The risk assessment should also, to the extent possible, assess how reliable controlling mechanisms will be in restricting land use in the future (USEPA 1995c); also see information regarding the Uniform Environmental Covenants Act (Kerr 2006). This assessment is critical because human health may not be protected if land use in the future does not reflect what was assumed in the risk management decision-making process.

At sites where risk-based justification of institutional controls, engineering controls, or interim remedial actions is needed, the risk assessment may not provide this information if the exposure scenarios are not quantified. Also, if existing controls are incorporated into the risk assessment, exposure scenarios excluded from the CSM that may ultimately be determined to be associated with acceptable risk (for example, site conditions may have improved and the restriction may no longer be needed), may not be evaluated. In addition, incorporating institutional controls and engineering controls may not identify land uses that may require only limited additional remedial action to achieve acceptable risk levels.

3.2.3.2 Option – Do Not Consider Institutional Controls, Engineering Controls, and Planned Remedial Action in the CSM

Conducting the risk assessment without incorporating institutional controls, engineering controls, and planned remedial action allows these controls or actions to be evaluated as part of the remedial action decision process. In some cases, institutional controls and engineering controls are viewed as remedial action and require specific mechanisms or actions that are appropriately conducted as part of the remedial action implementation process. When chemicals are persistent in environmental media, the effectiveness of institutional controls in mitigating exposure is less certain because of the time required (over 20 years) for these controls. In other cases, the responsible party or current landowner may not be able to ensure that institutional or engineering controls will be instituted and maintained. These cases are particularly problematic when future land use cannot be easily determined or the responsible party and landowner are not the same entity.

When a risk assessment is conducted without incorporating the existing institutional controls or engineering controls, an overly conservative site risk results and may lead to more extensive remedial action measures than are needed.

3.2.4 Issue –Identifying Which Sources, Receptors, and Exposure Pathways to Include in the CSM

Several questions can help to determine whether a receptor may realistically be exposed to a chemical in an environmental medium:

- What receptors and exposure pathways have been identified for the site?
- Will the environmental conditions support a complete exposure pathway (for instance, snow cover prevents surface soil exposure or windblown soil changes the exposure area)?
- Are the concentrations of a chemical in the soil too deep for ingestion or dermal exposure to occur? At what soil depth would the receptor likely be exposed?
- Do chemicals in the subsurface soil present an indoor or outdoor vapor inhalation risk?
- Are there concentrations of a chemical in soil that might eventually affect groundwater or surface water?
- Is groundwater in connection with surface water?
- Is groundwater or surface water used as a drinking water source?
- Is surface water used for recreation or any other purposes that result in a human exposure?
- Are foods (for example, fish, game, vegetation) consumed by receptors grown or present on or near the site?

The answer to these and similar questions requires an understanding of the site and its history, including patterns of land use (current or planned use of the property) and site conditions (classification of groundwater, nature of the soil and its potential for sustaining crops, grain size, and likely wind speed to generate dust).

3.2.4.1 Option – Consider All Exposure Pathways in the CSM

While potentially complete exposure pathways are the focus of the risk assessment (see Section 3.2.4.3), it may be helpful to discuss incomplete exposure pathways in the CSM for documentation purposes, including any unique or site-specific exposure scenarios (see Section 3.2.4.2). If questions arise later regarding why certain environmental media, exposure pathways, and receptors were not included in the risk assessment, then this documentation will explain the exclusion of these items. In the presentation of results, incomplete exposure pathways can be graphically differentiated from potentially complete or complete exposure pathways.

3.2.4.2 Option – Incorporate Unique and Site-Specific Exposure Scenarios

For some sites, unique or site-specific exposure scenarios may need to be considered while performing an exposure assessment. Such scenarios may include consumption of homegrown produce; consumption of game animals (for example, deer, wild turkey, and fish); and residential nonpotable groundwater use exposures (for example, using groundwater in a swimming pool). These exposure scenarios can result in significantly more exposure (chemical intake) than assumed in typical default exposure scenarios (such as residential direct contact with soil or maintenance

worker contact with groundwater). Failing to consider site-specific exposure scenarios may lead to unreliable risk assessment conclusions and thus inadequate risk management actions.

3.2.4.3 Option – Consider Only the Potentially Complete Exposure Pathways in the CSM

The risk assessment typically focuses on complete exposure pathways. With this focus, the exposure pathways included in the CSM may only be those that are determined to be complete or potentially complete based on the available information. In many cases, determining whether an exposure pathway is complete depends on the presence and location of an exposure medium. It is best to include potentially complete exposure pathways until adequate data is collected to eliminate pathways from the CSM.

Regulatory agencies vary as to whether an environmental medium is considered an exposure medium; for example, agencies differ in their definitions of surface soil and subsurface soil. Some regulatory agencies consider surface soil to be near surface or approximately the first few inches where an individual may come in contact with soil. Others may define surface soil to include the top two or three feet. In many cases, exposure media may be defined by statute, regulation, policy, or guidance, but it may also be determined as part of the planning process based on the current and reasonably anticipated future activity and land use. Exposure media may also be related to cultural or other activities unique to a site. For example, Native Americans who use clay for pottery may be exposed to chemicals in soil at varying depths, depending on where and how the clay is obtained.

The approach taken to identify receptors and define their specific activities on a site may vary based on the site and the type of activity. For example, it may be appropriate to address potential construction worker exposure through the use of Health and Safety Plans or other Occupational Safety and Health Administration (OSHA) criteria. Construction worker exposure may not need to be quantitatively evaluated if these risk management procedures are implemented. Certain sensitive receptors may require site-specific considerations.

3.2.4.4 Option – Consider Hypothetical Exposure Pathways in the CSM

In addition to the reasonably anticipated future exposure pathways, it may be helpful to assess the property for unrestricted use, which typically involves evaluating a residential land use scenario. In the remedial action stage, this evaluation may provide information that allows the responsible party and agency to identify the relative differences in remedial actions between the reasonably anticipated use and unrestricted use scenarios.

3.2.5 Issue – Developing the CSM When Limited Information is Known about Historical Site Sources

Knowledge of site history and potential sources of chemicals in environmental media is critical in determining how best to interpret sampling data to evaluate exposure. For example, estimating exposure concentrations from data collected in an area where a limited spill occurred may be

substantially different from estimating exposure concentrations from data collected within environmental media affected by a large-scale, ubiquitous release (for example, historical fill, former apple orchard). A proper understanding of the source of chemicals in environmental media and their environmental fate and transport are important in the development of a risk assessment.

Primary chemical sources indicate where the chemicals in environmental media may have originated. These sources are site specific, but examples may include tanks/drums, waste lagoons, underground piping, emission stacks, and fugitive emissions. Both known and suspected sources of chemicals in environmental media are identified in the CSM. The evaluation of the exposure pathways may be addressed during data collection activities to determine whether chemicals are present in environmental media as a result of these historical sources.

3.2.5.1 Option – Start with the Affected Media

When the original sources of chemicals are unknown, the CSM can start with environmental media that are known or suspected to have been affected by the original source and thus serve as both potential exposure media and secondary sources of chemicals. The secondary chemical sources can be represented by the environmental medium affected by a release. Examples include surface soil, subsurface soil, air, sediment, and surface water.

3.2.5.2 Option – Search for Additional Site Information

Historical site information and data can be used to learn about the potential sources at the site. This information may include site use, chemical storage and usage, geographic and topographic info, aerial photos, soil type, land records, Sanborn maps, as-built drawings, and community input. The site history helps to identify the primary and secondary chemical sources, the chemicals in environmental media, and potential exposure media. In some cases, this information can be obtained from a Phase I environmental site assessment or from the results of an appropriate inquiry.

3.3 Data Collection Program

Throughout the project life cycle, systematic planning should form the basis for collection and analysis of site data; see Section 3.0 of *Groundwater Statistics and Monitoring Compliance Statistical Tools for the Project Life Cycle* (ITRC 2013). The project planning team defines the data quality objectives (DQOs) and then determines the appropriate type and quality of data needed to answer questions of interest.

As discussed in the ITRC (2013) guidance, systematic planning results in clear data collection plans and objectives. The USEPA DQO process (USEPA 2006c) and the U.S. Army Corps of Engineers (USACE) technical project planning (TPP) process (USACE 1998) are two examples of systematic planning that can readily be used to plan data collection. Additional information on systematic planning can be obtained from the following ITRC documents:

- *Improving Environmental Site Remediation through Performance-Based Environmental Management* (ITRC 2007a)
- *Technical and Regulatory Guidance for the Triad Approach: A New Paradigm for Environmental Project Management* (ITRC 2003)
- *Triad Implementation Guide* (ITRC 2007b)
- *Incremental Sampling Methodology* (ITRC 2012a)

The CSM is an integral part of the development of data collection programs and "serves as a systematic planning instrument, a communication device, and an optimization and decision support tool" throughout the site investigation and risk assessment process (U.S. Navy 2014b). The CSM helps identify and focus the risk assessment on site decisions to be made throughout data planning, data collection, and risk assessment. The U.S. Navy provides a tool to assist in developing a CSM (U.S. Navy 2014a).

3.3.1 Issue – Determining the Adequacy of Data and Information for the Risk Assessment

The risk assessment data needs should be considered during the planning process. When a risk assessment is prepared, the site assessment information and data set should not be assumed to be acceptable for the risk assessment. For example, without risk assessor input, the available data may be collected from locations that are not pathways to site receptors or may be missing from critical exposure media. Rather, data needs for the risk assessment should be specifically identified. This input helps to determine the quantity and quality of data, sampling locations, and types of samples needed for the risk assessment. Identification of data needs for the risk assessment is an iterative process; as field data are collected and reviewed and the CSM is refined, additional data needs may be identified for the risk assessment. Engage risk assessors early in the project planning phase and keep them engaged during the iterative data collection and review process.

3.3.1.1 Option – Incorporating Risk Assessment Data Needs During the Planning Process

Incorporating risk assessment data needs into the field investigation minimizes data gaps for conducting the risk assessment and costly additional data collection efforts. The data collection programs must define the type of data that will be collected, the quantity of data, and level of quality that the data must achieve to support and defend environmental decisions. The data collection programs can be scaled based on site-specific conditions (for example, the size of the site, the number of environmental media, the number of samples to be collected, the project scope, and the available budget).

3.3.1.2 Option – Identify DQOs

The DQO process described in USEPA guidance documents such as Guidance on Systematic Planning Using the Data Quality Objectives Process (USEPA 2006c), provides information to support the development of data collection programs and the evaluation of site data to decide whether the

data are usable in the risk assessment. This process is iterative and flexible. As information is developed, the elements of the process can be reevaluated and revised to account for new information.

3.3.2 Issue – Determining the Availability of Samples from Site-Specific Exposure Areas

Sample collection and analysis is expensive, and thus few samples may be collected to represent a large area of the site. The result of this practice is that the calculated exposure concentrations may be biased low by averaging the sample set from too large an area. Conversely, the calculated exposure concentration may be biased high if the sample set is representative of a small area, such as only the source area, and not in other lower concentration areas over which receptors can also roam.

3.3.2.1 Option – Determine Exposure Areas

An exposure area (also called an exposure unit) is a geographic area over which a receptor is reasonably assumed to move at random and equally likely to come into contact with an environmental medium (for example, soil) at all sublocations (both spatially and temporally). An exposure area is further defined on the basis of observed or assumed patterns of receptor behavior, historical activity, and the nature and extent of chemicals in environmental media (USEPA 1989a).

Use of the exposure area concept can prevent bias in EPCs that might occur if data were averaged over an area not representative of the exposure area. Whether these areas are significant from a risk perspective depends on whether receptors and exposure areas have been accurately identified. Determination of exposure areas affects project costs because the number of samples needed (including duplicate and blank samples; see Section 4.3) depends on the variability in chemical concentrations within the exposure area (Hartmann et al. 1993). Section 6.2.2.1 of this document includes a discussion of exposure areas.

3.3.3 Issue – Assessing Hot Spots

Hot spots are most relevant when the potential exists for focused exposure to the area (for example, a play area or other feature that attracts particular attention).

Areas over which decisions will be made must be identified. For example, if the risk assessment combines data over the entire site, localized high concentrations (hot spots) and outliers might be masked. Hot spots are most relevant when they comprise a large part of an exposure area, for example, in play areas or around other features that attract people to the area, or if concentrations pose a significant risk. If nothing about the hot spot area draws or confines individuals for particular exposure and the concentrations do not pose a significant risk, then the hot spot likely does not present any greater actual exposure risk than the surrounding area. Likewise, outliers are extremely large (or small) measurements relative to the rest of the data in a data set and

have the potential to misrepresent (bias) the population from which they were collected. Refer to Section 4.3.5 for further discussion regarding potential outliers.

3.3.3.1 Option – Identify Hot Spots

Tools such as Gilbert's *Statistical Methods for Environmental Pollution Monitoring* (Gilbert 1987) and Visual Sampling Plan (Pacific Northwest National Laboratory 2012) are available to evaluate the probability that a sampling design will find an area of some assumed size or, conversely, that one was missed. Various approaches can identify hot spots and how these areas should be treated in the quantitative risk assessment when making site management decisions. Section 3.2.1 of *Use of Risk Assessment in Management of Contaminated Sites* (ITRC 2008) identifies the characteristics and definition of hot spots used by various state agencies and presents a discussion of theoretical and practical considerations for hot spots. If concentrations are at levels that may pose acute toxicity issues, then the project manager should be notified so that appropriate action can be taken.

If preferential exposures may occur at hot spots, then the need for, and type of, hot spot evaluation should be discussed during project planning. If hot spots are evaluated in the risk assessment, exposure factors should be adjusted appropriately to distribute the frequency and rate of exposure between the hotspot and the rest of the site.

3.3.4 Issue – Determining Whether the Data Set is Representative of the Exposure Areas

Requirements for data collection are site specific and vary according to the receptors and exposure pathways, the nature and distribution of the chemicals in environmental media, and multiple factors related to the size, location, and uses of the site. Data requirements for an industrial site with only indoor workers are different than those for an industrial site where workers are expected to be outdoors and be in contact with environmental media. In addition to concentrations of chemicals in environmental media, measurements and estimates of various environmental parameters (for example, wind speed and river flow rates) and physical parameters (for example, soil porosity, hydraulic conductivity, and permeability) can also be important input parameters for models used in risk assessment.

The issue of soil sampling to support risk assessment is discussed in Section 3.2 of *Use of Risk Assessment in Management of Contaminated Sites* (ITRC 2008). Data representativeness is key to the discussion of data quantity and quality and has received considerable attention in the literature (Crumbling 2002; Jenkins et al. 2005; Ramsey and Hewitt 2005). A representative sample should reflect the exposure concentrations to be considered for the pertinent exposure pathway. For example, exposure to shallow soil in a residential area is most often the average concentration throughout an area analogous to a residential lot. For a receptor that roams or spends time throughout an exposure area, a representative sample may reflect conditions over several acres.

For soil sampling in particular, and for other media as well, representativeness means that a sample is composed of the elements of interest in the population being sampled in the same proportion as

they occur in the population of interest (the population being sampled). The population of interest should be established before actual sampling. The representativeness of a data set depends on the type, number, and locations of the samples collected as well as the value of collecting additional data (see Section 4.1.1.1).

3.3.4.1 Option – Identify Media to Sample

Samples should be collected from environmental media identified in the CSM. At many sites, particularly larger and more complex sites, samples are typically collected from various environmental media including soil, groundwater, soil gas, sediments, surface water, air, and biota. The principles that guide the process for collecting soil samples also apply to other environmental media, types of data, and information used in risk assessments. In particular, a clear understanding of the mechanism or algorithm by which the results are interpreted should be in place and should determine the sample design. Similarly, a visual presentation of the sampling results is recommended (as for soil sampling).

3.3.4.2 Option – Define the Number of Samples to Collect

The minimum number of samples needed to develop a representative concentration for chemicals in each environmental media for each exposure area is established as part of the development of the data collection program. For soils, the primary question is, "Over what volume of soil should I estimate the average?" (Reynolds, Hadley, and R.M. 1990; Sedman, Reynolds, and Hadley 1992). For example, when evaluating residential soil ingestion, the appropriate volume reflects exposure in a residential setting, which could be on the order of many tons of soil. By analogy, the volume of groundwater of concern is estimated by the mass discharge that would be unacceptable for delivering suitable quality water from either a real or hypothetical well of a given extraction rate (Hadley and Newell 2012) and the screened interval of the well. Additional information needed to calculate appropriate groundwater EPCs for risk assessment are provided in USEPA's *Determining Groundwater Exposure Point Concentrations* (USEPA 2014b), and useful information on groundwater statistics is provided in ITRC guidance (ITRC 2013). In many cases, the mass discharge (and thus the projected exposure concentrations) may be best estimated not by a series of groundwater measurements from monitoring wells throughout an aquifer, but rather by results of a pump test from one location. Estimating the mean in a well-defined exposure area, however, is not particularly useful in addressing stakeholder concerns about hot spots.

USEPA's Web site "Resources for Planning New Data Collections" (USEPA 2008a) also offers useful planning guidance. Tools such as Pacific Northwest National Laboratory's Visual Sample Plan (Pacific Northwest National Laboratory 2012) or the University of Tennessee's Spatial Analysis and Decision Assistance (SADA) (University of Tennessee 2013) can assist in development of a sampling program that provides adequate sample density with an associated level of statistical confidence. Incremental sampling methodologies (ITRC 2012a) along with statistical sampling

design may also be used to address many of the issues regarding the adequacy of sample numbers and spatial density for solid media (soil and sediment).

USEPA guidance (1992d) states the following:

> Sampling data from Superfund sites have shown that data sets with fewer than 10 samples per exposure area provide poor estimates of the mean concentration (i.e., there is a large difference between the sample mean and the 95 percent UCL), while data sets with 10 to 20 samples per exposure area provide somewhat better estimates of the mean, and data sets with 20 to 30 samples provide fairly consistent estimates of the mean (i.e., the 95 percent UCL is close to the sample mean).

The number of samples to collect, however, is a site-specific decision that should be discussed by the project team during the planning stage. Defaulting to a minimum of 10 samples may not provide adequate characterization of a site or an appropriate data set for risk assessment, especially for sites with highly variable concentrations.

3.3.4.3 Option – Select the Appropriate Sampling Design

The applicable site-specific exposure locations, soil exposure depths, and sample types (for example, sieved versus unsieved for use in the integrated exposure uptake biokinetic (IEUBK) model (USEPA 2010a) should be identified during project planning and reflected in the site-specific CSM. The risk assessment data needs should include the site-specific exposure locations, soil depths, and sample types and should be incorporated into the planned sampling design. These data needs may be in addition to the sampling needs for other project objectives (such as nature and extent characterization of the site, which may require sampling at depths beyond those that may be contacted by site receptors).

Many risk assessments assume that human exposure can and will occur (no matter the locations or depths from which the soil samples were collected) or are based on depths established in regulations, policy, or guidance. This simplifying assumption minimizes the need to justify which depth intervals could be contacted either under current or potential use conditions. It is also reasonable, however, for a risk assessment to use only data that are relevant to current and potential exposures. Such assumptions may be appropriate if the soil is well characterized and if controls prevent or prohibit bringing subsurface soil to the surface, where receptors could contact the previously buried soil. In certain instances, assuming contact with soil only from certain depth intervals may require institutional or engineering controls to prevent exposures that were not evaluated.

3.3.4.4 Option – Evaluate the Benefits of Collecting Additional Data

Uncertainty is inherent in investigation and risk assessment, and an individual's comfort level should not be entirely based on an arbitrary metric that X samples are required for an area of Y.

Rather, the risk assessment process should effectively balance the value of spending more time and resources to obtain additional information to reduce uncertainty with the need to make a timely decision. Project managers should guard against "paralysis by analysis," when the desire to reduce uncertainty is used as an excuse to avoid or postpone decision making. Does additional information change the current understanding of the risks posed by the chemical or alter the nature of the eventual decision? If not, then no additional sampling and analysis is needed.

3.3.5 Issue – Recognizing Biases in the Data Set that Affect Risk Estimates

Three common types of bias are sampling bias, analytical bias, and data reduction bias. Additional data and more accurate data may lead to more confidence in the risk estimates, which can lead to greater confidence in risk management decisions. The additional data, however, must be of good quality and be representative of the exposure area. For most environmental media, bias in the field sampling can affect the outcome of the risk assessment. Regardless of the exposure medium, where and how the samples were collected may influence the concentrations and the analysis of the data set.

3.3.5.1 Option – Identify Types of Bias

In many cases, the only available data for the risk assessment are soil samples collected for purposes of source area characterization and delineation. These data are therefore biased to areas that are known or suspected to be contaminated or areas with the likely highest concentration of chemicals (for example, areas near the potential source of a chemical), even where those areas are small. In other instances, samples are sometimes collected from the perimeter of known source areas to define the extent of chemicals in environmental media (rather than characterize the maximum concentrations present on site). In the context of risk assessment, samples should be representative of the exposure concentration to be considered for the pertinent exposure pathway. For example, exposure to shallow soil in a residential area is most often the average concentration throughout an area the size of a residential lot. For a receptor that roams or spends time throughout an exposure area, a representative sample may reflect conditions over several acres. Biased samples may not represent the potential exposure area for a receptor, and may yield overly conservative EPCs.

3.3.6 Issue – Selecting Analytical Parameters

In some cases, the characteristics of a particular chemical may be important when evaluating potential risks. For example, the chemical form (for example, elemental, organic, or inorganic), chemical speciation (for example, hexavalent versus trivalent), degradation products, and polychlorinated biphenyl (PCB) congeners can affect how a chemical is addressed in the risk assessment. Chemical characteristics can affect the toxicity values chosen and the potential uncertainties. At some sites, specific emerging contaminants may need to be evaluated and should be incorporated into the planning process.

At other sites, the evaluation of nonspecific analytes (for example, total petroleum hydrocarbon, diesel, or gasoline, or PCB Aroclors) may be identified by stakeholders; expectations for how the

data should be screened and addressed in the risk assessment should be discussed during project planning.

3.3.6.1 Option – Consider Additional Analytical Parameters Where Appropriate

Site history and the CSM should be used to help determine additional analytical speciation and degradation products needed for the risk assessment. The potential presence of degradation products should be considered when developing a list of analytical parameters. For example, tetrachloroethylene (PCE) degradation products include trichloroethylene (TCE), dichloroethylene (DCE), and vinyl chloride. In addition, metals speciation may be needed (for example, hexavalent chromium versus trivalent chromium, inorganic arsenic versus organic arsenic). Chemists or other team members knowledgeable in biodegradation and biotransformation can be consulted as needed to identify potential degradation products.

3.3.7 Issue – Addressing Background Concentrations in the Risk Assessment

During the risk assessment planning process, the method for treatment of background concentrations of chemicals in environmental media should be established. If one or more site-related chemicals might also be naturally occurring or might be the result of an unrelated anthropogenic source, consider adding background samples to the data collection program.

Background concentrations are those that would exist in the environment if the source of chemicals on the site were not present. Both types of background concentrations, naturally occurring and anthropogenic, are unrelated to former site activities. In urban and industrial areas, anthropogenic background may be much higher than naturally occurring background for metals and certain organic chemicals. Under state and federal programs, sites are not typically remediated to concentrations below background concentration. Not all states, however, consider naturally occurring and anthropogenic background equally, and some states do not consider anthropogenic background when making remedial action decisions. As a result, the guidance is inconsistent among states and USEPA when addressing chemicals within background concentrations in risk assessment. Section 3.3 of *Use of Risk Assessment in Management of Contaminated Sites* (ITRC 2008) provides descriptions of anthropogenic and natural background and a summary of state-specific guidance on establishing and using background concentrations in risk assessment.

3.3.7.1 Option – Addressing Background Concentrations During Chemical Screening

Some state environmental agencies acknowledge that naturally occurring background concentrations of some inorganics exceed risk-based screening values and do not require carrying a chemical forward in the risk assessment process if it is within background concentrations (DTSC 2008; MDEQ 2005; NJDEP 2012a; FAC 2013) *Petroleum Contamination Site Cleanup Criteria*, among others). This approach focuses the risk assessment on only those chemicals that are site related and have the potential to be addressed in remedial action. For example, Arkansas has mineral deposits throughout the state (galena, cinnabar, and vanadium, for example). It would be

inappropriate, after confirmation of background concentrations, to require a responsible party to investigate those metals to a concentration smaller than naturally occurring mineral concentrations.

3.3.7.2 Option – Addressing Background Concentrations During Risk Characterization

USEPA's *Role of Background in the CERCLA Cleanup Program* (2002e) addresses background concentrations in risk assessments. This document notes that USEPA's preferred approach is that detected chemicals present at concentrations exceeding risk-based screening values are retained in the risk assessment, regardless of whether they are within background concentrations. The USEPA recommends discussing the contribution of background concentrations to the total site risk estimates in the risk characterization section of the risk assessment (see Section 6.2.5 for an example). With this approach, information is provided to the public regarding elevated risk levels attributable to background concentrations. This information allows the public to make informed decisions about exposure to affected environmental media. This approach, however, results in additional chemicals being carried through the risk assessment, beyond those chemicals that may be addressed in remedial action. In addition, at those sites where some or all detected concentrations are within background concentrations, the public may be left wondering how health will be protected when background concentrations exceed agency-acceptable risk levels.

3.3.7.3 Option – Addressing Background Concentrations During Uncertainty Analysis

In another approach to background concentrations, chemicals within background concentrations are eliminated in the data screening step, but a discussion of background risks is included in the uncertainty analysis section of the risk assessment. This approach requires less effort on non-site-related issues, while information is provided to the public regarding elevated risk levels attributable to background concentrations. The public can then make informed decisions about exposure to environmental media.

3.4 Resources and Tools

The following resources and tools were not cited in the sections above and are included here for further information:

Standard Guide for Developing Conceptual Site Models for Contaminated Sites (ASTM 2008a)
Hydrogeological Conceptual Site Models: Data Analysis and Visualization (Kresic and Mikszewski 2013)

4.0 DATA EVALUATION

Data evaluation may include the following tasks:

- comparing analytical data to DQOs established in the data collection program (see Section 3.3)
- identifying significant data gaps (if any)
- performing statistical evaluations
- conducting preliminary exposure and risk characterization calculations
- developing visual representations of data, data reduction
- grouping data by exposure area
- comparing chemical concentrations to risk-based screening values

This chapter provides guidance on key issues associated with evaluating data to develop a risk assessment that is representative of potential risks and acceptable to the stakeholders. The key issues are organized around five general topic areas:

Data Gaps

- Identifying and Filling Data Gaps
- Addressing Permanent Data Gaps

Data Usability

- Presenting Measurement Units and Significant Figures
- Determining Cross-Contamination
- Assessing Data Representativeness

Data Reduction Concerns

- Using Duplicate Samples
- Pooling Data
- Handling Flagged Data Concentrations
- Handling Nondetect Concentrations
- Considering Outliers
- Addressing Tentatively Identified Compounds (TICs)

Data Visualization and Analysis

- Accurately Displaying And Visualizing Data
- Statistically Analyzing Data

Data Screening and Chemical Selection Processes

- Identifying Appropriate Screening Values
- Identifying Chemicals for Evaluation in the Risk Assessment
- Addressing Chemicals that are Missing Screening Values
- Handling Nondetect Chemicals in Screening
- Addressing Data Bias in Screening Process
- Handling Background Concentrations

In many cases, the only data available for risk assessment are data collected as part of site characterization efforts, without considering risk assessment needs. A thoughtful data planning process (systematic planning, see Section 3.3) is needed to develop a data set that can support both site characterization and risk assessment.

As indicated in *Groundwater Statistics and Monitoring Compliance* (ITRC 2013), USEPA's DQO process is general enough to potentially incorporate different lines and types of data-based evidence. Statistics is one useful tool in this framework, as highlighted by USEPA's Data Quality Assessment (DQA) (USEPA 2006b). Additionally, USEPA (2013g) notes the following:

> [DQA] is used to assess the type, quantity, and quality of data in order to verify that the planning objectives, Quality Assurance Project Plan components, and sample collection procedures were satisfied and that the data are valid and suitable for [the] intended purpose … This assessment is a scientific and statistical evaluation of data to determine [whether] it is of the type, quantity, and quality needed. [DQA] may be performed either during a project to check the process of data collection or at the end of a project to check if objectives were met.

Guidance for how to conduct data validation and verification is provided on USEPA's "Quality Management Tools – Data Verification and Validation" website (USEPA 2015c).

DQA is a procedure for determining whether or not a data set is suitable for its intended purpose. The DQA Process includes the following steps, as depicted in Figure 11 of USEPA's guidance (USEPA 2006c; USEPA 2006b):

1. Review DQOs and sampling design.
2. Revisit DQOs if necessary.
3. Conduct preliminary data review.
4. Select the statistical test.
5. Verify the assumptions.
6. Draw conclusions from the data.

Based on these steps, application of statistics should incorporate an iterative approach, including:

- Conduct up-front exploratory data analysis (Section 3.3.3, ITRC 2013) to better understand the data set, its usability, and its representativeness.
- Clearly formulate the study questions and the statistical inferences that must be made.

- Select the appropriate target population (Section 3.2.1, ITRC 2013) from which data will be drawn.
- Perform data quality assurance and quality control (QA/QC) checks—do the data meet appropriate QA/QC requirements?
- Apply appropriate statistical methods, check the assumptions of those methods, and assess whether reasonable answers have been obtained.

Even with systematic planning, uncertainty is inherent in all scientific measurement. The level of uncertainty in a data set, however, must be low enough to answer the study questions with sufficient statistical confidence. In some cases, uncertainties can be addressed by collecting additional data or using more sensitive analytical methods. In other cases, uncertainty reflects a basic lack of knowledge about how the natural system functions. Identifying and managing uncertainty (ITRC 2011c) supports informed decisions in all stages of the project life cycle.

4.1 Data Gaps

A data gap exists when data or other site information is insufficient for adequately evaluating each potential exposure pathway identified in the CSM. Data gaps introduce some level of uncertainty; however, the project team can determine whether the level of uncertainty associated with the data gap is acceptable or if additional data must be collected. Data gaps in field data are generally filled by collecting additional field data (for example, soil, groundwater, or air samples). Data gaps in other information are generally filled through online or library research and through additional data requests to agencies or organizations that collect, develop, store, or otherwise manage the needed information.

4.1.1 Issue – Identifying and Filling Data Gaps

Data gaps can be defined as questions that cannot be answered based on existing field investigation data or other available information (for example, maps, site development plans, and demographic information). A data gap in the context of risk assessment is missing information that, if available, would allow a more refined analysis to be completed.

4.1.1.1 Option – Collect Additional Data

Data collection and evaluation is an iterative process; therefore sampling plans should be flexible, while also systematic, repetitive, and recursive. Many times the first samples collected may not provide data of sufficient quality and representativeness to satisfy the requirements of the data collection program. A well-designed sampling plan builds on this first event to improve subsequent sampling. An example of this iterative process is the USEPA's Triad approach, discussed in Section 3.2 of ITRC's guidance (ITRC 2008) and presented in detail in Triad Implementation Guide (ITRC 2007b). Flexible sampling plans with built-in iterative sampling and analysis strategies encourage team collaboration and usually yield better results. As data are collected and evaluated, the plan becomes progressively modified as necessary. During the evaluation, information may be

deemed significant and therefore emphasized, or may be found insufficient, creating more questions requiring additional sampling, or may be considered anomalous and possibly discarded altogether.

4.1.1.2 Option – Determine whether Additional Data Changes Risk Assessment Results

When data gaps are identified, ask "Would additional data likely change the conclusions of the risk assessment and affect the risk management decision?" Uncertainty is inherent in data collection and risk assessment; additional data collection does not eliminate all uncertainty. Also, while some types of uncertainty may be acceptable to team members, this uncertainty may not be acceptable to all stakeholders.

Sampling results should be reviewed as soon as possible to determine whether the data meets the objectives and is sufficient to appropriately characterize the risk. If data gaps are identified, then managers must decide whether the data gaps are significant and if additional data should be collected, while keeping in mind the uncertainty inherent in data collection. In order to make this decision, ask the following questions:

- Does sufficient data exist to effectively estimate the risk posed by chemicals in environmental media?
- Will additional data help support a better decision?
- Depending on the chemicals in environmental media and analytical methods, do funding limitations affect the collection of additional data? For example, dioxin analyses are relatively expensive compared to heavy metals analysis.

Ultimately, data are collected and evaluated until additional samples result in minimal gain in understanding of the site. The key decision metric is whether additional data would likely alter the risk assessment and subsequent risk management decisions.

4.1.2 Issue – Addressing Permanent Data Gaps

Permanent data gaps are data gaps that cannot be resolved. These gaps can be the result of lack of information concerning the site history, future land uses, or site-specific sampling information. For some investigations, data gaps in sampling information may exist because areas of the site are inaccessible. Sites may be inaccessible, for example, because a property owner has refused right of entry, sampling locations are too close to sensitive areas such as utilities, or unstable conditions such as severe slopes exist. Depending on the type of site, nature of the data gap, and concentrations of chemicals in environmental media, permanent data gaps associated with concentrations of chemicals can be handled in several ways.

4.1.2.1 Option – Take No Additional Action

Address data gaps in the uncertainty section of the risk assessment. The project team and stakeholders must agree on taking no additional action and on how risk management decisions will be made despite the lack of information.

4.1.2.2 Option – Assume the Concentrations Present

Assume a certain concentration of a chemical exists in an environmental medium over the area for use in the risk assessment. This concentration might be the maximum assumed concentration based upon historical data or data from surrounding areas, or a modeled concentration. Note that this option should be addressed in the planning stages and may not be accepted by all regulatory programs.

4.1.2.3 Option – Identify a Secondary Exposure Area

Develop a secondary exposure area and pathway that separately evaluates the area where data gaps exist, with some type of remedial action goal agreed upon by all stakeholders. Note that this option should be addressed early in the planning stages and may not be accepted by all regulatory programs.

4.1.2.4 Option – Conduct Long-Term Monitoring

Place the site in a long-term monitoring program to verify that site conditions have not changed (such as change in property ownership or change in land use) and that assumptions are still valid until further investigation can be conducted. The long-term monitoring is then documented in some form of land use plan, engineering control, or deed restriction.

4.1.2.5 Option – Use Professional Judgment

For data gaps resulting from missing historical or current site information, assumptions can be made using professional judgment based on information from similar sites with similar problems.

4.2 Data Usability

Data used for risk assessment must be validated to ensure that data are usable, in some cases requiring a third-party independent reviewer. The USEPA offers guidance (Chapter 5 of USEPA 1989a) on data evaluation necessary for risk assessment. Part of this data evaluation includes an assessment of data usability. Data usability is determined based upon certain QA/QC criteria. These QA/QC criteria include sampling and preservation requirements, detection limit adequacy, laboratory and matrix spike recovery accuracy and precision, and evaluation of blanks. Establishing

appropriate QA/QC criteria is an important consideration during the project planning phase and, ideally, should be determined before samples are collected and analyzed. Numerous data QA/QC criteria guidance resources are available, such as USEPA's Data Quality Assessment, USEPA's National Functional Guidelines (USEPA 2008b; USEPA 2010e; USEPA 2011h), Department of Defense Quality Systems Management (DOD QSM), as well as other federal and state guidance (USEPA 2006b; USDOD 2013).

For many sites, historical analytical data may be decades old. Selecting the data to use in a risk assessment depends on various factors, including the media being evaluated, the chemicals of concern, and whether newer data exist from the same location. For example, older data from a groundwater monitoring well may be used to examine trends in the data; however, data from only the last few years would be used to evaluate current conditions. The elimination of any data for risk assessment purposes should be based on whether newer and more representative data are available. Generally, data should not be eliminated unless better information is available, or the data are clearly unusable.

Evaluation criteria within the various guidance documents differ slightly regarding specific method detection or quantification limits, and the review criteria selected for use should be determined. The data usability evaluation should be conducted by someone qualified and familiar with the DQOs for the site and data evaluation procedures. Data with QA/QC deficiencies may still be used in a risk assessment, but must be qualified accordingly and its effect on the risk assessment clearly communicated. For example, results in which a chemical is positively identified, but the concentration is estimated (J-qualified), may be biased low if the surrogate recovery was low and could result in underestimate of risk. The data evaluation process determines whether data is usable for calculating risk estimates. Data that is unusable for calculating the risk estimates still may provide useful information for determining the distribution of chemicals in environmental media or identifying further sampling locations.

Laboratory results should also be checked to make sure they have been corrected for the percent moisture (in the case of soils), lipid content, or dilutions. The following issues should be evaluated to ensure data usability during the data validation process.

4.2.1 Issue – Presenting Measurement Units and Significant Figures

A number of issues arise with units and significant figures used for reporting laboratory data.

4.2.1.1 Option – Confirm that Consistent Units are Presented

Analytical results are not always reported in the same units as the screening values to which they are compared. Ideally, analytical data should be reported in the same units as the criteria that they are compared to, with applicable correction factors applied. For example, air measurements may be in parts per billion or $\mu g/m^3$. In this instance, conversion from one unit of measurement to another depends on the temperature, atmospheric pressure, and molecular weight of the compound. Several

online conversion applications are available to help with conversions, such as one developed by the Center for Disease Control (CDC 2014). Laboratory data packages, reports, tables, and figures should be checked against each other to make sure that the units used to report the data are consistent across the report. A mistake in units can result in order-of-magnitude data errors. Many measurement unit issues can be avoided by simply limiting the manual creation of data tables and conversion of units.

4.2.1.2 Option – Identify Significant Figures

Numerical rounding and the use of significant figures can also affect data usability. Significant figures reflect the accuracy and precision of a given result. A result should always be rounded to the number of significant figures that are consistent with the confidence that can be placed on it. When comparing two sets of values (for example, detected concentrations to screening values), comparisons should be made with consideration of the significant figures provided and appropriate rounding applied. For example, if the screening value is 10 mg/L and the detected concentration is 10.2 mg/L, the detected concentration does not exceed the screening value.

4.2.2 Issue – Determining Cross-Contamination

In order to determine its usability for risk assessments, site data should be evaluated for possible contamination that is the result of the field sampling or laboratory processes. To evaluate sample data for cross contamination, several types of blank sample analyses can be used along with the site samples, including laboratory blanks, trip blanks, and rinsate/equipment blanks. Site data may be either accepted for the risk assessment or rejected based on any detections reported in the blank analyses.

4.2.2.1 Option – Review Laboratory Contamination and Method Blanks

Analytical laboratories use both method and instrument blanks to demonstrate that no laboratory sources of contamination exist. Laboratory blank contamination can be determined by a qualified analytical chemist, who reviews the laboratory data report and evaluates the laboratory method and instrument blanks for any detection of target compounds. If detections are noted in the laboratory method blanks, then these compounds are qualified (flagged) and any samples that contain the same compounds are flagged as well. Data usability depends on the relative concentrations of the compound detected in the method blank and the site sample result. If a site-related chemical is detected in a field or laboratory method blank, then the effects of the blank concentrations on the sample concentrations (biased high) should be mentioned in the risk assessment report.

Note that some organic chemicals commonly used in the laboratory may cross-contaminate project samples during the analytical procedure. The USEPA recognizes acetone, 2-butanone, methylene chloride, toluene, and phthalate esters as common laboratory contaminants (Chapter 5, USEPA 1989a). Although they are recognized as common laboratory contaminants, positive results for these compounds in project samples should not be dismissed without verifying appropriate blank

contamination. If these chemicals are not found in the laboratory blanks, then they should be assumed to be site related. The USEPA provides guidance on evaluating laboratory method blanks (Chapter 5, USEPA 1989a) and guidelines for evaluating blanks are also included in the USEPA National Functional Guidelines for Inorganic (USEPA 2010e) and Organic (USEPA 2008b) Data Review, but other criteria may be considered in the project planning.

4.2.2.2 Option – Review Field Blanks and Trip Blanks

Field blanks are used to assess contamination associated with ambient field conditions. Trip blanks are analyzed for volatiles to assess potential contamination introduced during the field handling and shipping. An appropriate number of field method blanks and trip blanks should also be collected and analyzed for each medium and suite of analytes. A trip blank is required for each sample shipment container containing samples for volatiles analysis. Guidelines for evaluating these blanks are also found in the USEPA National Functional Guidelines for Inorganic and Organic Data Review (USEPA 2010e; USEPA 2008b).

4.2.2.3 Option – Review Rinsate and Equipment Blanks

Rinsate and equipment blanks are used to assess the adequacy of field decontamination processes and whether cross contamination may have occurred from one sampling site to another. The Quality Assurance Project Plan (QAPP) should detail the rinsate/equipment blank acceptance criteria for determining contamination effects on site data usability. If rinsate blank levels violate the acceptance criteria established in the QAPP, then investigate the source of contamination. If possible, the source should be eliminated (NJDEP 2004). Re-sampling and re-analysis may be required.

4.2.3 Issue – Assessing Data Representativeness

The USEPA defines representativeness as a data quality indicator of the degree to which data accurately and precisely represents a characteristic of a population (USEPA 2006c). This indicator answers the question: "Are the samples representative of actual site conditions?"

4.2.3.1 Option – Review Data Representativeness Components

The data collection program should be designed so that the samples collected from each medium at a site reflect the environmental conditions of the site and the parameter that is to be measured. In determining the number of samples collected for each medium, consider the size of the site, the exposure area for each receptor, and the feasibility of the sampling design rationale. For instance, groundwater samples collected adjacent to a source area may not adequately represent an entire aquifer from which people may drink. Rather, results from individual drinking-water wells might better represent exposure. Insufficient sampling may not adequately represent the spatial and temporal variability in site conditions and therefore not represent real site conditions.

Representativeness also depends on proper sample collection and laboratory analysis of samples. Sampling and preservation methods used for each medium can affect results. For instance, sampling volatiles in groundwater using a bailer may not adequately represent true groundwater concentrations because of the inherent loss of volatiles as the bailer is lowered, raised, and emptied. Likewise, if samples are not properly preserved, their integrity may be compromised and resulting data may not represent accurate site concentrations. Factors such as the selection of sampling schemes (for example, discrete, composite, multi-incremental), use of groundwater data from temporary monitoring wells, and use of filtered versus total groundwater results should be addressed in the project planning phase. Not all data may need to be incorporated into the risk assessment; however, justification for the data that are included or excluded from the evaluation should be documented.

Representativeness may also be compromised by laboratory sampling and subsampling variability. For instance, if a laboratory analyst preferentially selects an aliquot from the environmental sample collected, then the results may not adequately represent site conditions. Representativeness may also be affected by analytical precision and accuracy or data quality qualifications. If data are qualified because of low surrogate recovery, then the measured chemical concentration reported may be biased low. See Section 3.3 for information on developing the data collection program.

4.3 Data Reduction Concerns

Data reduction is an early step in evaluating the data used to develop a risk assessment. Reduction involves the processing of data produced by the analytical laboratory to create a data set that can be used to assess human health risks. The data set is then used to generate maps or other visual aids to understanding risk, summary statistics, statistical graphics (for example, box plots or histograms), and to perform statistical analyses. Data reduction activities may include handling of duplicate sample analyses; merging of data generated from more than one sampling event, sampling method, or analytical method; and the organization of the data.

The risk assessment report should provide a thorough discussion of data reduction methods. The product of the data reduction is a data set organized and formatted in a way that facilitates statistical analysis and visualization (for example, mapping).

4.3.1 Issue – Using Duplicate Samples

Different types of duplicate samples indicate precision in analytical measurements. Colocated field duplicate samples are collected in the field analysis and laboratory duplicate samples are collected from the same prepared sample. The number of colocated duplicate samples should be defined as part of the data collection program.

4.3.1.1 Option – Identify the Number of Duplicate Samples

The rule of thumb is to collect duplicate samples equal to 10% of the total number of samples for each medium and each analysis. The protocols used for the laboratory duplicate samples (number

and frequency) are generally outlined in the analytical laboratory's quality control plan (see Section 3.3.1.2).

4.3.1.2 Option – Determine How to Handle Duplicate Data

Primary and duplicate samples may be handled by one of the following methods:

- averaging the results for each analyte in the two samples
- retaining only the greater or lesser of the two analyte results
- simply treating the duplicate as a QA/QC sample while ignoring it in the risk assessment

Handling of duplicate data should be determined during the project planning phase.

4.3.2 Issue – Pooling Data

To generate a data set that is more representative of temporal or spatial variability in site conditions, or both, it may be useful to pool or combine data. These data may have been generated by different analytical methods, collected at different times, collected at different locations (for example, pooling data from a group of groundwater monitoring wells), collected by different organizations, or collected for different purposes.

4.3.2.1 Option – Consider How to Pool Data

Data can be successfully pooled if the analytical methods and detection limits are similar. Otherwise, each data set should be pooled on a case-by-case basis and qualified if the analytical methods are different. In these cases, develop and clearly document the pooling method so that the integrity of the data is not compromised. For example, method detection limits have significantly improved over time for some methods, thus it is inappropriate to pool older data (with higher detection limits) with more recent data (which has much lower detection limits). Spatial and temporal variability should be carefully considered prior to pooling data. If the older data show a detected concentration of a chemical, then those data are potentially useable. If the laboratory method detection limit is below the desired detection limit, then these data could also possibly be used. If the laboratory method detection limit for the older data is higher than the desired detection limit and concentrations of a chemical are not reported above the method detection limit, then these results may not be appropriate for use in pooled data. Finally, inconsistencies in sample collection may also prohibit the pooling of data; for example groundwater volatiles samples collected using a bailer would not be pooled with data from samples collected using low flow sampling methods.

4.3.3 Issue – Handling Flagged Data Concentrations

Some laboratory analyses generate concentration measurements that are below the laboratory detection limits (for example, method detection limit or reporting limit; see Section 5.7.1, ITRC 2013. Concentrations reported at less than detection limits are called "censored" or "flagged" data. In

addition, during the data validation process, data are validated for compliance with the analytical method requirements and data qualifier "flags" are applied to the data to indicate QA/QC issues to consider when using the data.

4.3.3.1 Option – Review Flagged Data

Flagged data can provide valuable information (such as the presence of a chemical between the method detection limit and the reporting limit), and the approach to handling these data points can change the outcome of a risk assessment. For example, if a chemical is present below the reporting limit and is flagged with a "J" qualifier (indicating an estimated concentration), the estimated concentration could be used when calculating the EPC for the chemical. In addition, if data qualifiers indicate that some data are biased high or low in concentration, this information may be useful in decision-making for the site, especially when risk estimates are close to a decision-making criterion (unacceptable risk level). The risk assessment report should provide a discussion of the handling of flagged data sufficient to inform the reviewer as to whether these data have been included and how their use affects the outcome of the risk assessment.

4.3.4 Issue – Handling Nondetect Concentrations

Often, reportable concentrations do not occur for a chemical reasonably expected to be present in the environmental media. These data are referred to as "nondetects." Nondetects provide valuable information, and the approach to handling nondetects can change the outcome of a risk assessment. Several methods may be considered for handling nondetect data.

4.3.4.1 Option – Use Simple Substitution

Simple substitution (for example, 0, one-half the detection limit, or the detection limit) for nondetects may be done for point-by-point comparisons when data sets are relatively small (for example, less than 10). Using simple substitution, if nondetect results for a chemical are reported at detection limits less than a screening value, then the chemical may be confidently eliminated from further consideration in the risk assessment. If detection limits are greater than the screening values, however, a chemical may not be eliminated with confidence from further consideration. Section 4.5.4 discusses handling nondetects in screening.

4.3.4.2 Option – Use Other Methods

Other methods of handling nondetect results may be applicable based upon the data distribution. The handling of nondetects should be discussed during project planning, and the risk assessment report should provide a discussion sufficient to inform the reviewer about how the nondetects affect the outcome of the risk assessment. Section 1.11 of the *User Guide for ProUCL Version 5.0* (USEPA 2013e), *Environmental Statistics* (USACE 2013), and Section 5.7 of ITRC's guidance (ITRC 2013) identify various ways to handle nondetects in data sets.

4.3.5 Issue – Considering Outliers

Outliers are extremely large (or small) measurements relative to the rest of the data in a data set and have the potential to misrepresent (bias) the population from which they were collected. For additional information about outliers in environmental data, see ITRC 2013 and USEPA 2010c.

4.3.5.1 Option – Consider Sources of Outliers

Outliers may arise from matrix interferences or errors in transcription, sampling technique, data-coding, analytical methods, or instrument calibration. Alternatively, data that appear to be outliers may simply represent inherent variability in a data set. This case is particularly true for metals when soil and sediment composition and geochemistry are heterogeneous. For example, at former small arms firing ranges where lead fragments may be present in soil samples, analytical results for samples containing these lead fragments may be significantly higher than for other samples. These samples may appear to be outliers in a phenomenon known as the "nugget effect," although these samples would still be part of the overall data set. On the other hand, apparent outliers may also represent observations from true hot spots on the site.

When outliers are not identified and removed from data sets, they can disproportionately affect the statistical descriptors of the data set. That is, the mean can be biased toward the direction of the outliers and artificially increase data variability and standard deviation. Outliers can result in impractically large (or small) and unstable upper confidence levels (UCLs), flawed statistical testing, and erroneous conclusions.

4.3.5.2 Option – Identify Outliers

Statistical outlier tests can be performed to determine whether some data points are considered outliers, but visual observation of the data is also recommended. Apparent outliers can be identified (ITRC 2013; ASTM 2008b) and, if appropriate, additional sampling may be warranted. The handling of outliers should be included in the planning for the risk assessment project (see Section 3.3.3) and clearly discussed in the report.

4.3.6 Issue – Addressing Tentatively Identified Compounds

Laboratories calibrate for a specific target analyte list based on the analytical method or upon request, and only those analytes are reported quantitatively. Tentatively identified compounds (TICs) are nontarget chromatographic peaks detected during gas chromatography/mass spectrometry (GC/MS) analysis. TICs may be qualitatively identified by searching the National Institute of Science and Technology (NIST) (NIST 2014) or similar mass spectral library. Estimated concentrations for TICs are calculated similarly to the target compounds. These estimated concentrations, however, should not be used in calculating risk. Thus, target analyte lists should be reviewed to ensure that chemicals actually used at a site are included on the analyte list, even if those chemicals may not be found on common target lists.

4.3.6.1 Option – Confirm TICs

A TIC typically is eliminated from further consideration unless a potentially high concentration is revealed in the analysis and detected at an actual point of exposure (for example, in a water supply well sample) or the TIC is a chemical suspected to be associated with the facility but not on the standard analyte list.

If a TIC is to be considered for use in risk assessment, it must be evaluated quantitatively (similar to how the target analytes are confirmed against a known calibrated standard). USEPA (2006f) notes that "if the TIC is only identified as a particular class of compounds, then the laboratory will need to conduct further investigations to determine the identity of that particular compound." Knowing only the class of compounds present, however, may be useful in site decisions.

4.3.7 Issue – Assessing Nonspecific Methods

Data from nonspecific methods such as those used to assess certain classes of chemicals (for example, petroleum hydrocarbons, PCBs, and certain metals such as chromium and mercury) can be problematic in risk assessment:

- Bulk petroleum hydrocarbons are typically divided into various hydrocarbon ranges, with each containing hundreds of constituent chemicals, but these ranges are not defined consistently between regulatory agencies.
- PCBs may be reported as total PCBs, specific congeners, or Aroclors, which can create confusion as to how to quantify risk. Agencies may dictate how PCB data are reported and risks calculated.
- Chromium is typically reported as total chromium, which includes both trivalent and hexavalent chromium ($Cr^{+3}$and Cr^{+6}).
- Mercury is reported as total mercury, which includes both inorganic and organic (methylmercury) forms. Each has its specific associated toxicity values, but which to use and how to assess risk are often an issue.

4.3.7.1 Option – Incorporate Nonspecific Methods Data

The need for, and specific analytical approach to, nonspecific methods should be discussed during project planning and documented in the sampling plan.

If petroleum hydrocarbon fraction data are used in the risk assessment, avoid overestimating risk by double-counting concentrations for components of the mixture that are also included in chemical-specific analyses (for example, benzene included in a specific carbon range and as a separate analyte). An example of the use of hydrocarbon ranges is presented in USEPA guidance (USEPA 2014e).

The reporting and use of PCB data components in the risk assessment should be defined during the planning stage. Some agencies prefer Aroclor analyses for all media, while others require congener-specific analyses for fish and other biota samples. Some older data may be reported as "total PCBs" only, with no Aroclor analyses. When Aroclor analyses are conducted, "total PCBs" can be calculated per sample (based on the sum of Aroclors) used in the data screening step.

The specific form of chromium to be reported and assumed in the risk assessment should also be defined during project planning. One approach could be to assume that all of the total chromium concentration is in the more toxic Cr^{6+} form and therefore require use of Cr^{6+} toxicity values to estimate chromium risk. Alternatively, the predominant form of chromium expected to be present at the site may be assumed, or a ratio of Cr^{3+} to Cr^{6+} may assumed, or analytical speciation may be performed to generate concentrations for each chromium species individually for use in the risk assessment.

The specific form(s) of mercury to be reported and assumed in the risk assessment should be identified. Depending on the site history, medium sampled, and environmental setting, it may be appropriate to assume one form over another, or it may be appropriate to analyze samples from selected media for methylmercury.

4.4 Data Visualization and Analysis

Data visualization and data analysis generally include the use of tabular, graphical, spatial, and statistical tools to:

- understand the magnitude of a chemical release, the location and migration of the release, the affected environmental media, and the exposure pathways;
- test hypotheses about data quality and site conditions (for example, mapping data can help assess the completeness of the data set);
- highlight shortcomings in common risk assessment assumptions (for example, a potential receptor cannot be simultaneously exposed to the maximum concentrations of two different chemicals if those chemicals occur in different locations); and
- communicate complex technical details about site conditions and management options.

4.4.1 Issue – Accurately Displaying and Visualizing Data

Data visualization reveals site-specific patterns that might not otherwise be observed in a report or a tabular summary of data.

4.4.1.1 Option – Use Common Data Visualization Tools

Maps and figures displaying site data are typical formats for data visualization to explain the magnitude of a release, the location and migration of that release, the affected environmental media, and the exposure pathways. Statistically derived visualizations can help test hypotheses about data quality and site conditions. Common data visualization tools are presented in the Table 4-1, Figure

4-1, Figure 4-2, and Figure 4-3. For more information about the visualization tools, see ITRC and USEPA resources (ITRC 2013; USEPA 2010c; USEPA 2013e).

Table 4-1. Common data visualization tools

Method	Benefits	Shortcomings
Box plot (see Figure 4-1)	Nonparametric Visual display of variability Outlier identification Provides summary statistics (for example, mean, median, quartiles)	No spatial information No temporal information Can lead to incorrect interpretation of data depending on scale of box plot
Histogram (see Figure 4-2)	Estimates the probability distribution of a data set	No spatial information No temporal information No summary statistics
Probability plot (quantile plot; see Figure 4-3)	Outlier identification Distribution identification	No spatial information No temporal information No summary statistics
Two-dimensional map	Provides spatial information Informs the CSM	Must be designed specially to present temporal information No summary statistics
Scatter plot	Provides temporal information (for example, concentration trends over time)	No spatial information No summary statistics

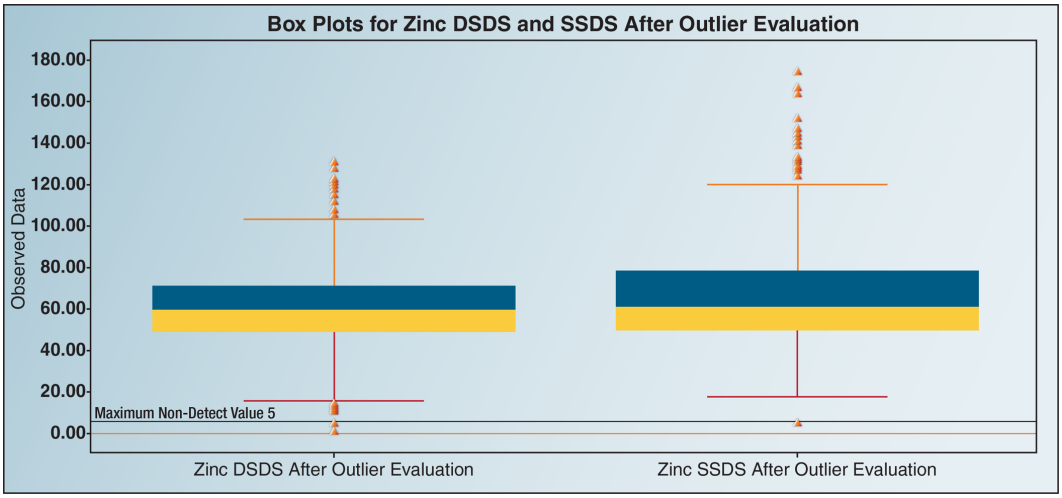

Figure 4-1. Box plot example developed using USEPA's ProUCL statistical software package.

Source: Data from Bradford et al. 1996 and Solt 2010.

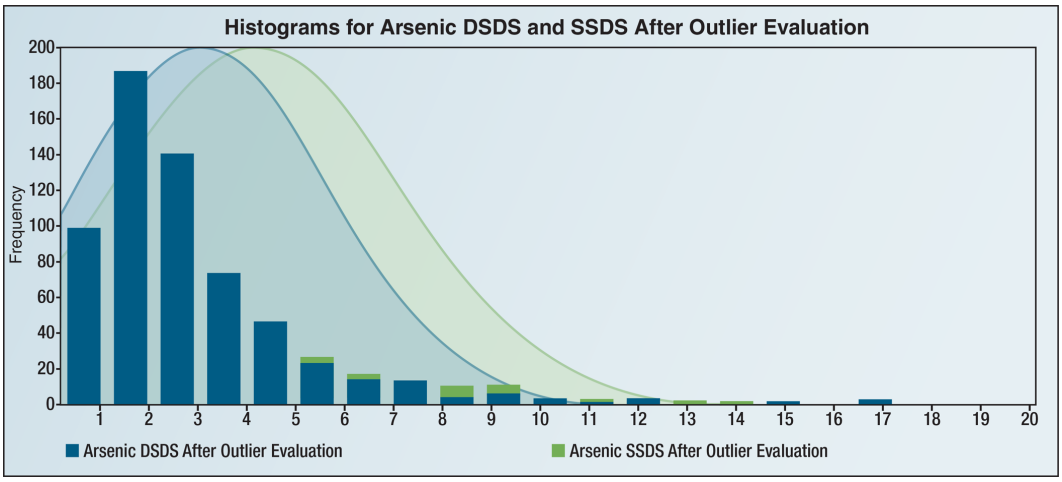

Figure 4-2. Histogram example developed using USEPA's ProUCL statistical software package.

Source: Data from Bradford et al. 1996 and Solt 2010.

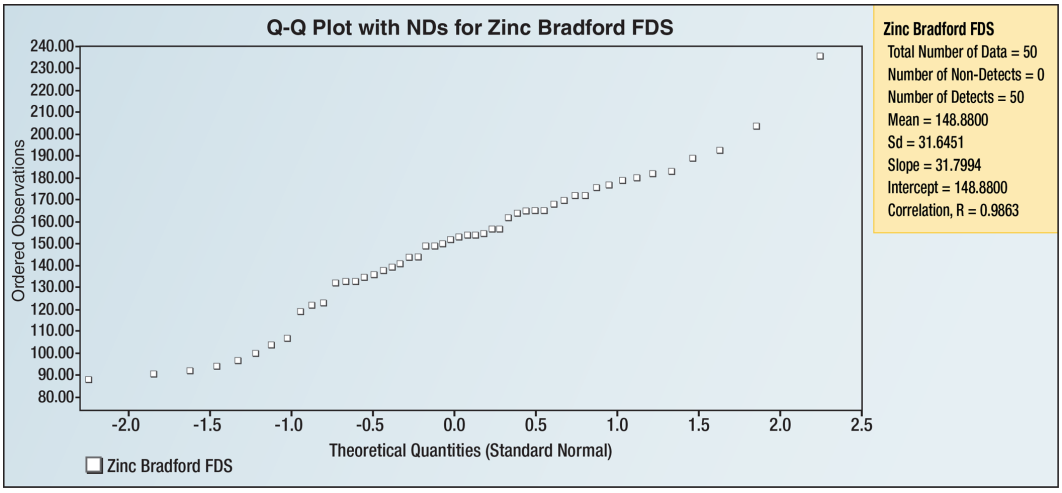

Figure 4-3. Q-plot example developed using USEPA's ProUCL statistical software package.

Source: Data from Bradford et al. 1996 and Solt 2010.

4.4.2 Issue – Statistically Analyzing Data

Agencies may have specific guidance, policy, or regulations about statistical approaches. Statistical analysis may require one or more of the following:

- quantitative evaluation of the central tendency in a data distribution (for example, mean or median concentrations)
- evaluation of the upper and lower bounds on that distribution (for example, upper or lower prediction limits, tolerance limits, confidence intervals, percentiles)

- identification of outliers (for example, data points that are unusually large or small as compared to the majority of the data points in a sample population)
- comparisons of concentrations of a chemical in environmental media to background concentrations

4.4.2.1 Option – Perform a Statistical Analysis

Performing a statistical analysis requires the selection of an appropriate statistical analysis method. A detailed discussion of the selection of an appropriate statistical analysis method is beyond the scope of this document. For a detailed discussion of the statistical analysis of groundwater data, please refer to ITRC's groundwater statistics guidance (ITRC 2013). Additional publications that explain statistical evaluation of environmental data include the technical documentation and user's guide published with USEPA's ProUCL statistical software package (USEPA 2010c), the USEPA *Unified Guidance* (USEPA 2009b), and many other publications from commercial publishers. Additionally, guidance from NIST (NIST/SEMATECH 2012) is particularly useful for understanding exploratory data analysis.

4.5 Data Screening and Chemical Selection Processes

Risk assessment generally begins with a conservative step. Screening values (based on default assumptions as opposed to site-specific values) are used to identify areas and chemicals in environmental media warranting further evaluation and to assess the adequacy of sampling data collected (for example, whether the nature and extent of concentrations are adequately characterized). The subsequent steps typically use calculations or models and more site-specific exposure assumptions and intake variables. This screening approach allocates resources based on the apparent significance of the concentrations of a chemical and its presence in an environmental medium.

Screening values, intended to be protective of human health or the environment, are often defined as chemical concentrations in environmental media below which no additional regulatory action is warranted. Screening values can be based on estimates of excess lifetime cancer risk or adverse noncarcinogenic effects, typically whichever is most conservative, using equations combining exposure assumptions with toxicity data. As illustrated in Figure 4-4, if chemical concentrations at a site exceed the screening values, then additional investigation or evaluation (for example, by risk assessment) of that chemical is warranted but does not necessarily require cleanup (ITRC 2005).

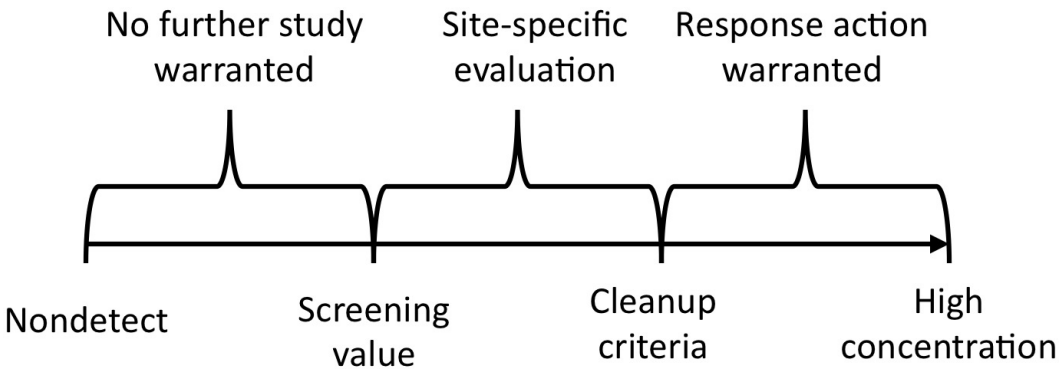

Figure 4-4. Risk-based decision process.

Source: Adapted from USEPA 1996b.

4.5.1 Issue – Identifying Appropriate Screening Values

There may be federal, state, or even local screening values that may apply to the site and that may differ. Additionally, there may be more than one screening value for a single chemical in a given medium to address multiple exposure scenarios. For example, based on current and reasonably anticipated future land use, chemicals may need to be compared to both residential and nonresidential screening values. In another example, for CERCLA sites, CERCLA Section 121(d) stipulates that applicable or relevant and appropriate requirements (ARARs) be met, meaning that levels must be applicable to the site, or relevant and appropriate to the chemical or contaminated media at the site.

A survey of 13 state agencies about their methodology for determining risk-based concentrations and establishing standards for chemicals in soil and water noted that:

> "…it is evident that there is variability in each agency's basis and intended use of screening values…published screening values for a chemical can differ from state to state by several orders of magnitude…" (ITRC 2005).

This variability in screening values is the result of the exposure assumptions, fate and transport approaches, and risk management targets used to calculate the various screening values. In addition, some screening values may not be derived using risk-based approaches, but instead be based on other factors such as laboratory quantification limitations or on concentrations of chemicals found naturally at background concentrations in the environment. The latter two factors are not risk-based or health-based screening values.

4.5.1.1 Option – Select Applicable Screening Values

Screening values to be used should be identified and documented early in the planning stage. Overall, the screening values chosen should be consistent with the assumptions outlined in the CSM and the regulatory framework in the jurisdiction in which the site exists. One value may be selected over another or the chemicals could be compared to each of the available regulatory screening val-

ues. The regulatory agency hierarchy as discussed in Section 3.1.3.1 may dictate which screening value is used.

Screening values may change over the course of the project. Screening values may be revised based on new toxicology studies, better understanding of site conditions, changes in exposure assumptions, or revised laboratory analytical methods. The project planning team should plan for a response if screening values change after the data has been screened and the risk assessment performed.

4.5.2 Issue – Identifying Chemicals for Evaluation in the Risk Assessment.

Although the screening values may differ among agencies, the initial screening evaluation (typically part of a Tier 1 evaluation) is generally well-defined and consistent. Typically, "the number of chemicals to be considered during the remainder of the risk assessment will be less than the number of chemicals initially identified" (USEPA 1989a).

4.5.2.1 Option – Select Chemicals for Further Evaluation

Chemicals detected at concentrations above the screening values are retained for further evaluation. Chemicals detected below screening values may be handled as follows:

- considered as having minimal influence on total risk and not retained in the quantitative risk assessment
- may be further evaluated and retained based on the toxicity, mobility, and persistence of a chemical
- considered essential nutrients (such as calcium, magnesium, potassium, and sodium) and not retained in the quantitative risk assessment
- further evaluated considering the frequency of detection (for example, chemicals detected at a frequency of less than 5% and not detected in multiple media may be eliminated from further consideration) and eliminated from further consideration

The approach for handling chemicals detected above and below the screening values should be discussed and resolved during the planning process, and the rationale for not retaining chemicals for further evaluation should be documented.

4.5.3 Issue – Addressing Chemicals that are Missing Screening Values

In the chemical screening step, analytes are often missing screening values. In some cases, these values are missing because toxicity or other data necessary to calculate a screening value are lacking. In other cases, toxicity data may be available, but a screening value has not been developed.

4.5.3.1 Option – Calculate a Screening Value

If toxicity data are available, a screening value can be calculated using the approach and assumptions used to calculate the other available screening values.

4.5.3.2 Option – Use a Surrogate

For chemicals that do not have screening values or data to calculate screening values it may be appropriate to identify surrogate chemicals with available screening values. Typically, chemicals with screening values for other isomers of the same chemical are used; for example, the level for cumene could be substituted for butylbenzene. Section 5.1.2.3 provides further guidance on the use of surrogates.

4.5.3.3 Option – Eliminate Chemicals without Screening Values

If screening values are not available, a chemical can be eliminated from further assessment if it is not related to site operations or to a release from a site (for example, it is an essential nutrient; see Section 5.9.4 of USEPA's guidance [1989a] for additional information on essential nutrients), or if the chemical may otherwise be qualitatively assessed.

4.5.4 Issue – Handling Nondetect Chemicals in Screening

When samples are analyzed for extended lists of analytical parameters, typically a fairly large group of chemicals are identified as nondetects in all samples. Sometimes the applicable regulatory context dictates the treatment method for nondetects in the screening process. When the regulatory context does not dictate the approach, however, several methods are used to evaluate nondetects in the screening step.

4.5.4.1 Option – Exclude from Further Evaluation in the Risk Assessment

Where the analytical results for a particular chemical are all below the laboratory analytical detection limit and the detection limit is below the screening value, the chemical can be eliminated from further consideration in the risk assessment.

If a sample-by-sample comparison of the detection limit to the screening value indicates a low frequency of detection and the detection limit is below the screening value, consider excluding that chemical from further consideration in the risk assessment. USEPA (1989a) recommends that a chemical be considered for elimination from a risk assessment

> if: (1) it is detected infrequently in one or perhaps two environmental media, (2) it is not detected in any other media or at high concentrations, and (3) there is no reason to believe that the chemical may be present.

4.5.4.2 Option – Retain for Further Evaluation in the Risk Assessment

Where the analytical results for a particular chemical are all below the laboratory analytical detection limit and the detection limit (including flagged values) is above the screening value, then the chemical should be considered for further evaluation in the risk assessment (if the chemical is known or suspected to be related to a release on the site). These inadequacies in the analytical detection limit should be discussed as a source of uncertainty in the risk assessment. If the chemical is not known or suspected to be associated with a release, then the chemical may be excluded from the risk assessment (with the reason documented).

If the chemical is a degradation product of another chemical detected on the site, consider retaining the chemical in the risk assessment.

4.5.5 Issue – Addressing Data Bias in Screening Process

Data bias in the screening process can significantly affect risk assessment conclusions. Biases should be accounted for in the risk assessment.

4.5.5.1 Option – Identify the Type and Significance of Data Bias

The concentrations in the data set may be biased (high or low) for various reasons and thus not be representative of the entire exposure area. In some cases, environmental samples may have been collected from only the areas of the site with the highest concentrations of chemicals (thus the exposure areas concentrations may be biased high). In other cases, environmental samples may have been collected from only the periphery of the impacted area (thus the exposure area concentrations may be biased low). When a surrogate concentration (for example, the reporting limit) is used for a chemical that was a nondetect in the screening, the exposure area concentration for that chemical may be biased high. When the screening value for a surrogate chemical is used for an analyte missing a screening value, the bias in the screening, high or low, may be known (for example, when using hexavalent chromium to screen total chromium concentrations and hexavalent chromium is not expected to be present). If the bias in the data is expected to affect the remedial action decision for the site, then additional data collection may be needed to make a more informed decision (see Section 6.2.5).

4.5.6 Issue – Handling Background Concentrations

It is common for chemicals such as metals or polycyclic aromatic hydrocarbons (PAHs) to be identified at sites at concentrations higher than risk-based screening values due to naturally occurring or non-site-related anthropogenic conditions. Most state and federal remedial action programs do not require remediation of impacts below background or in some cases only require remediation to address site-related impacts.

Some states may have published or unpublished approaches for comparisons of site and background data sets. Various references are available providing approaches for comparison to background (for example, DTSC 1997, DTSC 2008, DTSC 2009b, and DTSC 2009a).

If limited background data are available, then the background screening may be performed by using a point-by-point comparison or by comparing the maximum detected site concentrations to a background value (see Section 3.3.7 and Section 6.2.5).

4.5.6.1 Option – Use Site-Specific Background Data

For some sites, a large and site-specific background data set may exist and background screening can be performed using a statistically derived background number or using a statistical test to determine whether the background data and the site data are from the same population. The availability of agency requirements for establishing site-specific background concentrations should be determined (for example, DTSC 2008).

4.5.6.2 Option – Use Background Data from Other Sources

In some cases, applicable regional background data may be available from other sources. This data may have been collected as part of studies for unrelated sites such as preconstruction environmental assessment studies, monitoring programs (drinking water, landfill monitoring), or research studies. These sources should be explored to determine the availability of applicable background data.

4.5.6.3 Option – Use Background Values Collected From General Background Studies

Some states and agencies have published or unpublished background values collected as part of state-wide projects that can be used for comparison to site data (for example, Boerngen and Shacklette 1981, Gustavsson et al. 2001, Shacklette and Boerngen 1984, and USGS 2012).

4.6 Resources and Tools

The following resources and tools were not cited in the sections above and are included here for further information.

Spatial Analysis and Decision Assistance (University of Tennessee 2013)

ProUCL software (USEPA 2013d)

Drinking Water Standards (USEPA 2014c)

Preliminary Remediation Goals for Radionuclides (USEPA 2014i)

Regional Removal Management Levels for Chemicals (USEPA 2014k)

Risk Assessment Information System, Oak Ridge National Laboratory (ORNL 2014)

Using the Triad Approach to Streamline Brownfields Site Assessment and Cleanup – Brownfields Technology Primer Series (USEPA 2003f)

5.0 TOXICITY

Chemical-specific toxicity values are frequently reassessed and are updated over time as new information becomes available. For some chemicals, consensus is established on the appropriate toxicity values to be used. For others, however, agencies have differing toxicity values. Selecting toxicity values without understanding how they were derived can lead to over- or underestimates of potential risks associated with chemical exposure, which may result in risk management decisions that are not defensible or protective of human health.

This chapter discusses and provides guidance on key issues associated with conducting toxicity assessments for risk assessment. The key issues are organized around the following topic areas:

Sources of Toxicity Values

- Choosing Among Toxicity Values from Multiple Sources
- What To Do When a Toxicity Value is Not Readily Available
- Assessing Toxicity of Chemical Groups/Mixtures
- Assessing Toxicity of Mutagenic Carcinogens
- Addressing Lead Toxicity

Effects of Toxicity Value Uncertainty on Risk Management Decisions

- Understanding Uncertainty in Toxicity Values

A discussion of toxicity value derivation and uncertainty as they relate to risk management decisions is provided in Appendix B.

5.1 Sources of Toxicity Values

Differences in regulatory agency policies for risk assessments, including the toxicity values used by the agencies, can result in large variations in decision outcomes (ITRC 2008). An uninformed selection of a toxicity value may result in inadequate protection of human health, overly conservative risk management decisions, or rejection of the risk assessment by the regulatory agency.

5.1.1 Issue – Choosing Among Toxicity Values from Multiple Sources

A variety of toxicity values are available to quantify the relationship between the degree of exposure to a chemical and the incidence or severity of health effects. For some chemicals, consensus exists in the scientific community on the appropriate toxicity values to be used, while consensus does not exist for others. This lack of consensus sometimes results in differences in toxicity values (and resulting risk estimates) from state to state. Consequently, controversy occurs over the protectiveness of the risk estimates resulting from the use of these toxicity values.

How risk assessors choose the toxicity values may significantly affect results of the risk assessment. Appendix A provides a table that lists some of the common sources of toxicity values as well as links to each for convenient reference. At times, specific state regulations limit the choice of toxicity values, while at other times the risk assessor must use professional judgment to determine the best toxicity values for a specific chemical.

Toxicity values should be chosen based on the best available science for a specific chemical at the time the risk assessment is prepared (USEPA 2003d) using scientifically sound professional judgment.

Although the USEPA and some states have developed source hierarchies for use in selecting toxicity values, sources may have varying schedules for reassessing toxicity values. Depending on when new information becomes available or is evaluated, toxicity values for a chemical in one source may be more up-to-date than those in another source.

Guidance documents listed in Section 5.3 provide more detail regarding each toxicity value type, the fundamentals associated with toxicity values, and other key definitions (for example, the difference between acute, chronic, and subchronic exposure durations defined in (USEPA 1989a). Toxicity values should be chosen based on the best available science for a specific chemical at the time the risk assessment is prepared (USEPA 2003d). This approach requires scientifically sound professional judgment by the risk assessor.

5.1.1.1 Options – Use USEPA Guidance

Initially, USEPA (1989a) presented an approach for selecting toxicity values by recommending a hierarchy of sources. Because the field of toxicology evolves rapidly, however, USEPA does not require rigid application of this hierarchy. Instead, USEPA recommended that "EPA and State personnel may use and accept other technically sound approaches." Protection of human health can only be achieved by using the best available science as the basis for risk assessments, therefore USEPA generally recommends a three-tier hierarchy of toxicity information sources (USEPA 2003d):

- Tier 1 – USEPA's Integrated Risk Information System (USEPA 2015e)
- Tier 2 – USEPA's Provisional Peer Reviewed Toxicity Values (USEPA 2013f)
- Tier 3 – Other Sources – additional USEPA and non-USEPA sources, including toxicity values prepared by states and agencies. Priority is given to sources that provide toxicity information based on similar methods and procedures as those used in Tier 1 and Tier 2 sources, and that are peer-reviewed, available to the public, and transparent in the methodologies and processes used to develop the values. USEPA provides examples, including the California EPA's toxicity value database (CalEPA 2013), the Agency for Toxic Substances and Disease Registry Minimal Risk Levels (MRL) (ATSDR 2013), and the USEPA Health Effects Assessment Summary Tables (HEAST) (USEPA 1997d).

5.1.1.2 Option – Use USEPA Guidance Supplemented with ECOS Guidance

The Environmental Council of the States (ECOS) offers guidance on the characteristics of preferable Tier 3 toxicity values (ECOS 2007). ECOS recommends assigning preference to toxicity values that are developed as follows:

- using a "previously established and publicly available methodology"
- using methods reflecting "…the current best scientific information and practices; new assessment methods should provide reproducible results and meet quality assurance and quality control requirements"
- considering "…the quality of studies used, including the statistical power or lack thereof to detect effects"
- using durations "…consistent with the duration of human exposure being assessed"

5.1.1.3 Option – Use State Agency Toxicity Values

Many states have adopted USEPA's recommended hierarchy or a modified version of USEPA's hierarchy (for example, NJDEP 2008; Pennsylvania Revised Code 2011; University of Florida 2005). Also, some states (for example, California) stipulate specific toxicity values within their state regulatory framework and may require that their values be used to supplement or supersede USEPA's hierarchy of sources. Even if an agency does not stipulate the toxicity values, it may have guidance on this issue.

5.1.1.4 Option – Consult Experts in Toxicology

If experts and agencies disagree about which toxicity value is best when multiple values are available, the Superfund Health Risk Technical Support Center (STSC) (USEPA 2013h) or a professional toxicologist can be consulted. This approach is not an option if the state stipulates the toxicity value source in its code or regulations.

5.1.2 Issue – What to do When a Toxicity Value is Not Readily Available

Generally, when toxicity values are not available from a higher-tier source (Tier 1), lower-tier sources should be used (for example, Tier 2 sources, if available, followed by Tier 3 sources). For some chemicals (for example, 4-ethyltoluene, sec-butylbenzene), toxicity values are not readily available from Tier 1, 2, or 3 sources, and other options should be pursued.

5.1.2.1 Option – Determine whether the Toxicity Value is Needed

If a chemical with missing toxicity values is unlikely to affect risk management decisions, searching for toxicity information is not warranted.

It may not be necessary to search for toxicity values if, based on professional judgment, the chemical is unlikely to significantly affect the risk assessment results or risk management decisions (for example, the concentrations of other chemicals colocated in the area would warrant remediation action already). For example, if a volatile compound is missing an oral toxicity value but has an inhalation toxicity value, then the missing oral toxicity value may not be a significant issue because, for volatile chemicals, the inhalation pathway may be more significant than the ingestion pathway. Also, if the frequency of detection of a chemical is low (for example, less than 5%) and if the chemical is detected at low concentrations, then missing toxicity values may not be a significant issue (see Section 4.5.2 for additional information on selecting chemicals for evaluation).

5.1.2.2 Option – Use Chronic Toxicity Values for Subchronic Exposures or Vice-versa

Chronic toxicity values are typically used in risk assessments and are available in the Tier 1 source (IRIS), whereas both chronic and subchronic toxicity values may be available in Tier 2 and Tier 3 sources. When a subchronic toxicity value is needed, a lower tiered source (Tier 2 or Tier 3) can be searched for a subchronic toxicity value or the chronic toxicity value (from the Tier 1 source) can be used. For example, a chronic oral RfD could be used as a surrogate for a subchronic oral RfD. Conversely, subchronic toxicity values could be used as surrogates for unavailable chronic toxicity values (for example, a subchronic inhalation reference concentration (RfC) from a Tier 2 source could be used as a surrogate for an unavailable chronic inhalation RfC). A subchronic toxicity value should not be used as a surrogate for a chronic toxicity value, however, without making adjustments to account for the duration of exposure used to define the subchronic value, and without consideration the sensitivity of the endpoint used to define the subchronic value.

5.1.2.3 Option – Use Toxicity Values for a Similar Chemical

Toxicity values available for other chemicals with similar chemical structure can be used as surrogates (see Section 4.5.3.2) when a toxicity value is not readily available in Tier 1, Tier 2, or Tier 3 sources, and it is not possible to substitute a chronic or subchronic toxicity value (as discussed in Section 5.1.2.2), Currently there is no general consensus on assessing similarity for chemicals used as surrogates. Historically, risk assessors chose surrogate chemicals with little consideration for similarity in chemical structure, but USEPA now provides guidance on surrogate similarity. Consult a professional toxicologist before a chemical is used as a surrogate.

USEPA's STSC (USEPA 2013h) uses quantitative structure-activity relationship models to compare chemical structures, determine the similarity between chemicals, and provide surrogate chemical toxicity data. USEPA's regional screening levels (RSL) table (USEPA 2014e) incorporates the surrogate chemical toxicity data that have been endorsed by the STSC. For chemicals not on the RSL table and for chemicals on the table with missing toxicity values, the STSC can be queried directly. USEPA's RSL table is updated approximately every six months, so the most recent version of the RSL table should be checked for current toxicity values to use as surrogates. Another source of toxicity values is the Oak Ridge National laboratory (ORNL) Risk Assessment Information System (RAIS) database (ORNL 2014). RAIS is updated as new information becomes available.

5.1.2.4 Option – Use Oral Toxicity Values for Inhalation Exposures or Vice-Versa

Toxicity values derived using route-to-route extrapolation may be reasonable in limited cases. For example, it may be possible to extrapolate an inhalation toxicity value from an oral toxicity value and vice-versa. In general, however, route-to-route extrapolation is discouraged because the pharmacokinetic differences between the two routes of exposure may be overlooked. Route-to-route extrapolation also adds additional uncertainty to the risk estimates (USEPA 2009a). The inhalation dosimetry methodology (USEPA 1994b) provides specific examples of situations in which route-to-route extrapolation from oral toxicity values might not be appropriate.

5.1.2.5 Option – Consult Experts in Toxicology

Should none of the potential options above help to address the lack of toxicity information for a particular chemical of interest, the STSC (USEPA 2013h) or a professional toxicologist can be consulted.

5.1.3 Issue – Assessing Toxicity of Chemical Groups/Mixtures

The toxicity values discussed above are specific to individual chemicals. Stakeholders may express concerns about a chemical-by-chemical approach to toxicity assessment because multiple chemicals typically are detected at a site, in addition to the numerous chemicals unrelated to the site that people encounter daily in air, water, and food. Questions about how these chemicals may interact with each other in human bodies have generated considerable interest among scientists and the general public.

The toxicological literature defines four types of potential chemical interactions that influence the toxicity of chemicals: additive effects, synergistic effects, potentiation, and antagonism. Additive effects occur when the combined effect of two chemicals is equal to the sum of the effects of each chemical alone (for example, 2 + 3 = 5). Additive effects can be further subdivided into dose addition and response addition. Synergistic effects, potentiation, and antagonism are not typically addressed in risk assessment because of the lack of toxicity information for most chemical mixtures present at sites under investigation. Additivity of dose/risk is generally assumed because the scientific knowledge on interactions among chemicals is inadequate to support other approaches.

5.1.3.1 Option – Use USEPA's Default Approach, Additivity

The recommendations from USEPA's first mixtures risk assessment guidance (USEPA 1986) were incorporated into RAGS, Part A (USEPA 1989a), which still serves as general guidance for risk assessments today. While this guidance acknowledges the four different types of chemical interactions listed above, it recommends dose addition (for noncarcinogens) and response addition (for carcinogens) as the default approaches for addressing chemical mixtures in risk assessment.

Dose addition is the most commonly used mixtures approach and is the assumed approach underlying the hazard index, the relative potency factor (RPF), and toxic equivalency factor (TEF) approaches discussed below. Dose addition assumes toxicological similarity between the chemical components of a mixture (that they have similar mechanisms for exerting toxicity and similarly shaped dose-response curves), and that they differ only in potency. With dose addition, the toxicological effect of the mixture is predicted by the sum of the individual chemical doses (adjusted for potency).

Response addition assumes that the chemical components of a mixture act on different organs and systems or produce effects that do not influence each other (USEPA 2000c). This form of additivity is most commonly used to estimate risks from exposure to multiple carcinogens, where the cumulative cancer risk estimate is the sum of the probabilities associated with exposure to each carcinogenic chemical.

USEPA's supplementary mixtures guidance provides additional scientific updates and methods for addressing different types of chemical mixtures in human health risk assessments (USEPA 2000c). Although USEPA recognizes the need to better understand the nature and toxicological significance of chemical mixtures, additivity, which implies a lack of interaction, remains the current default approach.

5.1.3.2 Option – Use an RPF Approach

The RPF approach relies on the existence of toxicological dose-response data for at least one chemical of the mixture (referred to as the index chemical), the toxicity of the other individual chemicals in the mixture, and the toxicity of the mixture as a whole. The toxicity of the related chemicals is predicted from the index chemical, and a scaling factor for the toxicity of the related chemicals is used. This scaling factor (the RPF) represents the relative toxicity with respect to the index chemical. For example, if chemical A is considered to be one-tenth as toxic as the index chemical (it requires 10 times the exposure to cause the same toxicity), then the RPF for chemical A is 0.1. USEPA currently uses the RPF approach for assessing cancer risk for PAH mixtures and for cumulative risk assessments of five groups of pesticides (for example, organophosphates).

5.1.3.3 Option – Use a Toxic Equivalency Factor Approach Where Applicable

The TEF approach is a form of the RPF approach, but is reserved for groups of chemicals for which more robust information is available about the mechanisms of chemical toxicity. "TEFs are consensus estimates of chemical-specific toxicity/potency relative to the toxicity/potency of an index chemical. TEFs are the result of expert professional judgment using all available data and taking into account uncertainties in the available data" (USEPA 2010d). Two classes of chemicals for which TEF approaches have been developed by USEPA and other agencies are dioxins/furans and polychlorinated biphenyls.

5.1.3.4 Option – Consult Experts in Toxicology

Should none of the potential options above help to address how to evaluate the particular chemical mixtures of interest, the STSC (USEPA 2013h) or a professional toxicologist could be consulted.

5.1.4 Issue – Assessing Toxicity of Mutagenic Carcinogens

Chemicals with potential mutagenic mode of action (MOA) for carcinogenesis are considered to be more toxic during early life (under age 16). Not correctly accounting for the potential mutagenic MOA in evaluating the risks involving early life exposures underestimates risk for these chemicals. Prior to 2005, the generic adjustments for potential mutagenic MOA were not made to the cancer risk estimates. Since USEPA published guidance on this topic (USEPA 2005d), however, many agencies have required adjustments for chemicals with a potential mutagenic MOA to avoid underestimating cancer risk.

USEPA maintains a list of chemicals that have a potential mutagenic MOA for carcinogenesis (USEPA 2013a). Since complete consensus may not exist on some study data interpretations, state agencies may have their own list of chemicals that they deem to have a potential mutagenic MOA.

5.1.4.1 Option – Use a General Approach for all Mutagenic Carcinogens as Appropriate

For most carcinogens with a potential mutagenic MOA, chemical-specific age-dependent adjustment factors (ADAFs) are not available (USEPA 2013a). In the absence of chemical-specific ADAFs, USEPA recommends the use of default ADAFs when calculating cancer risk estimates for exposures during early life (USEPA 2005d):

- an ADAF of 10 (10 times higher toxicity) for ages under 2 years
- an ADAF of 3 (3 times higher toxicity) for ages over 2 and under 16 years
- an ADAF of 1 (no adjustment) for ages 16 years and older

USEPA's Handbook for Implementing the Supplemental Cancer Guidance at Waste and Cleanup Sites (USEPA 2012b) provides details on applying recommended potency adjustment factors in the risk calculations.

5.1.4.2 *Option – Use a Chemical-Specific Approach where Chemical-specific Adjustments are Warranted*

USEPA recommends applying chemical-specific modifications to the risk estimates for two mutagens: TCE and vinyl chloride (USEPA 2005d; USEPA 2005b)

Currently, USEPA recommends applying chemical-specific modifications to the risk estimates for two mutagens: TCE and vinyl chloride. Nonstandard ingestion and inhalation risk equations apply to TCE and vinyl chloride. For all other carcinogens with a potential mutagenic MOA, the default ADAFs specified in USEPA guidance are used (USEPA 2005d).

Mutagenic MOA Adjustments for TCE and Vinyl Chloride

For mutagenic MOA adjustments for TCE and vinyl chloride, as explained in detail (with example calculations) in the IRIS Toxicity Assessment for TCE (USEPA 2011d), USEPA recommends that kidney risk be assessed using the mutagenic equations and that liver and non-Hodgkin lymphoma be addressed using standard cancer equations. Not applying this modification results in an overestimate of exposure risks.

The following table presents details on calculating cancer risk estimates for ingestion and inhalation of TCE in soil, accounting for contributions to kidney cancer (adjusted using ADAFs) and non-Hodgkin lymphoma (NHL) + liver cancer (not adjusted using ADAFs). For more information, see the Toxicity Review (USEPA 2011g) and the RSL User's Guide (USEPA 2014e).

Table 5-1. Cancer risk estimates for residential soil ingestion

Residential soil ingestion				
	Age group			
	0 to 2	2 to 6	6 to 16	16 to 30
Soil concentration (mg/kg)	1	1	1	1
Ingestion rate (mg/day) Conversion factor (kg/mg)	200 1.00E-06	200 1.00E-06	100 1.00E-06	100 1.00E-06
Exposure frequency (days/year) Exposure duration (years)	350 2	350 4	350 10	350 14
Body weight (kg) Averaging time (days/year)	15 25,550	15 25,550	70 25,550	70 25,550
Lifetime average daily dose (mg/kg/day)	**3.65E-07**	**7.31E-07**	**1.96E-07**	**2.74E-07**
Oral slope factor $(mg/kg/day)^{-1}$	0.0460	0.0460	0.0460	0.0460
SF for kidney cancer* $(mg/kg/day)^{-1}$	0.0093	0.0093	0.0093	0.0093

Table 5-1. Cancer risk estimates for residential soil ingestion (continued)

Residential soil ingestion				
SF for NHL + liver cancer (mg/kg/day)$^{-1}$	0.0367	0.0367	0.0367	0.0367
ADAF (unitless)	10	3	3	1
Risk of kidney cancer (unitless)	3.4E-08	2.04E-08	5.46E-09	2.55E-09
Risk of NHL + liver cancer (unitless)	1.34E-08	2.68E-08	7.18E-09	1.01E-08
Sum of risks (unitless)	4.74E-08	4.72E-08	1.26E-08	1.26E-08
Total risk	**1.2E-07**			

*From Section 5.2.3.3.2 of the September 2011 Toxicological Review of TCE

5.1.4.3 Option – Determine whether Mutagenic MOA is Appropriate for Site

At sites where receptors under age 16 are not exposed, potency adjustments for early life exposures are unnecessary. In addition, at sites where mutagens are not detected, adjustments are not applicable. Currently some state agencies and programs do not require or incorporate adjustments for mutagenic MOA. In these cases, at sites where receptors under age 16 may be exposed and chemicals with a mutagenic MOA are present, risk estimates for mutagenic carcinogens may be underestimated.

5.1.4.4 Option – Consult Experts in Toxicology

Should none of the potential options above help to address how to evaluate the particular mutagenic chemical, the STSC (USEPA 2013h) or a professional toxicologist can be consulted.

5.1.5 Issue – Addressing Lead Toxicity

Lead is considered a potential human carcinogen, and certain regulatory agencies may require evaluation of the associated cancer risk (for example, California). The sensitive toxicity endpoint, however, is neurotoxicity, which is not evaluated through the traditional risk assessment process. Typically, toxicity values are not used for lead in the same way that they are used for other chemicals in risk assessments. Instead, lead models are used to evaluate the potential toxic effects of lead exposure in various exposure scenarios.

Toxicity from exposure to lead is not evaluated in the same manner as it is for other chemicals, reflecting the unique method of toxicity for lead. Lead toxicity is estimated using various lead uptake models and federal and state regulatory levels are frequently policy based.

Lead risk assessment is unique because scientific research has linked adverse human health effects

to blood lead levels (BLLs) rather than a dose rate. A child's developing nervous system is particularly sensitive to lead, and increasing BLLs have been linked to a variety of cognitive deficits in children. Once lead enters the body, it can spread into bone and soft tissues, which act as reservoirs that release lead over time, even after the original source of lead exposure has been removed. For these reasons, several mathematical models have been developed to estimate BLLs based on lead intake via various exposure routes. Although a detailed discussion of these models is beyond the scope of this document, the following links are provided for additional information:

- USEPA's Integrated Exposure Uptake Biokinetic Model (IEUBKwin v1.1 build 11) (USEPA 2010a)
- USEPA's Adult Lead Methodology (ALM) Model (USEPA 2003a)
- California EPA's LeadSpread 8 Model (DTSC 2011a)
- USEPA's draft All-Ages Lead Model (USEPA 2005a)

The issue often arises as to which receptor groups should be modeled for specific land use scenarios. Rather than spend resources modeling all potential receptor groups, options are provided below based on the most sensitive receptor groups, which drive site cleanup for residential and industrial land uses.

5.1.5.1 Option – Model Child Exposures When Assessing Residential Scenarios

When modeling child exposures for lead, an important consideration is which BLL to use. Longstanding USEPA policy stipulates that the probability of a child's BLL exceeding a 10 µg/dL BLL of concern should fall below 5%. This criterion is the basis for the 400 mg/kg residential USEPA RSL for lead that USEPA has used for many years (USEPA 1994a).

USEPA currently recommends 10 µg/dl, CDC's ACCLPP recommends 5 µg/dl, and California recommends a BLL change of 1 µg/dl.

In January 2012, the CDC's Advisory Committee for Childhood Lead Poisoning Prevention (ACCLPP) released a report regarding child BLLs. ACCLPP recommended eliminating the use of the term "blood lead level of concern" and replacing it with the term "blood lead reference level" (CDC 2012b; CDC 2012a). This committee also recommended the use of a blood lead reference level of 5 µg/dL (as opposed to the previously recommended 10 µg/dL) in children to trigger medical and prevention actions. The newly proposed BLL is based on the 97.5th percentile of BLL distribution among children ages one to five from the National Health and Nutrition Examination Survey (NHANES) data. In May 2012, CDC concurred in principle with the ACCLPP's January 2012 recommendations (CDC 2012a).

As of November 2013, USEPA has not changed the risk reduction goal for lead. The USEPA's current risk reduction goal for contaminated sites is to limit the probability of a child's BLL exceeding 10 µg/dl to 5% or less (USEPA 2015f).

Lead models may warrant modifications to appropriately evaluate exposures that are not continuous or chronic (see Section 5.1.5.3).

In 2007, California EPA revised its lead policy as a result of the concerns about potential toxicity to children at BLLs less than 10 µg/dL. California EPA's Office of Environmental Health Hazard Assessment relied on data from scientific studies that quantified the relationship between BLLs in children and IQ scores. The Office of Environmental Health Hazard Assessment concluded that a 1 µg/dL increase in BLL corresponds to a 1 point decrease in IQ and selected 1 µg/dL as a benchmark BLL change due to a specific exposure source (California Environmental Protection Agency 2007). In current practice, the value for BLL in children that is typically used is 10 µg/dL, unless the state regulatory agency recommends another value.

Another consideration is which model to use. In current practice, USEPA's IEUBK model for lead in children is the most common model used to evaluate lead exposures in residential settings and to establish lead remedial action levels (USEPA 2007f). This model consists of four components (exposure, uptake, biokinetics, and variability) that can be adjusted based on site- or scenario-specific conditions. Through adjustments of these four components, the model estimates a distribution of BLLs for a hypothetical child or group of children.

Although IEUBK is typically used, states may specify other models. California EPA has its own biological model (LeadSpread) for evaluating childhood lead exposures. This model uses the 1 µg/dL change in BLL benchmark with other exposure and variability factors to estimate the highest soil concentration predicted to result in a 1 µg/dL change in the 90th percentile of the population of exposed children. This soil lead screening value is 80 mg/kg (California Environmental Protection Agency 2009).

5.1.5.2 Option – Model Adult Worker Exposures when Assessing Nonresidential Scenarios

USEPA's recommended approach for evaluating adult exposure to lead in soil is detailed in USEPA's *Recommendations of the Technical Review Workgroup for Lead for an Approach to Assessing Risks Associated With Adult Exposure to Lead in Soil* (USEPA 2003e). In this guidance, USEPA describes a method for assessing potential risks associated with nonresidential adult exposures to lead in soil. The method focuses on estimating fetal BLLs in women exposed to lead in soil. Rather than recommend a single soil concentration that would represent an acceptable risk for adults exposed in nonresidential settings, a range of 750 mg/kg to 1,750 mg/kg is presented; see Figure 2 of the 2003 ALM guidance (USEPA 2003a).

In 2009, USEPA published a memorandum which provided updated estimates for baseline BLLs and the geometric standard deviation using data from NHANES studies that were conducted from 1999–2004 (USEPA 2009c). As a result of these updated inputs, acceptable soil lead concentrations were revised to a range of 750 mg/kg to 2,240 mg/kg (see USEPA 2014g for additional information).

The following table presents the assumptions, inputs, and results of USEPA's current

recommended soil lead model for adults and shows the source of the acceptable soil lead concentration range noted above (USEPA 2003a). Alternative inputs or assumptions from specific agencies can also be incorporated into the model.

Table 5-2. Results of USEPA recommended soil lead model

Input	Variable	Units	USEPA (2003a) Pregnant workers		USEPA (2009b) Pregnant workers
Soil Ingestion – Model Input Values					
Gastrointestinal absorption	AF	unitless	0.12	0.12	0.12
Ingestion rate	IR	mg-soil/day	50	50	50
Exposure frequency	EF	days/year	219	219	219
Averaging time	AT	days/year	365	365	365
Typical adult blood lead concentration	PbB_0	µg-Pb/dL	2.2	1.7	1.0
Biokinetic slope factor	BKSF	µg-Pb/dL per µg-Pb/day	0.4	0.4	0.4
Geometric standard deviation	GSD	–	2.1	1.8	1.8
Ratio of fetal PbB to maternal PbB	$R_{f/m}$	unitless	0.9	0.9	0.9
Fetal blood goal, 95th percentile	PbB_{goal}	µg-Pb/dL	10.0	10.0	10.0
Soil Concentrations – Model Output Values					
Soil Pb concentrations, 95th percentile value	–	mg/kg	749	1,754	2,240

5.1.5.3 Option – Assess Child or Adult Intermittent or Variable Exposures to Lead where Applicable

USEPA's IEUBK model (USEPA 2010a) and USEPA's ALM (USEPA 2003a) are commonly used to evaluate standard residential or continuous nonresidential exposure scenarios. These models may warrant modifications when the exposures are not continuous or chronic. Such scenarios may include trespassing, recreational, and daycare exposure scenarios. In these cases, a wider variety of exposure scenarios may need to be considered (such as including exposure from more than one location, or different intensities of exposure). USEPA's *Assessing Intermittent or Variable Exposures at Lead Sites* (USEPA 2003b) provides guidance on using the IEUBK and ALM models to assess exposures using a time-weighted exposure. The guidance presents methods, assumptions, limitations and uncertainties associated with this approach, and example calculations are provided.

5.1.5.4 Option – Consult Experts in Toxicology

Should none of the potential options above help to address how to evaluate exposure to lead, the STSC (USEPA 2013h) or a professional toxicologist can be consulted.

5.2 Effects of Toxicity Value Uncertainty on Risk Management Decisions

5.2.1 Issue – Understanding Uncertainty in Toxicity Values

The decision and the response urgency can vary depending on the chemicals driving the risk estimates.

The toxicity values and uncertainty in the toxicity values vary by chemical, and project managers must understand these uncertainties when making risk management decisions. Since toxicity values and exposure estimates are used to calculate risk estimates, the specific toxicity values used in the risk assessment directly impact the risk estimates. Estimated risks or hazards that exceed agency defined target risk/hazard levels do not have the same implication at all sites. Therefore, numeric risk estimates presented in the risk assessment must be properly interpreted and understood. The decision and the response urgency can vary depending on the chemicals driving the risk estimates.

Generally, there is a higher degree of certainty in toxicity values from higher tier sources (Tier 1 versus Tier 3 sources, see Section 5.1.1.1), and a higher degree of certainty in chemical-specific versus surrogate chemical toxicity data. In addition, uncertainty factors that accompany the non-cancer toxicity values indicate the degree of confidence to which the values are considered protective of human health. For example, if the risk estimates for a site exceed agency-acceptable levels due to only one chemical, no chemical-specific toxicity values were available for that chemical, and toxicity values for a surrogate chemical were used in the risk estimates, then a high degree of uncertainty is likely present in the risk estimates.

Chemicals classified as carcinogens have chemical-specific carcinogenic potential, and the studies on which their carcinogenic classification is determined vary in quality. The USEPA has established weight-of-evidence classifications, with the most recent in (USEPA 2005b). For example, risk estimates associated with benzene may warrant a higher sense of urgency than chloroform. According to USEPA's IRIS database (USEPA 2000a):

> Benzene is a known human carcinogen based upon evidence presented in numerous occupational epidemiological studies. Significantly increased risks of leukemia, chiefly acute myelogenous leukemia (AML), have been reported in benzene-exposed workers in the chemical industry, shoemaking, and oil refineries.

Conversely, USEPA's IRIS database (USEPA 2001a) lists chloroform as a probable human carcinogen based on observations of increased incidence of cancer in mice and rats exposed to this chemical and inadequate evidence of increased cancer in humans in human epidemiological data and studies.

As another example, hazard index estimates associated with the soil ingestion pathway may warrant a higher sense of urgency for arsenic than thallium due to the large differences in uncertainty in the toxicity values for the two chemicals. The oral RfD for arsenic from the Tier 1 source (USEPA 1993a) is based on human chronic oral exposure studies and has a very low uncertainty

factor (3), whereas the oral RfD for thallium from the Tier 2 source (USEPA 2012g) is a provisional screening value based on a 90-day rat oral exposure study and has a very high uncertainty factor (3000). The PPRTV derivation document for thallium (USEPA 2012g) states the following:

> The conclusion reached in the IRIS Toxicological Review of Thallium and Compounds (USEPA 2009a) was that the available toxicity database for thallium contains studies that are generally of poor quality…However, Appendix A of this document contains Screening Values (screening subchronic and chronic p-RfD) that may be useful in certain instances.

5.2.1.1 Option – Review the Risk Characterization to Obtain Uncertainty Information for Chemicals Having the Most Influence on the Risk Estimates

The uncertainty information for the toxicity assessment can be obtained from the last step of the risk assessment (see Chapter 7), which should include the risk estimates for the site and a discussion of the overall uncertainties associated with the risk estimates. In addition, if risk estimates exceed agency-acceptable levels, a discussion of the uncertainties in the toxicity values for the risk-driving chemicals should also be presented in the risk characterization. Section 8.4.2 of USEPA's 1989 guidance (USEPA 1989a) presents the recommended types of uncertainty information to be included in the risk characterization section. Page 8-24 of the USEPA guidance (USEPA 1989a) provides a checklist of the uncertainties that apply to most toxicity assessments.

5.2.1.2 Option – Review Uncertainty Information in the Toxicity Assessment Section of the Risk Assessment

The uncertainty information for the toxicity assessment can be obtained from the toxicity assessment section of the risk assessment, which should cross-reference the specific tables containing the toxicity values for the chemicals evaluated in the risk assessment, including the weight-of-evidence classification for carcinogens and the uncertainty factors for noncarcinogenic toxicity values. When using this information, focus on the chemicals (and toxicity values, cancer classifications, and uncertainty factors) having the most influence on the risk estimates.

5.2.1.3 Option – Consult a Risk Assessor or Toxicologist

If the risk characterization and the toxicity assessment sections do not include uncertainty information associated with the toxicity of chemicals having the most influence on the risk estimates, or if it is unclear where the uncertainty information is, consult with a risk assessor or toxicologist.

Risk management decisions vary by site and chemical due to differing uncertainties in toxicity values.

5.3 Resources and Tools

The following resources and tools were not cited in the sections above and are included here for further information.

Concise International Chemical Assessment Documents, World Health Organization, International Programme on Chemical Safety (WHO 2013)

Maximum Permissible Risk, Netherlands National Institute for Public Health and the Environment, Ministry of Health, Welfare and Sport, (Netherlands National Institute for Public Health and the Environment 2013)

Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors, (Health Canada 2010)

Reference Dose (RfD): Description and Use in Health Risk Assessments, Integrated Risk Information System (IRIS) (USEPA 1993c)

6.0 EXPOSURE ASSESSMENT

Differences in how risk assessments are conducted under various state regulatory programs that oversee site cleanup can result in significant variation in outcomes (ITRC 2008). Additionally, differences in how exposure assessments are conducted, and how key issues related to the exposure assessment are handled in different jurisdictions can result in varied outcomes. This chapter provides guidance on key issues associated with quantifying exposure during the exposure assessment and provides options for addressing each key issue. The key issues are organized around two general topic areas:

Determining Appropriate Exposure Factors

- Justifying Site-Specific Exposure Factors
- Exposure Factors Which May Warrant Prorating
- Accounting for Bioavailability

Estimating Exposure

- Exposure Areas are Often Not Representative of Actual Exposure Patterns
- Selection of Measured Versus Modeled Exposure Concentrations
- Fate and Transport Models are Sometimes Overly Conservative
- Uncertainty When Estimating the Exposure Concentration from Measurements
- Estimating Site-Specific Exposure Concentration Versus Background Concentration

In the planning stages of the risk assessment (prior to beginning a site investigation), a preliminary CSM is developed. The CSM provides a basis for the risk assessment (for example, which receptor and exposure scenarios are relevant). As a result, the preliminary CSM can be an extremely useful tool to support decisions on data collection and sampling (what to look for, where, and why). As data and information are gathered during the site investigation process, the CSM (see Section 3.2.4) should be reviewed and updated as appropriate. The scenarios for potential human exposure that are evaluated in the exposure assessment should be consistent with the CSM.

6.1 Determining Appropriate Exposure Factors

The performance of the exposure assessment involves (1) identifying potential receptors and exposure populations; (2) identifying current and future exposure scenarios for each receptor; and (3) quantifying the magnitude, duration, and frequency of exposure for each receptor under each exposure scenario. Quantifying exposure involves two elements: (1) determining appropriate exposure factors to use in

Chemical exposure calculations use simple algebraic equations along with exposure factors that describe how individuals interact with their environment.

calculating chemical intake by a receptor and (2) estimating exposure concentrations to use for each receptor in the chemical intake calculation (USEPA 1989a).

In most cases, a set of relatively simple algebraic equations are used to estimate chemical intake by a receptor, with exposure factors (for example, exposure time, exposure frequency, exposure duration, body weight, and averaging time) describing how individuals interact with their environment. Exposures for the ingestion and dermal exposure pathways are typically quantified in terms of a dose (mass of chemical per unit body weight per unit time, for example, mg/kg-day) (USEPA 1989a).

Exposure via inhalation is estimated by calculating a time-weighted average air concentration (for example, mg/m^3) for each receptor. More specifically, inhalation exposure concentration (EC) is expressed as an air concentration that is time-weighted over the duration of exposure for the receptor, reflecting the activity patterns of the specific receptor (USEPA 2009a).

Determining the appropriate values to use for each exposure factor (such as exposure time, exposure frequency, and exposure duration) in a dose or exposure concentration equation can be complex, since in reality each of these exposure factors is not represented by a single value. These factors are most appropriately represented by a distribution of possible values because different individuals in the potentially exposed population will be exposed to varying degrees and for different periods of time. The range of values and the likelihood of any given value are characteristic of the behavior of different receptors.

Examples: Residential Drinking Water Exposure Scenario

For example, consider a residential drinking water exposure scenario. In order to estimate the amount of exposure to a particular chemical that a given resident might incur, the exposure duration must be determined (for example, years of exposure). Specifically, this exposure factor represents an estimate for how long people tend to live in one home before moving. According to USEPA (1997b), the 50th percentile (the median) is 9 years and the 95th percentile is 33 years (Figure 6-1).

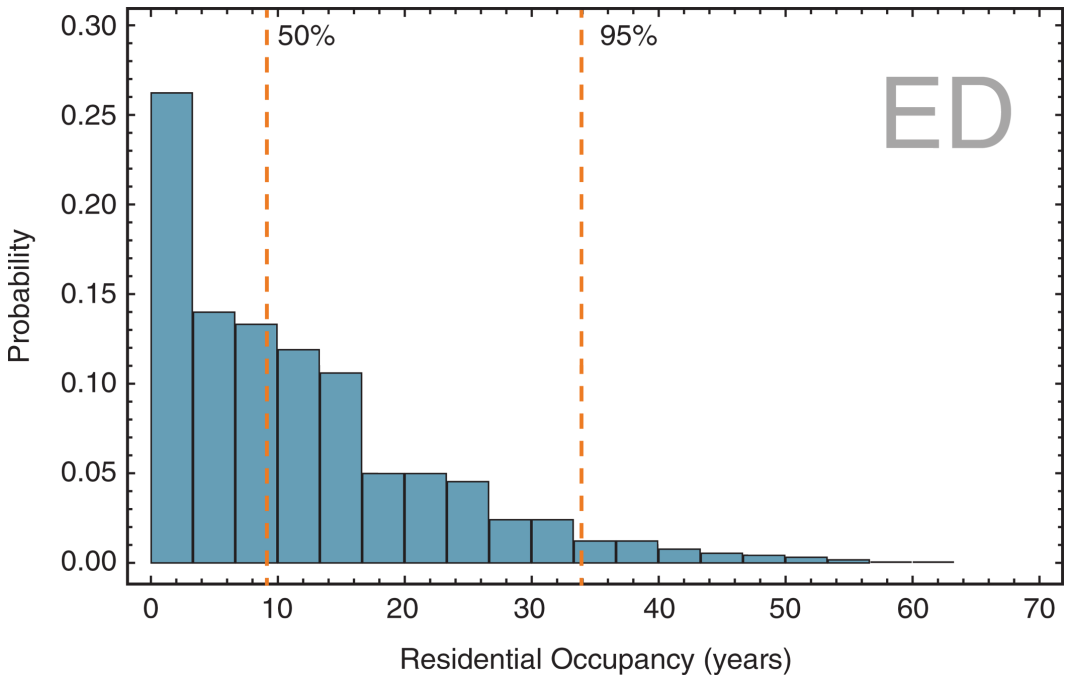

Figure 6-1. Probabilities of time spent living at one residence (exposure duration).

As with exposure duration, ingestion rate (L/day normalized by body weight) and exposure frequency (days/year) can also be appropriately represented by possible ranges of values rather than by single values (Figure 6-2 and Figure 6-3).

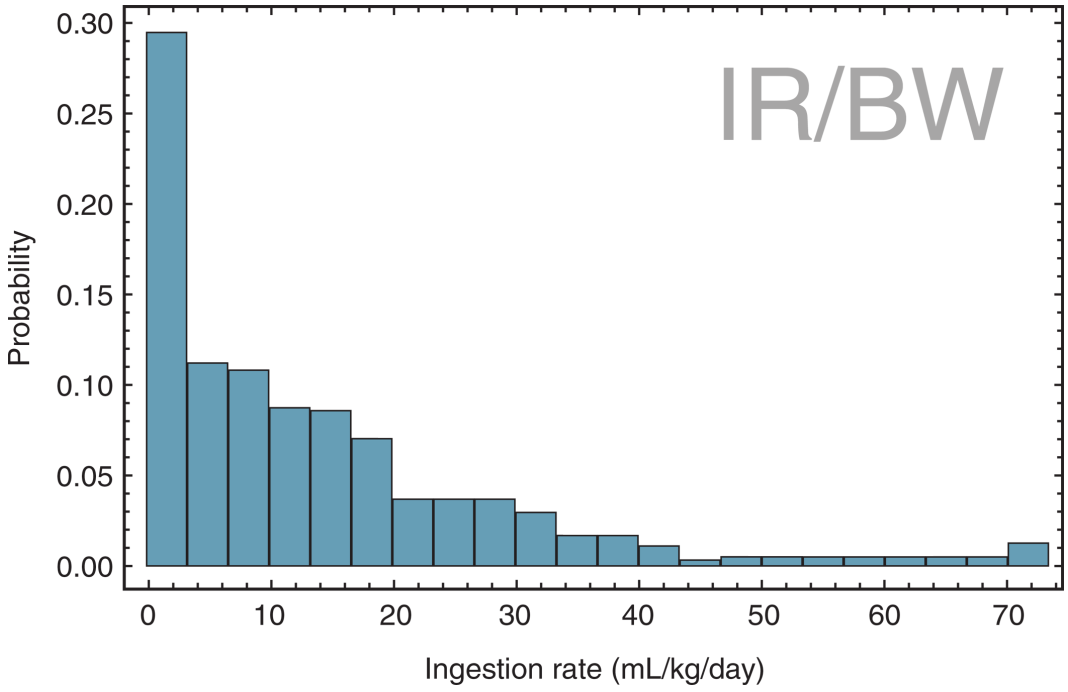

Figure 6-2. Drinking water ingestion rate probabilities (normalized by body weight).

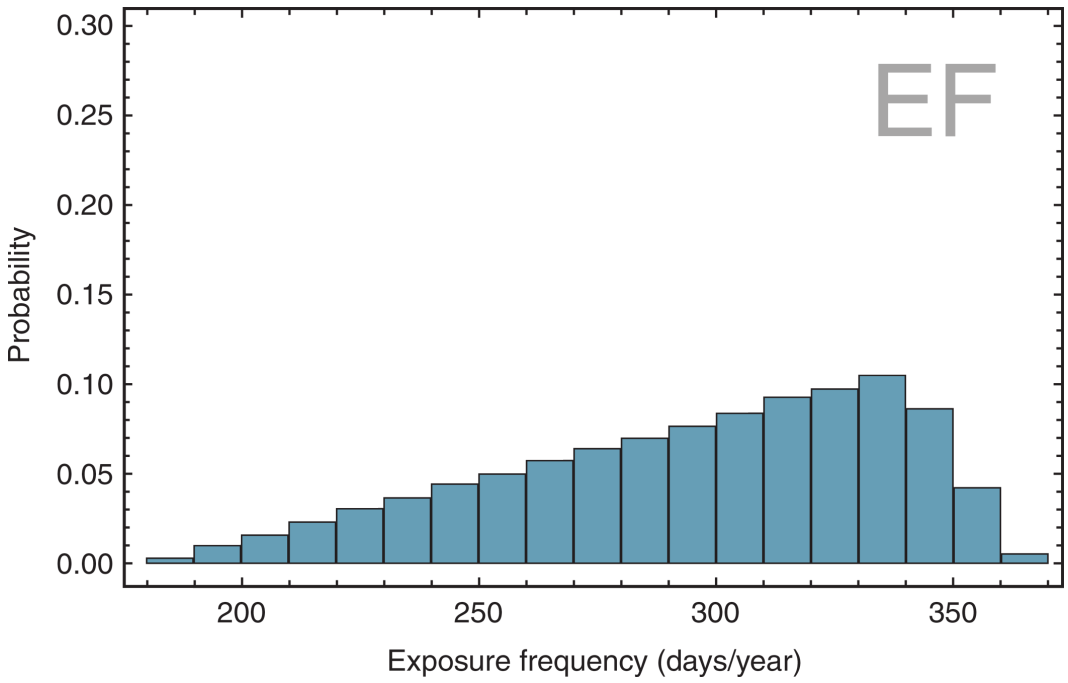

Figure 6-3. Exposure frequency probabilities.

These examples show that any exposure factor can be represented by many possible values covering a broad range (a distribution). As a result, quantifying a particular exposure for a potentially exposed receptor population does not yield a single result. The actual exposure (or intake) can be represented by a distribution of possible values, each with a different probability. This probabilistic analysis of environmental data can be performed using a Monte Carlo simulation.

Any exposure factor can be represented by a range or distribution of possible values each with a different likelihood (or probability).

Example: Distribution Calculation – Monte Carlo Simulation

Continuing with the drinking water exposure scenario as an example, the distribution for the lifetime average daily dose (LADD) can be determined using the distributions above for ingestion rate (normalized by body weight), exposure frequency, and exposure duration. The resulting distribution for the exposure is shown in Figure 6-4.

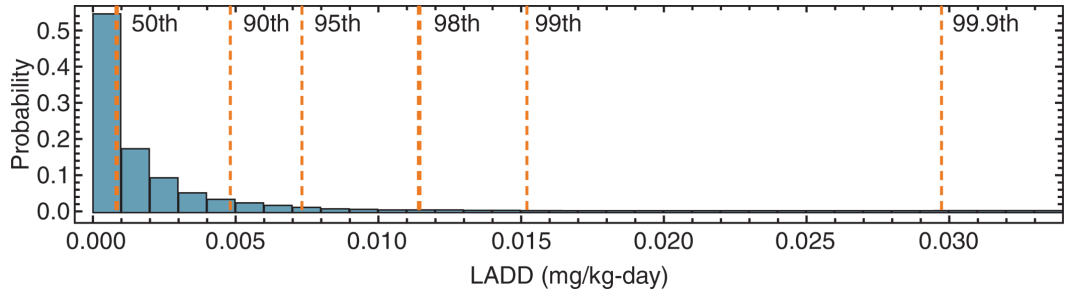

Figure 6-4. Drinking water exposure distribution for LADD.

While exposure factors are represented most realistically as distributions rather than single numbers, for simplicity most exposure assessments use single values (a point estimate) from the distribution or range of possible values for each exposure factor. In some cases, these single values are often selected by regulatory agencies (typically referred to as "default exposure factors") to produce an overall estimate of exposure that is at the higher end of the range of plausible exposures—an approach that is used to ensure that the resulting exposure assessment would be protective of human health. This higher end of the plausible range of exposure is typically referred to as the "reasonable maximum exposure." The reasonable maximum exposure (or RME) can be defined as "the highest exposure that is reasonably expected to occur at a site" (USEPA 1989a). More specifically, USEPA defines the RME as an exposure that falls within the 90th percentile to 98th percentile (USEPA 1992c); see Figure 6-5.

While exposure factors are not represented by single numbers, most risk assessments use single values selected individually. Together, these values produce an estimate of exposure that is at the higher end of the range of plausible exposure values and ensure that the risk assessment is protective.

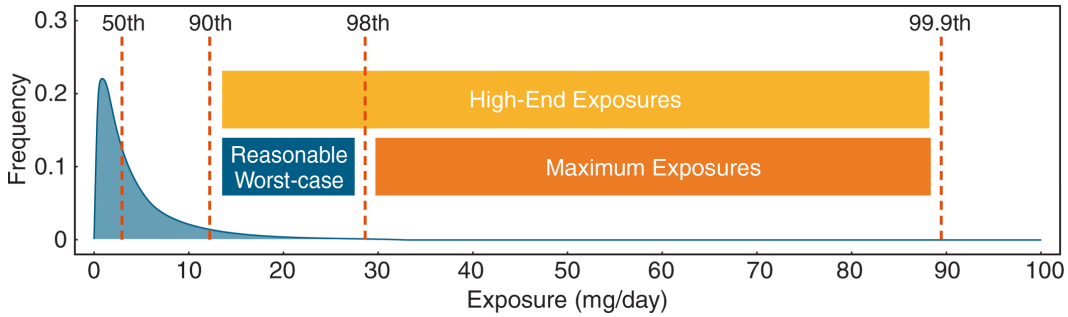

Figure 6-5. Reasonable maximum exposure.

The following sections discuss key issues encountered when determining appropriate exposure factors to use in calculating chemical exposure for a receptor. Options for addressing these issues are provided.

6.1.1 Issue – Justifying Site-Specific Exposure Factors

The RME of a given receptor to chemicals by a particular pathway can be defined as "the maximum exposure that is reasonably expected to occur within a potentially exposed population." USEPA notes that each exposure factor used to estimate the RME should be selected so that the resulting estimate of exposure is consistent with the higher end of the range of plausible exposures (USEPA 1991d). This approach does not require that the value of each exposure factor used in the calculation of chemical exposure be an upper percentile value (a value from the upper end of the possible range, such as the 90th or 95th percentile). More importantly, if

If high-end values are chosen for every exposure factor, the resulting exposure estimate may not fall within the range of plausible exposures.

high-end values are chosen for every exposure factor, then the resulting exposure estimate may no longer be consistent with the RME and may exceed the realm of possibility altogether.

USEPA's earliest risk assessment guidance document, *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual, Supplemental Guidance, Standard Default Exposure Factors* (USEPA 1991d) recommended default exposure factors for residents and commercial/industrial workers based on the RME concept. Because these receptors tend to be evaluated in many risk assessments, the default exposure factors provided in this guidance have become standard in the risk assessments performed under the jurisdiction of the USEPA and many state regulatory agencies. Default values are often used, even when recent research indicates that some exposure factors are no longer reflective of current population statistics (for example, body weight). USEPA (2011c) has provided recent research on human behaviors and characteristics. In 2014, USEPA updated the standard default exposure factors for use in evaluating human health risks at Superfund sites (USEPA 2014e; USEPA 2014h). Many of these factors reflect the more recent information and recommendations provided in USEPA's *Exposure Factors Handbook* (USEPA 2011c).

For receptor scenarios that are less frequently evaluated, certain default exposure factors (such as generic soil ingestion rates) are used in combination with other exposure factors that are based on site-specific or scenario-specific considerations (such as site-specific and receptor-specific exposure frequency and exposure duration). In these cases, the risk assessor must demonstrate that using site-specific exposure factors results in an overall exposure estimate that is still consistent with the concept of RME for the receptor scenario. Demonstration requirements can vary depending on the jurisdiction and individual regulatory agency. Some site-specific exposure factors may be justifiable based on professional judgment, while others may require more detailed study, supporting data, and analysis. The summary data on human behaviors and characteristics that affect exposure to chemicals in the environment as presented in the *Exposure Factors Handbook* (USEPA 1997b; USEPA 2011c) are useful in determining and supporting site-specific exposure factors.

Many risk assessments require the evaluation of exposure for receptors which are not typically encountered because default exposure factors have not been established.

Consider whether using default exposure factors results in the calculation of RMEs that reflect the receptors and exposure pathways that are both currently occurring and that could reasonably occur (or be anticipated to occur) in the future. Many regulatory agencies prefer the use of default exposure factors when possible to ensure consistency in the management of potential health risks from site to site. Many risk assessments, however, require the estimation of exposure for receptors or exposure scenarios that are not routinely encountered. In these cases, default exposure factors may not be established. Site-specific factors may be used when default exposure factors are inconsistent with current and reasonably anticipated future receptors, and exposure pathways or default exposure factors are not available. The following sections provide options that can be used to justify the use of site-specific exposure factors.

6.1.1.1 Option – Collect Information to Justify Site-Specific Exposure Factors

Site-specific exposure factors can be developed by collecting information relevant to the behaviors and activities patterns of current and potential occupants of a site. Surveys can provide information regarding these patterns of potentially exposed receptors and can be performed during the site investigation process. Several methods can be used to perform surveys, including activity diaries and questionnaires (USEPA 1992c). Information can also be collected for site-specific activities from sources such as standard construction practices documentation or interviews with workers or other occupants of a site.

Activity diaries are used to gather specific information and data on the activity patterns of individual types of receptors, since they provide a sequential record of a person's activities during specific periods of time. Typically these types of surveys can be performed over days or weeks. The individuals participating in the activity diary survey report all of their activities and locations for the period of the survey. When numerous participants are surveyed, forms must be carefully crafted for consistently tracking time and activities so that data generated by each individual is comparable.

Questionnaires can also be used to collect basic data regarding the activity patterns of individuals. The design of questionnaires can be a complex and detailed process and may require the help of professionals well-versed in survey techniques (USEPA 1992c).

The information gained from survey studies such as activity diaries or questionnaires can be used either to develop site-specific exposure factors or to provide technical justification for site-specific exposure factors already developed. The use of a survey, however, and the information to be requested in the survey should be discussed in advance with the regulatory agency and other stakeholders so that the data generated will be acceptable in the risk assessment. Additional discussion regarding the use of surveys can be found in Section 4.3.1 of USEPA's Guidelines for Exposure Assessment (USEPA 1992c). Additional guidelines and information on survey techniques is provided in USEPA's Survey Management Handbook (USEPA 1984).

6.1.1.2 Option – Using Institutional Controls or Engineering Controls to Justify Use of Site-Specific Exposure Factors

Most risk-based regulatory programs have provisions that allow for use of site-specific exposure factors, but using these assumptions can require institutional controls or engineering controls to ensure that the assumptions regarding exposure are maintained in the future.

Institutional controls (for example, deed restrictions or restrictive covenants) are legally binding and help to minimize the potential for exposure and protect the integrity of a risk management action (USEPA 2012d). Institutional controls generally require the landowner or operator either to refrain from using land in a certain way or to proactively maintain and use the land only in a certain way (for example, disallowing residential land use, disallowing the use of groundwater for potable purposes, or maintaining an asphalt surface). Deed restrictions and restrictive covenants are also typically recorded with local land records.

Institutional controls help to ensure that assumed land uses and specific assumptions regarding exposure (site-specific exposure factors) are maintained and are consistent with the future use of the site.

Example: Using Institutional Controls to Justify Site-Specific Exposure Factors in a Commercial Facility

Consider a risk assessment in which indoor vapor intrusion exposure is evaluated as a current and reasonably expected exposure scenario. Assume that the occupied building in question is a commercial facility with two floors and a subgrade basement.

Currently, operations in this commercial building are mostly performed on the first floor and second floor, while the basement is only used for storage and utilities. Workers spend little time in the basement (generally no worker spends more than 1 hour each week in the basement). The risk assessment is performed assuming that the exposure time (ET) of any worker in the basement is 1 hour/week. The risk assessment also assumes that workers could be present in the first and second floor of this building for 40 hours/week. Vapor intrusion related exposure concentrations, in each of these exposure units (specifically, the basement and the first/second floor), are evaluated and the associated risks are shown to be acceptable. However, the conservative risk estimates for a worker's exposure within the basement exposure unit are only 10 times below the acceptable risk management goal.

While the risk assessment demonstrates that current risks are acceptable given the described exposure conditions, in the future, if workers spend more time the basement (for example, 10 hours/week), then potential vapor intrusion exposure may exceed acceptable levels. In this case, an institutional control mandating that access to the basement be controlled to less than 10 hours/week could be used to support and justify the site-specific exposure factor used in the risk assessment. This approach would also provide assurances that acceptable risks are maintained in the future.

6.1.1.3 Option – Use Probabilistic Exposure Assessment to Justify Site-Specific Exposure Factors

Probabilistic exposure assessment is also a tool that can be used to support and justify site-specific exposure factors. As shown in Figure 6-5, RME represents exposures that would be at the high-end of the range of plausible exposures (within the 90th percentile to the 98th percentile exposure) (USEPA 1992c).

Probabilistic analysis can be used to define the range of RME (90th–98th percentile exposure). Then, if the "point values" used for each exposure factor can be shown to result in an estimate of exposure that falls within this range, the values can be justified as conservative yet reasonable exposure factors.

Developing probabilistic distributions for each individual exposure factor, for example using the data and information provided in the USEPA's*Exposure Factors Handbook* (USEPA 2011c), and then combining these distributions using Monte Carlo simulation as explained in Section 6.1, provides a way to understand the range and likelihood of possible exposures (see Figure 6-4 above). In particular, this method can be used to determine the exposure concentrations that would fall inside the RME range (between the 90th to 98th percentiles).

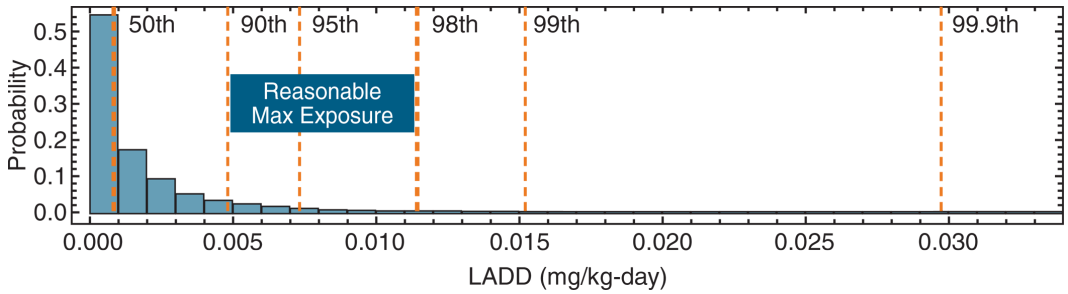

Figure 6-6. RME for residential drinking water exposure scenario.

As illustrated in Figure 6-6, the RME for residential drinking water would fall between about 0.005 mg/kg-day and about 0.012 mg/kg-day (based on a constant concentration of 1 mg/L in drinking water).

Example: Using Probabilistic Exposure Assessment to Justify a Site-Specific Drinking Water Exposure Factor

Consider the equation used to estimate the LADD for drinking water exposure. Assuming a constant chemical concentration of 1 mg/L and an averaging time equal to 70 years, point values for the remaining exposure factors can be justified by ensuring that they would result in a combined exposure that would fall inside the RME range noted above. For example, using generic default assumptions for an adult for ingestion rate (IR) = 2 L/day, exposure frequency (EF) = 350 days/year, exposure duration (ED) = 30 years, and body weight (BW) = 70 kg, would yield a LADD of 0.0117 mg/kg-day. This value falls at the top of the 0.005- 0.012 mg/kg-day RME range detailed above. Thus, the individual point values used for each exposure factor can be justified

since, taken together, they yield an exposure that would represent an RME. Drinking water exposure is presented here as an example, because the exposure factors above are generic and routinely used in evaluating such exposures. A similar analysis and approach can be used to justify site-specific exposure factors when nonroutine exposure scenarios are encountered.

Probabilistic exposure assessment (USEPA 2001c) is infrequently used in risk assessment and may not be appropriate for all analyses. One limitation that may be encountered is whether data are available for exposure factors in order to develop the distributions similar to those shown in Figure 6-1 to Figure 6-3. Further information on probabilistic risk assessment for site risk assessments is available from USEPA (2001c). Another guidance document, *A Review Article of Probabilistic Risk Assessment of Contaminated Land*, defines remedial action objectives using probabilistic methods for the Superfund program (Oberg and Bergback 2013).

6.1.2 Issue – Exposure Factors Which May Warrant Prorating

Many exposure factors that are based on rates of intake, such as incidental soil ingestion rates and incidental groundwater ingestion rates during swimming, are typically treated as "event driven" processes. For these factors, the amount of time on a given day when an event (for instance, soil ingestion) occurs or does not occur is usually not accounted for in the selection of the value to be used as the exposure factor. As a result, prorating such exposure factors to account for this issue may be warranted.

For soil ingestion, it would be logical to assume that the soil ingested by an individual on any given day (for example, 50 mg/day) comes from the various places that individual visited during the entire day (for example, home, workplace, school). Studies of incidental soil ingestion by humans, however, only provide information on the total amount of soil consumed in a given day. These studies do not provide relative amounts of soil ingested from different locations visited by an individual in a given day. As such, prorating exposure factors to account for these considerations may be warranted on a site-specific basis.

6.1.2.1 Option – Prorating Exposure Factors or Using a Fraction Contacted Exposure Factor

Prorating soil ingestion rates is appropriate on sites where multiple, separate exposure areas (or units) exist. If a worker is likely to spend equal time in each of these areas, then using a standard default soil ingestion rate as an exposure factor for each exposure area could greatly overestimate the worker's total exposure and associated risk. In this instance, it would be appropriate to prorate the daily soil ingestion rate (for example, 50 mg/day) across the multiple areas of exposure (for example, exposed to Area 1 50% of the time, Area 2 25% of the time, and Area 3 25% of the time). Thus, the worker's total daily soil ingestion would still equal the default value soil ingestion value (25 mg/day + 12.5 mg/day +12.5 mg/day = 50 mg/day), but that value would be assumed to come from multiple areas within the site, each with potentially different degrees of contamination. Use of a fraction contacted (FC) exposure factor in evaluating the dose for each unique exposure area facilitates this approach.

With the proration of exposure factors, some regulatory programs may require institutional or engineering controls so that the final assumed exposure factors used in the exposure assessment are consistent with future land uses. For example, if it is assumed that a worker is exposed evenly to two different areas of a site, and the exposure assessment prorates the soil ingestion amount evenly between these two areas (for example, 25 mg/day and 25 mg/day), then the exposure assessment may not be protective when a worker is exposed to one of the areas for a greater period of time (for example, 75% in Area 1 and 25% in Area 2).

Using an FC exposure factor allows for the exposure assessment to account for situations when only a portion of a receptor's total daily exposure would result from a given area.

6.1.3 Issue – Accounting for Bioavailability

An assumption of 100% bioavailability can lead to an overestimate of the exposure and thus risk to human health, particularly in the case of metals. According to USEPA, "metals can exist in a variety of chemical and physical forms, and not all forms of a given metal are absorbed" equally (USEPA 2007c). Toxicity values are generally expressed in terms of ingested dose (rather than absorbed dose); therefore, potential differences in absorption efficiency between different environmental media must be accounted for in evaluating site risks.

An assumption of 100% bioavailability can overestimate the exposure.

6.1.3.1 Option – Incorporate a Bioavailability Factor into the Exposure Equation

Where site-specific or media-specific data on bioavailability are known, the chemical exposure calculation (the potential dose) can be converted to an applied dose and internal dose by adding a bioavailability exposure factor (range: 0 to 1) to the dose equation.

The bioavailability factor should take into account: (1) the ability of the chemical to be extracted from the environmental medium (for example, soil); (2) the ability of the chemical to be absorbed into the body; and (3) other losses between ingestion and contact with the lung or gastrointestinal tract. When no data or information are available to indicate otherwise, the bioavailability factor is usually assumed to be 1 (USEPA 1992c). For example, ingestion of a metal adhered to soil may result in less absorption through the gastrointestinal tract than would occur if the metal were ingested in water or food. In this scenario, use of toxicity values (for example, oral reference dose or slope factor) that were derived based on exposures to the metal in water or food would likely overestimate the calculated risks from ingestion of the metal in soil. USEPA (2007c)

Add a bioavailability factor to the dose equation. A bioavailability factor of 1 is usually assumed where no data or information are available.

has published guidance on evaluating the bioavailability of metals in soil, specifically with regards human health risk assessment. USEPA has also published specific guidance for lead and arsenic, accounting for their relative bioavailability by including a bioavailability exposure factor (USEPA 2007c; USEPA 2007a; USEPA 2009d; USEPA 2012h).

6.2 Estimating Exposure

Many available guidance documents discuss how to develop, refine, and use the concentration in the exposure equation of the risk assessment for risk management decision making at contaminated sites. Many risk assessments, however, use only default approaches to establish the concentration. Too often, these default approaches are irrelevant at a given site because of uncertainties in current or future uses, limits on site data collection, or a lack of information about the nature and extent of the distribution of chemicals in environmental media.

The concentration in the exposure equation is intended to be the average concentration (typically the 95% UCL on the mean) contacted by the receptor. This concentration should ideally represent the average concentration over the exposure area (space) and throughout the exposure period (time). In practice, however, only one or two statistical methods are used to calculate this average concentration, thus other equally plausible (and in some situations more appropriate) alternatives are either overlooked or unduly scrutinized. The following sections identify a few of the more common issues associated with calculating the exposure concentration and some options to overcome these issues.

6.2.1 Issue – Exposure Areas are Often Not Representative of Actual Exposure Patterns

Default exposure areas often are not conducive to evaluating potential exposures, because these predefined exposures areas were established based on release history rather than potential human exposures.

One key issue inherent in the exposure assessment is identifying the appropriate area for evaluating risks for current and potential exposure. In many instances, exposure areas are based on default half-acre lot sizes (for residential exposures), operational units or areas of concern designations, or some other investigational area designation and are not based upon the areas where exposure is likely to occur. Establishing a common understanding of how the risk assessment will be used, as well as the spatial and temporal limitations inherent in the assessment, aids in understanding and communicating the assessment results (NRC 2009). If the quantitative aspects of the exposure assessment (for example, the use of half-acre parcels for residential exposure areas) are inconsistent with the qualitative description of exposures (for example, a residential receptor is expected to be exposed to chemicals in environmental media throughout a multi-acre site as part of a housing development rather than an individual half-acre parcel), then understanding how to use and explain the results becomes challenging. This disconnect between how the exposure assessment was performed (quantitative aspect) and the general understanding of what exposures can occur (qualitative aspect) can be particularly obvious at sites where future uses are unknown.

The following sections describe two options for using default exposure areas to ensure consistency between the CSM and the calculations and inputs used in the exposure assessment, while still maintaining the flexibility to evaluate multiple future site conditions. The examples provided below can be applied to other situations or calculations.

6.2.1.1 Option – Establish Exposure Areas Based on Known or Anticipated Uses

When quantitatively evaluating exposure to chemicals in environmental media at a site as part of the risk assessment, consider the spatial distribution of chemical concentrations relative to the exposure scenario being evaluated. Assuming that potential exposure of receptors to chemicals can occur at any depth throughout the entirety of the site or investigation area may overlook alternatives to laterally or vertically refining the exposure area.

In general, exposure areas in the risk assessment should be based on the exposure scenarios defined in the CSM, and not on the investigational areas.

Such refinements could include:

1. Using different lateral exposure areas based on an understanding of differing activity patterns of different receptors at a site (for example, residents would be exposed only over half-acre areas, whereas construction workers would be exposed over the entire area).
2. Using different vertical exposures units that are relevant to the exposure scenario or pathway being assessed. For example, residential incidental ingestion, dermal contact, and particulate inhalation exposure to soil would commonly involve only contact with chemicals in surface soil, whereas construction workers or maintenance workers could be potentially exposed to chemicals in surface and subsurface soil (USEPA 1989a).

Establishing exposure areas that are designed to evaluate potential exposures is critical to understanding, using, and communicating the results of the risk assessment. Similarly, understanding inherent limitations of a risk assessment that results from the exposure areas evaluated is equally important to using and communicating the results in decision making. For example, risks calculated for a half-acre residential area many not be relevant if the area is further subdivided into smaller residential parcels in the future.

In general, exposure areas in the risk assessment should be based on the exposure scenarios defined in the CSM, and not on the investigational areas. Defining exposure areas based on activity patterns generally requires additional information on potential uses. The additional data are used to support the assumptions regarding potential uses and to support decisions made in calculating the average concentration.

6.2.1.2 Option – When Exposure Areas Cannot be Reasonably Established

Considering the spatial distribution of chemical concentrations relative to the exposure scenario is important in the exposure assessment, however, in cases where redevelopment is possible, information on the location and type of activities is not available. In these cases, certain exposure assessments might evaluate receptors by assuming equal likelihood of exposure across the entire site, or the assessment may be performed by comparing individual data points to cleanup criteria (for example, preliminary remediation goals). While these approaches may be conservative for some sites, they are not conservative for all.

When information on the location and type of future activities is not available, an alternative to the common approaches discussed above is to initially perform the exposure assessment using conservative assumptions regarding the size of hypothetical exposure areas for a given receptor. For example, start by assuming that every sampled location represents its own exposure area in which receptors will be exposed for their entire exposure frequency and exposure duration. This approach is analogous to comparing data to screening values and does not rely on areas that were identified based on historical releases or investigation to dictate future uses. Additionally, the initial definition of exposure areas based on activity patterns is not required. To illustrate this concept, the polygons on Figure 6-7 represent hypothetical exposure areas represented by each soil sample (specifically, each polygon is a hypothetical exposure area represented by the individual sample location).

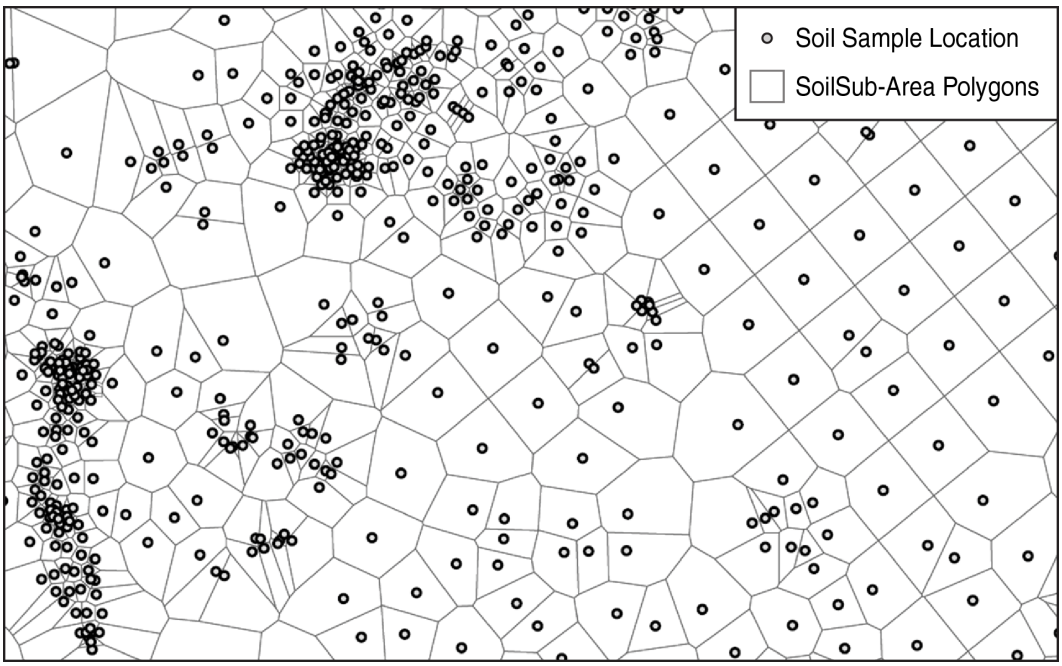

Figure 6-7. Soil sampling locations as individual exposure areas (represented by Thiessen polygons).

If the risks at each location are acceptable, then the risk assessment could conclude that the area represented by the boring location does not pose an unacceptable risk, regardless of how an actual

future exposure area is eventually defined. Conversely, if the risks at certain locations are not acceptable, more realistic hypothetical exposure areas could be formed (for example, areas that consist of the initial location and adjoining locations to obtain a reasonable area where exposures could occur) to determine whether additional action would be warranted (Figure 6-8). Overall, this approach can help streamline the risk assessment by limiting the area over which difficult decisions regarding potential future activity patterns must be made.

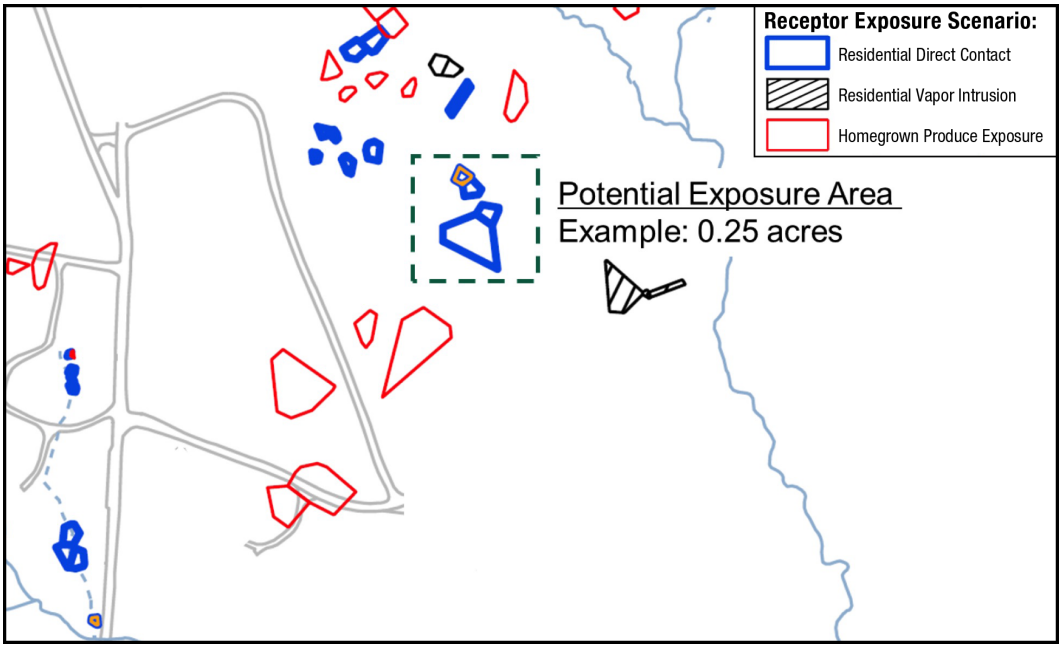

Figure 6-8. Locations potentially warranting further assessment or risk management.

6.2.2 Issue – Selection of Measured Versus Modeled Exposure Concentrations

EPC should be selected as representative of the concentration over the exposure duration.

In order to evaluate exposure, estimates of concentrations of chemicals in the environment to which receptors could be exposed, called EPCs, are needed. In many situations, EPCs can be based on measured concentrations of chemicals. Measured concentrations can provide good estimates of current EPCs, but they can also misrepresent EPCs over a long period of time (for example, over years or decades). For example, volatile chemical concentrations may change over time due to natural processes such as volatilization to ambient air or leaching to groundwater. As a result, using the concentration measured today would not represent the average concentration to which a receptor could come into contact with over an extended period of time. As a result, the risk estimates based upon these concentrations could overestimate risks. In some instances, it may not be appropriate to use measured concentrations, and models may be required to estimate EPCs.

Determining whether measured or modeled concentrations of chemicals are appropriate to determine EPCs depends on whether the measured concentrations of chemicals reasonably characterize the average concentration to which receptors will be exposed during their entire exposure period. The following sections offer some options for addressing this issue.

6.2.2.1 Option – Using Measured Data for the EPC

Measured concentrations may be helpful in characterizing the current average concentrations to which receptors will be exposed. In some cases, measured concentrations can be conservative estimates of future conditions (for example, current concentrations in soil versus future concentrations following leaching or volatilization) and may be appropriate for evaluating future receptors, especially when these conservative estimates of cumulative risk are acceptable.

Using measured concentrations to estimate current EPCs is generally appropriate when exposure of a receptor involves direct contact with the medium (for example, direct exposure to chemicals in soil). Using measured concentrations is also generally appropriate when site monitoring data were collected directly at an exposure point (for example, a drinking water well or indoor air) (USEPA 1989a).

Measured concentrations may not be appropriate when concentrations measured over a short period are used to characterize a long-term exposure. For example, indoor air concentrations, obtained from a discrete sample collected over a relatively short period of time, would not be appropriate as the EPCs in a risk assessment evaluating chronic indoor exposure (25 or 30 years of exposure). These EPCs could overestimate or underestimate risks, since the measured concentrations over a short period (for example, 24 hours) generally do not characterize the long-term average exposure concentration. While the collection of samples over a longer period of time may help in understanding the variability in potential exposure with time, in many cases modeling EPCs may be more appropriate for long-term exposures.

6.2.2.2 Option – Using Modeled Exposure Concentrations for Determining the EPC

While measured concentrations of chemicals to determine the EPC may be helpful in understanding current conditions, these concentrations may not predict EPC over the entire exposure period (for example, use of short-duration indoor air monitoring data to evaluate and make decisions regarding long-term chronic vapor intrusion exposures).

Using modeled concentrations of chemicals to determine the EPC is useful for estimating future and long-term exposures to chemical concentrations in environmental media. EPCs derived from modeled concentrations can also be useful for estimating current or future EPCs in environmental media in areas where existing measured concentrations are unavailable (USEPA 1989a) or where measurements cannot be collected (for example, to evaluate vapor intrusion exposure into a future building). Finally, modeling concentrations can be used in conjunction with available site data from the source medium to estimate the change in concentrations over the exposure period (USEPA

1989a) for chemicals that degrade in the environment (for example, anaerobic dechlorination of tetrachloroethene in groundwater) or deplete over time (for example, volatilization from soil or leaching from soil to groundwater).

Specific instances where EPCs derived from modeled concentrations could be considered include the following:

- when the exposure being evaluated will occur in the future (for example, on- or off-site ambient air, off-site groundwater)
- when data regarding the change in chemical concentration over time is unavailable or lacking (for example, situations when chemical concentrations could change with time or when the collection of discrete samples over short periods of time can capture the potential variability in concentration over a longer period)
- when the collection of direct measurements would not be possible (for example, vapor intrusion sampling in areas where buildings do not currently exist but are planned in the future)
- when using measured concentrations is limited by the laboratory detection limit (for example, to predict concentrations of chemicals that may be present below quantitation limits, but which could still cause unacceptable site-related exposures)

Appendix C provides a list of models routinely used to calculate EPCs for different exposure scenarios and exposure pathways. The basis, derivations, details, assumptions, and limitations of these models are not discussed in this document, however, references and links to additional guidance are provided for each model.

6.2.3 Issue – Fate and Transport Models are Sometimes Overly Conservative

Fate and transport models used to evaluate exposure often assume an infinite mass of chemicals when the actual mass of chemicals is finite. In these cases, there may not be enough mass to sustain the calculated exposure concentration over time. Methods are available to check whether or not the conservation of mass principles is violated.

One potential issue inherent in many exposure assessments is that many of the fate and transport models commonly used to estimate exposure concentrations do not account for limited mass of a chemical. In many instances, initial exposure estimates are based upon models that assume infinite source mass (for example, the mass of chemicals never depletes, despite being volatile or soluble). Many of the simple models used to evaluate exposure (such as inhalation of vapors and leaching from soil into groundwater) may violate the law of mass conservation for certain chemicals, such as volatile organic compounds (VOCs) (USEPA 1996b). In these cases, a finite source of chemical is recognized to have the potential to deplete over time as the chemical mass moves (or is transformed) in the environment, migrating away from the source to the receptor. For small sources, it may not be possible to maintain the exposure concentration over the duration of exposure, and the resulting exposure estimate using an infinite mass assumption may not be reasonable or possible. This result is particularly important for

VOCs when they are assumed to volatilize or leach from a finite source. For chemicals that are relatively persistent and immobile in a specific media, however, steady-state assumptions may be practical for evaluating fate and transport (for example, assuming that such chemicals would not deplete significantly and thus could be treated as an infinite source).

The following subsections describe two options to address this issue.

6.2.3.1 Option – Use a Finite-Source Model

Using a finite-source modeling approach generally requires chemical concentrations to be well defined, which may require additional field information as compared to a standard, infinite source model. The additional field data are generally used to support necessary assumptions for finite mass calculations, for example, defining the vertical extent of volatile chemicals in vadose zone soil.

An example of a finite model used for outdoor inhalation exposure due to volatilization of chemicals from soil is the Jury model to estimate vapor flux from a finite soil source (Jury, Spencer, and Farmer 1983). This volatilization model estimates the flux of a chemical from either an infinite (the default approach used in calculating most criteria) or a finite soil source (USEPA 1996b). The finite source equations are shown in Section 3.1.1 of USEPA's 1996 Soil Screening Guidance Technical Background Document (USEPA 1996b) The EMSOFT screening model is also available (USEPA 2002b), which is based on the work of (Jury, Spencer, and Farmer 1983).This program may be used to:

1. Determine concentrations of chemicals remaining in the soil over a given duration.
2. Quantify the mass flux (rate of transfer) of chemicals into the atmosphere over time.
3. Calculate chemical concentrations in air by inputting the mass flux values into atmospheric dispersion models (USEPA 2002b).

6.2.3.2 Option – Use a Mass Balance Check

The results from infinite source models in some cases (for example, equilibrium partitioning for chemical migration from soil to groundwater) can violate mass balance considerations (USEPA 1996c). To address this issue, incorporate a mass balance check when estimating the finite chemical mass that can infiltrate into groundwater. A mass balance check in the evaluation of soil migration to groundwater verifies that the assumed mass of a chemical migrating to groundwater over the assumed exposure period does not exceed an upper-bound estimate of the chemical's mass in soil. The check can be performed by calculating concentrations in soil that would still result in acceptable risks even if the entire mass of contamination in the source area were to leach into groundwater over the exposure period.

If the chemical mass in soil is less than the mass to which a potential receptor could be exposed over the exposure period, then the exposure concentration would not be reached because there is

insufficient mass in the soil to maintain the calculated drinking water concentrations using an infinite mass approach (Figure 6-9).

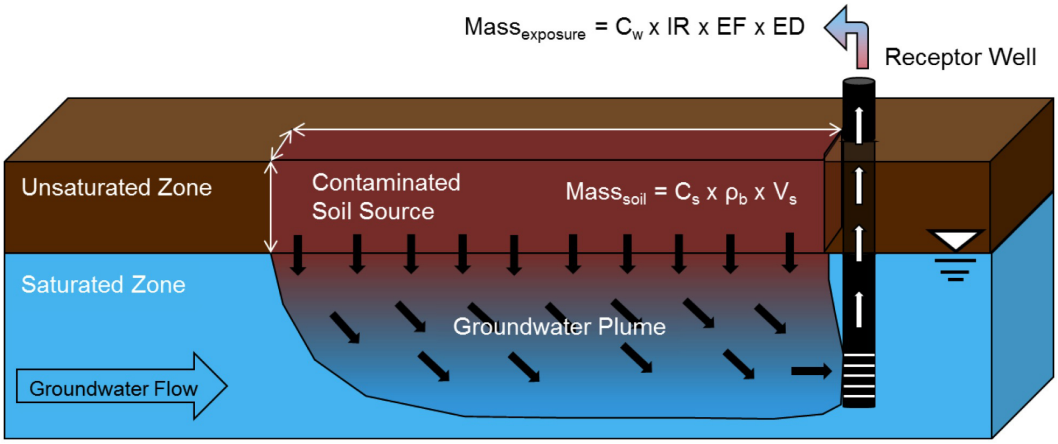

Figure 6-9. Soil migration to groundwater – mass limited check.

In these instances, the average concentration that would result over the exposure period, assuming all of the mass were to leave the source and migrate to the exposure point, could be used as a conservative upper-bound estimate of potential exposure over the exposure period.

6.2.4 Issue – Uncertainty When Estimating the Exposure Concentration from Measurements

Risk assessments typically assume the exposure concentration is the average chemical concentration to which a receptor would be exposed.

Various statistical methods can be used to estimate the average exposure concentration.

The concentration used in the exposure assessment is intended to be the average site-related concentration contacted by receptors over the period of exposure. In many cases, risk assessments may use results from actual monitoring data to develop estimates of the exposure concentration. The arithmetic average (mean) concentration of monitoring results, however, may not provide a reasonable estimate of the true mean to which a receptor is exposed. In reality, if an infinite number of samples could be collected, the true mean within an exposure area could be determined and used as the exposure concentration. Infinite sampling is not practical, thus the exposure assessments routinely rely on estimates of the true mean calculated using monitoring sampling results collected from an exposure area. These samples are often collected with a bias to those locations with the greatest likelihood of identifying higher concentrations.

This section briefly discusses routine statistical methods that are commonly used in estimating mean concentrations within an exposure area.

6.2.4.1 Option – Use Upper Confidence Limits (UCL) on the Mean

The upper confidence limit (UCL) on the mean provides a conservative estimate of the average exposure concentration and accounts for uncertainties such as limited sampling data (USEPA 1992d). For example, the 95% UCL is the concentration at which only a 5% chance exists that the true mean of the data set would be higher. The more sampling data that is available, the closer the UCL should come to the true mean. In other words, fewer samples result in a higher UCL for the mean concentration and thus in higher potential risk or hazard.

UCLs can be calculated using a number of methods (for example, methods that assume the data are normal, lognormal, or gamma distributed, or the data are nonparametric and thus do not rely on the assumption of an underlying distribution). Software packages are available to perform UCL calculations. For example, USEPA's ProUCL is a statistical software package (with graphical tools) that can calculate UCLs (USEPA 2013d).

The following issues and limitations should be considered when calculating UCLs on the mean:

- The fewer the number of samples, the greater the uncertainty that the sample mean is representative of the true mean. These uncertainties result in large confidence limits around the mean and potential estimates of the mean that are biased high. Consider the benefit of collecting appropriate additional samples to increase confidence that the sample mean is more representative of the true mean.
- Compare the UCL result with the maximum detected or modeled concentration. If the calculated UCL is greater than the maximum detected concentration, then the maximum detected or modeled concentration should be used to estimate exposure concentrations (USEPA 1989a; USEPA 2002a). Statistical software such as ProUCL may recommend alternative computations if the UCL on the mean exceeds the observed maximum concentration (USEPA 2013e).
- Application of the UCL statistic assumes the sample collection locations are generally unbiased across the exposure area. In contrast, data collection for many site assessments focuses on the chemical source areas and areas of highest chemical concentrations to document the nature and extent of the chemical release. Thus, sampling locations are not often evenly distributed throughout and are biased within the exposure area. In these instances, the UCL on the mean concentration may also be biased high. Such high bias on the mean, while conservative, may not be suitable for use in a risk assessment if it excessively overestimates the risks. Other data analysis methods may provide better estimates of the true mean in these situations (see Section 6.2.4.2).

6.2.4.2 Option – Use Area-Weighted Averages

Area-weighted averages may be used to estimate appropriate exposure concentrations (Pedersen and LaVelle 1997; NJDEP 2012b) when exposure units are fairly well defined and when data for

an exposure area are so unevenly distributed that UCLs on the mean do not provide reasonable estimates of the exposure concentration. For example, Figure 6-10 depicts a case in which a number of surface soil sample locations are clustered in one corner of the exposure area. The sample concentrations (mg/kg) are depicted in the figure. These cases typically arise from focused sampling of a small area in which many samples with high concentrations are clustered. In this example, this distribution could result in a significant overestimate of the mean concentration in an exposure area.

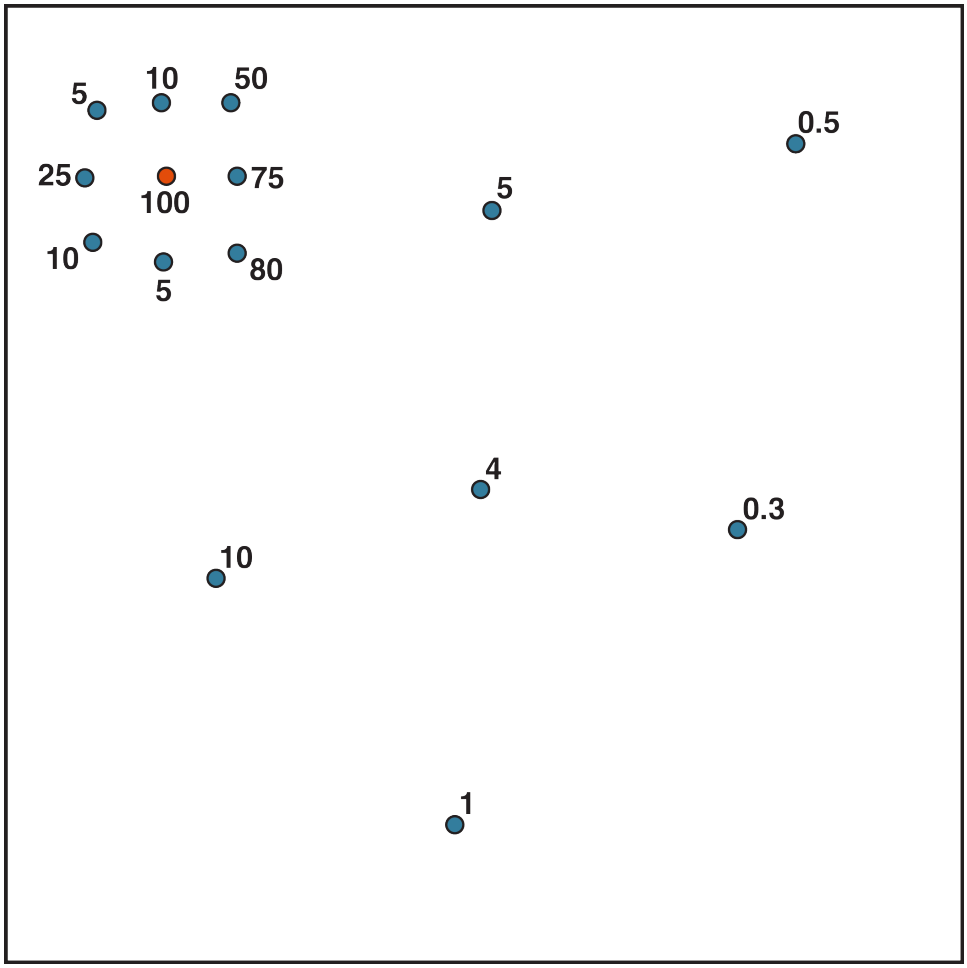

Figure 6-10. Hypothetical exposure area with clustered data.

One approach for estimating the area-weighted average is to use Thiessen polygons (ESRI 2012) to determine the portion of the larger area which is represented by a single sampling location. Thiessen polygon boundaries define the area that is closest to each point relative to all other points; the boundaries are mathematically defined by the perpendicular bisectors (or half-way point) of the lines between all points (NJDEP 2012b). Figure 6-11 depicts the Thiessen polygons constructed for the sampling locations shown in Figure 6-10. These polygons can be developed efficiently using GIS software, but they can also be constructed by simply using a ruler and a pencil.

Additional spatial interpolation methods, such as kriging and nearest-neighbor algorithms, may also be appropriate for supporting the calculation of areal averages. Consult with a risk assessor, however, to determine the applicability of these methods before using them in the evaluation of risk.

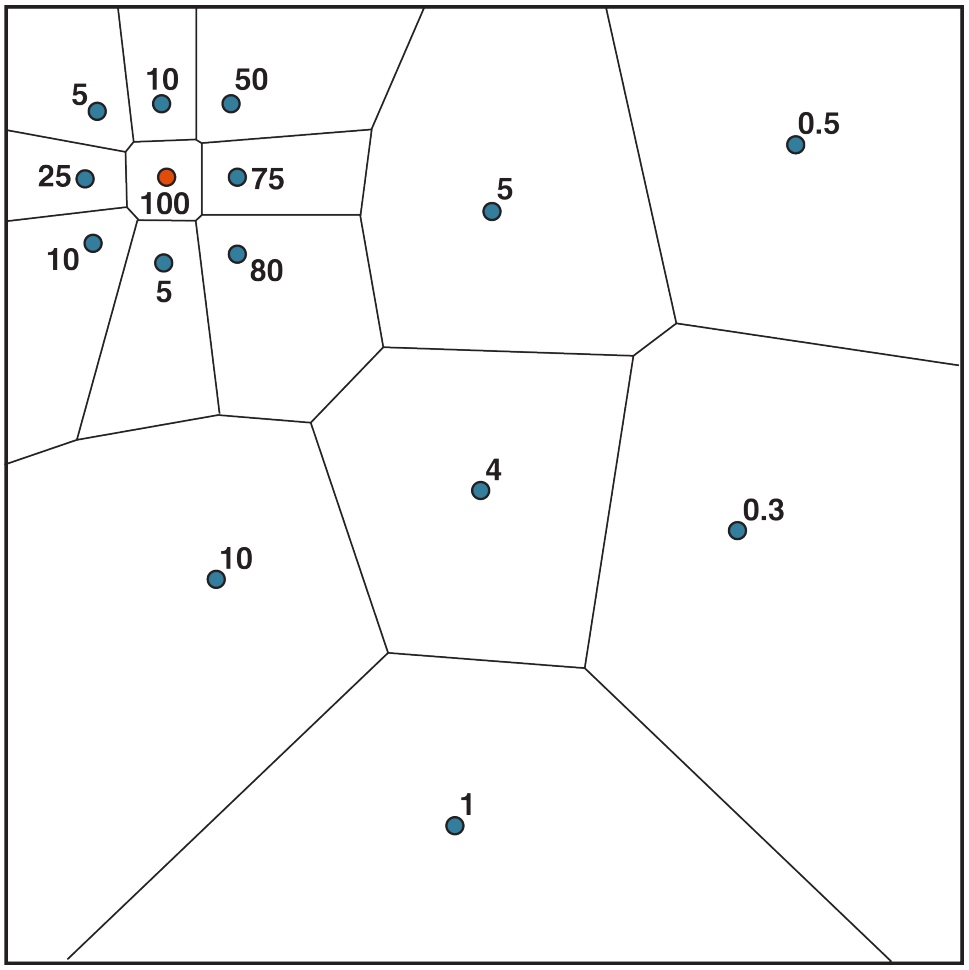

Figure 6-11. Hypothetical one-acre exposure area with Thiessen polygons.

Area-weighted (or spatially weighted) average concentrations for the exposure area can be calculated by weighting concentrations from each location by the area which they represent. The area-weighted average concentration for the exposure area is thus the sum of the products of the chemical concentration and surface area for each individual subarea, divided by the total surface area of the exposure area.

Table 6-1 presents the area-weighted average calculations performed for the hypothetical exposure area presented in Figure 6-10 and Figure 6-11.

Table 6-1. Example area-weighted average calculations

Sample location	Concentration (mg/kg)	Area (acres)	Area x Concentration
1	1	0.34	0.34
2	10	0.05	0.53
3	5	0.04	0.18
4	10	0.02	0.21
5	50	0.06	2.87
6	75	0.03	2.18
7	100	0.01	1.31
8	24	0.02	0.47
9	5	0.05	.023
10	80	0.07	5.65
11	5	0.2	1.00
12	0.5	0.24	0.12
13	0.3	0.39	0.12
14	4	0.18	0.71
15	10	0.32	3.2
	Totals:	2.0	19.12
	Area-weighted average:		**9.48**

For comparison purposes, the 95% UCL on the mean for this data set would be 58 mg/kg.

Statistical methods can assess the uncertainty in area-weighted averages. For example, it would be possible to calculate a 95% UCL on the area-weighted mean by using a nonparametric bootstrap method with weighted bootstrap resampling. With this approach, the bootstrapped data set would consist of a number of draws equal to the total number of original samples in the hypothetical exposure area. The probability of drawing a sample from the original distribution is equal to the Thiessen polygon area divided by the total area of the exposure area to give an area weighting factor. As a result, each data point in the original data set contributes, on average, to the area weighted average according to the relative area that it represents within the exposure area. Bootstrap techniques such as the Efron's percentile method can be used to establish the lower confidence limit (LCL) and UCL at a particular level of confidence.

6.2.4.3 Option – Composite Samples

Unless carefully designed, collected, and processed, composite samples may dilute or otherwise misrepresent concentrations at specific points. Composite samples, however, may be useful to quantify the mean concentration for nonvolatile chemicals by physically mixing samples to yield an average concentration (USEPA 1989a; USEPA 1996b).

Techniques such as incremental sampling methodology (ISM) offer a structured composite sampling and processing protocol to reduce data variability. This approach can be an appropriate, reliable, and cost-effective means for assessing exposure risk (estimating mean concentration within an exposure area). ISM provides an unbiased estimate of mean chemical concentrations

within an exposure unit (ITRC 2012a), rather than simply indicating the presence of individual hot spots. This technique is also useful at large sites where relatively similar chemical concentrations are suspected, and at sites where exposure units are well defined and the average concentration across the exposure unit is of interest. ISM is consistent with sampling theory that is long accepted in the mining industry. Currently, ISM is accepted for use in risk assessments by some state agencies, the U.S. Department of Defense, and various USEPA regions.

6.2.4.4 Option – Weighted UCLs on the Mean

Weighted UCLs on the mean can also be used where exposure units are well defined and data for an exposure area are so unevenly distributed that UCLs on the mean do not provide reasonable estimates of the exposure concentration in an exposure area. Consider the example presented in Section 6.2.4.2 and Figure 6-10. In this example, a number of surface soil sample locations are clustered in one corner of the exposure area. One approach to estimate an exposure concentration in this area would be to calculate UCLs on the mean for two subareas of the overall exposure area (Figure 6-12). In Subarea 1, where the data are clustered, a UCL of the mean is calculated. A UCL on the mean is also calculated for Subarea 2. The resulting UCLs on the mean can then be weighted together account for the relative portions of the area over which they are located.

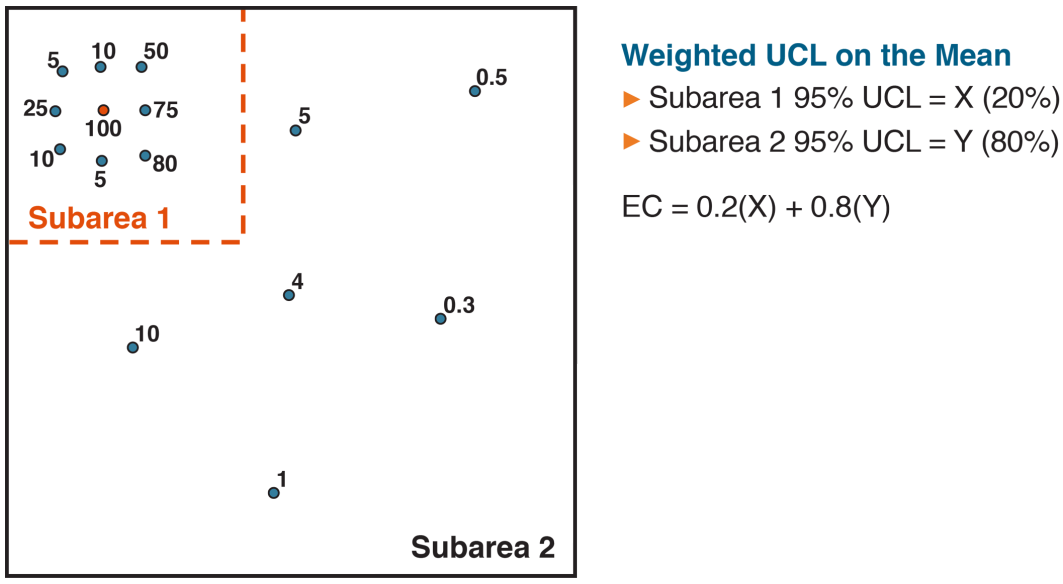

Figure 6-12. Hypothetical exposure subareas.

6.2.5 Issue – Estimating Site-Specific Exposure Concentration versus Background Concentration

Agencies generally agree that cleanup to below background concentrations should not occur and that decisions to remediate contaminated sites should be based on the increased risks releases pose to human health from these sites above background. Not considering background exposure can lead to an overestimate of the site-related risk.

Many chemicals may be present in environmental samples because of natural or anthropogenic sources that are not related to current or past site activities. Agencies generally agree that cleanup to below background concentrations is not reasonable (USEPA 2002c; USEPA 2002e; USACE 1999; United States Navy 2008). State and federal agencies, however, have published various methods for comparison of site and background data and presentation of background-related risks, which can result in different decisions. Section 3.3 of ITRC's guidance on this issue (ITRC 2008) provides an informal summary of state-specific recommendations for the collection, treatment, and application of background concentration data in risk assessments. Information related to background sampling and the use of background concentration data for identifying chemicals in environmental media to be included in the risk assessment is discussed in Section 3.3.7 of this document.

Environmental data related to natural or anthropogenic background concentrations are commonly either site- or area-specific, or from the literature if site-specific data are not available or practical. Site-specific background concentration data may be the preferred alternative because the relationship of regional or state-wide concentrations to site-specific concentrations can be difficult to establish (see Section 3.3.7 for more information). Published data for background soil concentrations may be obtained from various sources, such as USGS (2012), Dragun and Chekiri (2005), and state-specific publications (see Section 4.5.6).

In some cases background-related risks may not be presented in the risk assessment. This omission may simplify the assessment when initial screening against background concentrations indicates that concentrations of chemicals that significantly affect risk are well above background concentrations, or when no background data are available for chemicals that significantly affect risk. When background concentrations are likely to represent a significant portion of overall risk, risk management decisions may require distinguishing the contribution from background concentrations relative to total site risk. Not considering the contributions from background concentrations can lead to an overestimate of site-related risk, which can result in unnecessary risk management decisions, undue public concern, or distrust of the protectiveness of the remedy.

The decision regarding appropriate options for characterizing risk (including site-related versus background risk) should consider risk communication needs. Two options for using and presenting background exposure concentrations and risks versus site-related exposure concentrations and risks are provided below.

6.2.5.1 Option – Present Separate Risk Calculations

One option, which is consistent with recommendations in USEPA's *Role of Background in the CERCLA Cleanup Program* (USEPA 2002e), is to "address site-specific background issues at the end of the risk assessment" by distinguishing in the risk characterization "the contribution of background to site concentrations." With this approach, total and background chemical exposure concentrations are calculated for receptor risk estimates for both background and site-related exposures and included in the risk characterization section of the risk assessment. In this process, consider the following:

- Compare background risks and site risks based on similar sampling designs. Ideally, samples considered in the analysis are collected using the similar sampling design and methods (apples to apples comparison), or at least are considered to be equivalent as to what is represented by the data set (for example, similar sample depths, soil types, native soils versus recent fill placement, soil removal or site regrading). For example, background concentrations should be characterized using ISM when site data are collected using ISM (ITRC 2012a). Another example is to compare data of the same time series when data may have temporal trends or patterns, which is commonly observed for environmental media such as water or air.
- Use a regulatory definition of background concentration to calculate health risks. Regulatory programs may define regional or statewide background concentrations for certain chemicals. Sometimes these background concentrations are based on risk management considerations to help identify chemicals in environmental media for evaluation in a risk assessment. These defined background concentrations are a convenient screen against calculated risk-based concentrations (back-calculated risk assessment; see Section 2.1). Background risks calculated using these defined concentrations, however, are unlikely to accurately represent background contributions to site risks since they often represent the upper end of the range of possible background concentrations. These values should not be used to estimate background risk because background risk should be based on an estimate of the mean concentration. Instead, add commentary to the risk assessment to note the defined regulatory background concentration for the chemical and its basis, so that this value can be factored into the risk management decision process.

6.2.5.2 Option – Subtract Background Concentrations from Exposure Concentrations

Background concentrations of chemicals may be subtracted from detected concentrations of chemicals at a site. The resulting site-related concentrations could be below the screening value, leading to a decision that the chemical is no longer retained for evaluation in the risk assessment. In these cases, the risks presented

Background exposure concentrations may be subtracted from the exposure area exposure concentrations, if these concentrations are calculated similarly.

then focus on those risks present based on the difference between site and background concentrations. This method is appropriate if the statistical basis for the two data sets are the same and if the same statistical methods are used to analyze both data sets (apples to apples comparison). When subtracting background concentrations, consider the following:

- Subtract a background 95% UCL on the mean concentration from a site 95% UCL on the mean concentration to estimate the site-related concentration. Because the 95% UCL on the mean is a function of sample size and variability in concentrations, both of which may differ between site and background areas, a simple subtraction may not be defensible. In particular, if fewer background samples than site samples are available from an exposure area, the background 95% UCL on the mean may be biased high as compared to the site 95% UCL on the mean, and the site-related risk may be underestimated (not conservative). Conversely, if the background data set is larger than the data set used to calculate a 95% UCL on the mean for the exposure area, then the bias for the 95% UCL on the mean for background may be lower than that of the exposure area UCL on the mean, in which case the mean concentration for the site may be overestimated (overly conservative). Overestimating the exposure area mean concentration may be suitable for purposes of site screening or for remedial decision making, if acceptable to reviewers.
- Subtract background concentrations from site concentrations when their mean concentrations have been estimated using different statistics. For example, subtracting a 95% upper tolerance limit (UTL) of background concentration from an exposure area with a 95% UCL on the mean is not appropriate (apples to oranges comparison). Subtraction may be appropriate if the background and exposure area concentration data sets are analyzed with the same statistical method.

6.3 Resources and Tools

The following resources and tools were not cited in the sections above and are included here for further information.

Distributions of Total Job Tenure for Men and Women in Selected Industries and Occupations in the United States (Burmaster 2000)

Heuristic model for predicting the intrusion rate of contaminant vapors into buildings (Johnson and Ettinger 1991)

Environmental Response Division. Part 201, *Generic Groundwater and Soil Volatilization to Indoor Air Inhalation Criteria: Technical Support Document* (MDEQ 1998)

Comparative Climatic Data for the United States Through 2010 (NOAA 2010)

Petroleum Vapor Intrusion: Fundamentals of Screening, Investigation, and Management. PVI-1. (ITRC 2014)

Soil Ingestion in Adults—Results of a Second Pilot Study (Stanek et al. 1997)

Guidelines for predictive baseline emissions estimation procedures for Superfund Sites (USEPA 1995a)

Land Use in the CERCLA Remedy Process (USEPA 1995e)

An Examination of EPA Risk Assessment Principles and Practices (USEPA 2004a)

Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) (USEPA 2004b)

User's Guide for Evaluating Subsurface Vapor Intrusion into Buildings (USEPA 2004c)

Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (USEPA 2005d)

Background Indoor Air Concentrations Volatile Organic Compounds in North American Residences (1990-2005): A Compilation of Statistics for Assessing Vapor Intrusion (USEPA 2011b)

Risk Assessment Forum White Paper: Probabilistic Risk Assessment Methods and Case Studies (USEPA 2014l)

Child-Specific Exposure Scenario Examples (USEPA 2014a)

Exposure Assessment Tools by Routes - Dermal (USEPA 2015)

USEPA EPI Suite. Estimation Program Interface (EPI) Suite Version 4.11 (USEPA 2012a)

7.0 RISK CHARACTERIZATION

Risk characterization has been described as the bridge between risk assessment and risk management because it provides a basis for the calculations, an understanding of the uncertainties inherent in the evaluation, and an understanding of the results of the risk assessment. USEPA (1995c) notes the following:

> The risk characterization integrates information from the toxicity assessment and exposure assessment and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers.

The challenge of the risk characterization is refining the data gathered and clearly communicating the key findings and the context of those findings. For more information regarding risk characterization, refer to USEPA's Human Health Risk Assessment web page (USEPA 2012c) and select Step 4, Risk Characterization.

This chapter provides guidance on key issues associated with risk characterization. The key issues are organized around three general topic areas:

Risk Results

- Default Assumptions
- Summation of Risk Results
- Probabilistic Risk Assessments

Presentation of Risk Results

- Unclear Presentation of Risk Results

Uncertainty and Bias

- Unclear Presentation of Uncertainty and Bias in Risk Results

7.1 Risk Results

7.1.1 Issue – Default Assumptions

The utility of site-specific alternatives to default assumptions can arise as part of the risk characterization. In these cases, the default assumptions are typically considered to be more uncertain than the site-specific alternatives. In other cases, the default assumptions are conservatively selected to overcome any uncertainties that could affect decision making.

7.1.1.1 Option – Alternatives to Default Assumptions

Appendix D presents a table summarizing some of the common default assumptions in a risk assessment and alternate assumptions that may reduce uncertainties but still protect health at a particular site. Site-specific information should be well documented so the project team clearly understands how this information was derived and how it applies to the site.

7.1.1.2 Option – Evaluate Central Tendency Exposure

The RME scenario based on the default assumptions does not fully characterize the range of possible exposures and conditions at a site. Evaluation of a central tendency exposure scenario may provide risk managers with an understanding of the degree of protectiveness of the RME scenario, which can aid in the decision-making process.

7.1.2 Issue – Summation of Risk Results for Multiple Media or Pathways

Estimating potential site-related risks based on RME is the goal of the risk assessment for CERCLA and RCRA sites. In general, a risk assessment performed in this context expresses results as site-related, cumulative cancer risk and hazard index estimates (USEPA 2003c). Results of these types of assessments are intended to support decisions on whether a remedial action is warranted at a site. In some instances and in some regulatory programs, combining these risks across exposure pathways and exposure media may be appropriate to represent the RME to a hypothetical individual. In other instances, however, the risks for multiple exposure media or exposure pathways should not be summed.

7.1.2.1 Option – Considerations for Summation of Risk Results

Where relevant, decisions regarding whether remedial action is warranted at a site should be based on site-related cumulative cancer risk and the noncancer hazard index for RME under current and reasonably expected future land use (USEPA 1991e). Estimating these RME risks is the goal of the baseline risk assessment. While in some instances combining risks across exposure pathways and media may be appropriate to represent the RME, in other instances this practice is not appropriate. Most, if not all, of the default exposure scenarios and toxicity values represent the RME for an individual pathway and media. These values are estimated assuming only one exposure medium and are based on default residential or worker exposures for RME.

At sites with more than one exposure medium or potential for exposure from multiple exposure pathways from the same exposure medium (for example, soil contact and inhalation of vapors from the soil), the risks may be summed if those risks may represent a one RME due to consistency in both time and location of exposure. Clearly presenting the RME risks by each exposure pathway and medium most accurately describes potential exposure risks at the site, while also allowing flex-

ibility to add RME risk estimates to satisfy other requirements. As USEPA RAGS Part F (USEPA 2009a) states:

> Risk assessors should first identify reasonable exposure pathway combinations. Then, risk assessors should examine whether it is likely that the same individuals would consistently face the reasonable maximum exposure by more than one pathway.

A related issue is presentation of risk results when multiple chemicals may have a significant contribution to site risk. An assumption of additivity of the chemical-specific toxic effects is commonly invoked when calculating risk for chemical mixtures. This assumption and other options are described in Section 5.1.3.

7.1.3 Issue – Probabilistic Risk Assessments

As discussed in Section 2.4, deterministic risk assessments that result in point estimates of risk are the most common. If the results of a deterministic risk assessment depict a potentially unacceptable risk, a probabilistic risk assessment that results in probability distributions of risk may be performed to aid decision making. As discussed in Section 1.3 and Section 2 of USEPA guidance (USEPA 2001c), this approach should be considered after adequate point estimate calculations have been performed.

7.1.3.1 Option – Considerations for Probabilistic Risk Assessments

Both deterministic and probabilistic methods can support risk management decisions at sites. The methods are similar in concept and approach, but differ in the values supplied for variables in the risk equations. Deterministic methods use single point values for the equation variables, while probabilistic methods use probability distributions for these variables. The probabilistic approach quantitatively characterizes variability and uncertainty in the risk estimates (USEPA 2001c).

A probabilistic risk assessment can characterize the probability distribution of the risk assessment results and provide information on the sensitivity of the input variables to help the risk assessor refine the risk assessment (collect additional site-specific information for an especially sensitive parameter) or to help in making risk management decisions. Chapter 7 of USEPA's guidance (USEPA 2001c) describes the interpretation and use of probabilistic risk estimates in remedy decision making. Generally, a specific upper-bound level can be selected from the range of percentiles of risk estimates to inform the ultimate decision of whether a potential exposure risk meets the applicable risk level. A probabilistic risk assessment, however, is sometimes limited by the quality and applicability of data available to develop probability distributions for site input parameters and requires more time, resources, and expertise than a deterministic risk assessment.

7.2 Presentation of Risk Results

7.2.1 Issue – Unclear Presentation of Risk Results

A large amount of information may be incorporated into the risk assessment. Sometimes this information and the results of the risk assessment are not clearly organized, and thus the key findings and context are difficult for project managers and other reviewers to discern.

7.2.1.1 Option – Organized and Systematic Presentation of Risk Results

The information and results presented in the risk characterization (the final step of the risk assessment) should address the issues and questions that were developed in planning the risk assessment (see Chapter 3). As USEPA (1989a) recommends, an important use of a risk assessment's results is to highlight potential sources of unacceptable risk at a site in order to allow them to be addressed effectively (for example, through remediation or development of institutional or engineering controls).

The risk characterization should communicate in text and tables the key results, assumptions, and uncertainties of the risk assessment in a transparent, clear, and consistent manner (USEPA 2000b; USEPA 1995c). The risk results should identify the major factors contributing to the risks:

- What exposure scenarios would result in unacceptable risk?
- What are the chemicals contributing to the unacceptable risk?
- What exposure pathways are resulting in the unacceptable risk (for example, groundwater ingestion, dermal contact with soil, inhalation of particulates, or inhalation of vapors)?
- Is the unacceptable risk due to current exposures or based upon reasonably anticipated future exposures that have not yet occurred?
- Does the uncertainty analysis identify the nature and magnitude of key uncertainties and bias in the risk results?

If the risk characterization clearly addresses these questions, then the risk assessment will serve as an effective tool for supporting risk management decisions. A clear, well-organized risk assessment is also effective in supporting the risk communication needs of the project. While the format for presenting these results can vary based on the needs of the project, the presentation of the risk characterization results should include concise tables and clear presentations of necessary information. An example table is presented in Appendix E.

At the time that risk management decisions are made, the risk characterization should be reviewed and it should be confirmed that no significant changes in current or future exposure scenarios and toxicity values of site-related chemicals have occurred. If significant changes in exposure scenarios or toxicity values have occurred, applicable components of the risk assessment should be reviewed and updated if needed so that risk management decisions are based on the latest information (see Section 8.2.1).

7.3 Uncertainty and Bias

Despite the advanced state of current methods, uncertainties and bias are inherent in the risk assessment process. Uncertainty in the results of a risk assessment refers to a lack of knowledge of how well the calculated risk results represent the actual risks. When only a single risk value is presented for any chemical and exposure pathway, uncertainty may also refer to the unknown amount of variability among possible risk assessment results. Available data quality, incomplete information about existing conditions and future circumstances, as well as other factors contribute to these uncertainties. The uncertainty can lead to an over- or under-estimation of potential risk.

A common approach for addressing uncertainty in a risk assessment is to apply conservative assumptions to help ensure that risk estimates are protective of most potential receptors. This approach introduces a protective bias in an attempt to ensure that risks are not underestimated. This protective bias is reflected in the methods for developing chemical-specific toxicity criteria (Section 5.2) and in the emphasis on identifying RME (Section 6.1) in the exposure assessment.

Risk assessment results presented without an accompanying evaluation of the key uncertainties and biases specific to the chemicals and exposure pathways at a particular site may be of limited use in supporting risk management decisions.

7.3.1 Issue – Unclear Presentation of the Uncertainty and Bias in the Risk Results

The presentation of the risk results does not always include enough information for project managers to identify and evaluate the uncertainty and bias in the calculated results. When there is uncertainty in the quantitative risk assessment, the general practice is to err on the health-protective or "safe" side, so that potential risks are not underestimated. This practice helps to preclude the need for additional risk management actions to overcome ambiguity or variability in the assessment.

7.3.1.1 Option – Provide Information so that the Uncertainties and Bias Can be Understood.

The information and results presented in the risk characterization include the uncertainties and bias inherent in the assumptions, models, and input parameter values used in the risk assessment (as discussed in Chapter 4, Chapter 5, and Chapter 6). Generally, when bias is recognized in selected input parameter values, the intent is to be protective of human health and to overestimate likely exposures and risks. Underestimation of potential site risks is usually related to deficiencies in sampling and analysis or improper modeling of exposure concentrations. A clear explanation of the uncertainties and bias inherent in the risk assessment is key to the transparency of the risk characterization.

Information about the uncertainty and bias in the risk results should be presented in tables and text as appropriate for the project. This clear presentation allows project managers to understand, interpret, weigh, and decide on a course of action for a specific site.

If it is determined that the overall bias may result in underestimating the risks, then multiple alternatives are available to overcome these uncertainties (for example, revisiting the planning and scoping of the data collection; see Section 3.3).

7.3.1.2 Option – Detailed Consideration of Toxicological Assumptions

In general, it is not necessary for the risk assessment to include details regarding specific toxicity values unless adjustments are made (for example, relative bioavailability) or site-specific considerations warrant such discussion. It is important, however, to provide insight into the degree of uncertainty and potential bias inherent in the derivation of a specific toxicity values for chemicals driving the risk assessment. Some of the potential issues to address include:

- uncertainty related to extrapolation from animal studies to human toxicity
- applying dose-response information from homogeneous animal populations or healthy human populations to predict effects that may occur in the general population, including sensitive subpopulations
- using high-to-low-dose linear extrapolation methods to develop toxicity values, which can result in overestimates of risk for chemicals with a threshold dose or nonlinear low-dose responses
- using surrogate chemicals or route-to-route extrapolation to account for the lack of toxicity values
- possible synergistic or antagonistic effects associated with multiple chemical exposure, which could underestimate or overestimate the final risks
- using toxicity values derived for a different exposure period (such as subchronic) to exposure periods evaluated in the risk assessment (such as chronic)

7.3.1.3 Option – Detailed Consideration of Exposure Assumptions

The exposure assumptions used in the risk assessment generally include uncertainties and bias that must be recognized when making risk management decisions. Some of the potential issues to address may include:

- sampling methods, which are often selected to provide the worst case scenario (for example, biased sampling, grab groundwater sampling, or sampling only from the interval of likely highest chemical concentration)
- sampling methods that are designed to evaluate the site-wide average concentration (for example, composite sampling or incremental sampling methods) and may not be appropriate to identify potential hot spots (especially if the receptor's long-term exposure could be consistent with the areal extent of any hot spots)
- sensitive analytical methods, which typically provide detection limits below risk-based screening values, even if such limits are below a site-specific background concentration developed to screen out chemicals

- EPCs, which can be calculated for large areas where exposure could regularly occur over the assumed exposure period; or EPCs, which can be calculated for very small areas where regular exposure would not likely occur over the exposure period
- exposure scenarios, exposure pathways, and exposure parameters evaluated in the assessment, which may not completely account for land use assumptions and restrictions, or parameters that overestimate the RME (such as applying fish ingestion rates to a small water body when these rates came from a combination of rates in multiple water bodies)
- common fate and transport models used in the risk assessment, which assume steady-state or assume simultaneous complete phase change and infinite source for different simultaneous routes of exposure

7.3.1.4 Option – Include Multiple Descriptors of Risk

The risk assessment calculations can incorporate multiple risk descriptors in addition to RME, such as the central tendency exposure, population-level risk, and risk for important subgroups (for example, children, and subsistence anglers). Evaluating multiple risk descriptors provides the project manager with information on a range of possible exposures (and thus risk) to consider when using the risk assessment results to manage a site.

7.4 Resources and Tools

The following resources and tools were not cited in the sections above and are included here for further information.

The following documents provide useful resources on risk characterization:

Elements to Consider When Drafting EPA Risk Characterizations (USEPA 1995b)

Risk Assessment Guidance for Superfund (USEPA 1989a; USEPA 1991c; USEPA 2004b)

Risk Assessment Forum White Paper: *Probabilistic Risk Assessment Methods and Case Studies* (USEPA 2014l)

Multiple tools are also available to calculate risk:

Spatial Analysis and Decision Assistance (SADA) (University of Tennessee 2013)

Adaptive Risk Assessment Modeling System (ARAMS) (USACE 2009)

USEPA Regional Screening Levels (USEPA 2014e)

The Risk Assessment Information System (RAIS), United States Department of Energy (ORNL 2014)

8.0 RISK MANAGEMENT

Risk management is "…the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health" (Commission 1997a). Risk management can involve a combination of decisions based on science, policy, and professional judgment, as well as social, political, and economic concerns. These decisions can occur prior to, during, and after completion of a risk assessment. The relationship between risk assessment and risk management at first seems simple and linear, with the risk assessment informing risk management; however, risk assessment and risk management are interconnected (Figure 8-1).

Figure 8-1. Risk management process.

Source: Adapted from (Commission 1997a)

Often, individuals associated with risk management decisions come from different entities that may have different perspectives on the definition of risk and on cleanup; these entities can include the

potentially responsible party, federal environmental regulators, state environmental regulators, state or local health departments, tribes, and the affected public. One of the reasons that risk management can be so difficult is that it must balance the perspectives and interests of many people.

This chapter reviews the relationship between risk assessment, risk management, and sustainability and discusses key issues that may affect the risk assessment development. The key issues are organized around three general topic areas:

Risk Management in Project Planning

- Identify the Appropriate Regulatory Context
- Define the Problem Statement

Using Risk Assessment to Inform Risk Management

- Accounting for Changes in Scientific Understanding or Land Use Since the Risk Assessment was Completed
- Full Consideration of the Uncertainty in Numerical Risk Estimates

Other Factors in Risk Management

- Integrating Factors in Addition to the Risk Assessment to Support Risk Management Decisions

8.1 Risk Management in Project Planning

Usually the project manager plays a critical role in project planning. Implementation of a formal project planning process as discussed in Chapter 3 can be an effective approach to managing risks associated with the preparation of a health risk assessment that will be used to support environmental risk management decisions. Chapter 3 provides guidance on managing risks associated with the basic elements of a risk assessment and ensuring that the risk assessment meets or exceeds regulatory requirements. Two areas in which the project manager should focus risk management efforts include identifying the appropriate regulatory context and defining the problem statement in a manner that is technically and scientifically sound, and consistent with the regulatory context and the interests of stakeholders.

8.1.1 Issue – Identify the Appropriate Regulatory Context

Section 3.1.3 discusses regulatory context and a useful approach to accounting for the statutes, regulations, policies, guidance, and recommendations that form the regulatory framework within which a risk assessment is prepared. As discussed in Section 3.1.1.1, multiple agencies or programs may have some jurisdiction, and therefore the project manager should identify the controlling regulatory context for the site.

8.1.1.1 Option – Establish the Jurisdiction for Site Decisions and Understand the Pertinent Regulations, Policies, and Guidance

The project manager should clarify the relevant jurisdiction for the site. This process may involve contacting federal, state, or local agencies, which may include the state environmental regulatory agency as well as local pollution control districts, health districts, fire districts, or other agencies charged with maintaining environmental and public health and safety. The appropriate jurisdiction and regulations applicable to the risk assessment for a specific site should be reflected in the risk assessment. A memorandum of agreement between agencies or other formal documentation of the regulatory authority may be warranted.

8.1.1.2 Option – Ensure that the Risk Assessment is Prepared Using the Appropriate Regulations, Policies, and Guidance

After verifying the lead agency, project managers should ensure that the risk assessment is prepared following the appropriate regulations policies and guidance for the site. Often, health risk assessments are prepared incorrectly, using exposure assumptions and models that were developed for a regulatory program other than the program that applies to a given site. For example, the default indoor air exchange rate applicable to vapor intrusion modeling under USEPA differs from that under Cal/EPA oversight.

8.1.2 Issue – Define the Problem Statement

Developing an accurate problem statement is a critical first step in formulating the risk assessment and is consequently the first part of a systematic planning approach such as USEPA's DQO process (USEPA 2006c); see Section 3.3.1. A problem statement is a succinct description of an issue or the issues to be addressed in the risk assessment. The problem statement should focus the risk assessment approach and provide the context for managing project risk, as well as for the environmental risk present. Defining the problem statement shares many activities in common with development of the CSM (Section 3.2). Both involve gathering and interpreting information on historical site operations, current and future land use, and physical site characteristics.

8.1.2.1 Option – Consult the Stakeholder Groups

Section 3.1 provides information on identifying and engaging stakeholders in the risk assessment. When stakeholder groups are vocal, engaged, and have an expectation that their interests will be considered, the project manager can benefit from consulting with these groups upfront to develop an acceptable problem statement. Consulting stakeholder groups during planning helps to develop a risk assessment that addresses key stakeholder concerns. Project managers should research the social, political, aesthetic, and economic considerations that could affect risk management decisions. Such information can be obtained from scoping meetings open to the public. Other options include contacting local leaders or advocacy groups active in the area, or the owners or

lessors of property adjacent to the site. These efforts are not necessary for every risk assessment project, but ensuring that the right stakeholders are involved in defining the problem supports successful project solutions.

8.1.2.2 Option – Assemble a Complete Technical Project Team

Assembling a team with the appropriate expertise as part of project planning is essential. The nature of the subject matter experts may vary for specific projects, but commonly includes individuals with expertise in toxicology, risk assessment, data evaluation, statistics, and chemistry. Other disciplines such as hydrogeology and atmospheric dispersion modeling may also be relevant.

8.1.2.3 Option – Meet with the Team to Identify Data Gaps

In some instances, the project manager or a stakeholder is given the opportunity to review the problem statement only after the project has already moved forward (for example, they receive a final risk assessment report for review). If the project manager or stakeholder does not concur with the problem statement that served as the foundation for the environmental investigation and risk assessment, then project delays could ensue. In these instances, the most timely and cost effective option may be to meet with the project team that was involved in the investigation to learn their perspective first hand. Sometimes, the project team simply may not have described the problem statement adequately. Talking directly with the team may save time and avoid lengthy back-and-forth written communications.

8.1.2.4 Option – Agree to Disagree

Sometimes not all stakeholders concur with an aspect of the problem statement. At times, it may not be possible to gain full team or stakeholder consensus on every aspect of the problem statement. In these instances, the project manager should determine whether the point of disagreement is something that would affect the site remedy. If not, then the team can maintain this point of disagreement in the official records for the project, and move forward to address the site remediation. If so, then the project manager must weigh the facts in order to best meet the needs of the majority of the stakeholders and to protect human health and the environment in accordance with the regulatory framework.

8.2 Using Risk Assessment to Inform Risk Management

As described in Chapter 7, the risk characterization consists of both the numerical estimates of hazard and risk and an evaluation of the uncertainties and biases that may be inherent in the risk assessment. Both the numerical risk assessment results and the uncertainty analysis must be considered when using a risk assessment to inform site management decisions.

8.2.1 Issue – Accounting for Changes in Scientific Understanding or Land Use Since the Risk Assessment was Completed

Scientific understanding of nearly all aspects of risk assessment is continually evolving and state and federal risk assessment guidance is also subject to change. This process can result in changes to risk assessment methods and inputs, most commonly with respect to toxicity values and exposure factor assumptions. The most current and applicable information should be reflected in risk management decisions for contaminated sites, but it is not always practical, economical, or even necessary to revise a risk assessment due to these changes. To some extent, the CERCLA process formally acknowledges that scientific understanding evolves over time and requires that some previous site decisions be reviewed every five years to ensure continued protection of human health and the environment.

Similarly, land use and activities at a site are also subject to change over time. Changes in land use can affect the exposure assumptions and parameters selected for the risk assessment.

8.2.1.1 Option – Have Ongoing Communication between Project Managers and Risk Assessors

Project managers must communicate with risk assessors (see Section 3.1.2) regarding potential scientific changes that may affect the conclusions and recommendations of the risk characterization. When risk management decisions are being made some time after a risk assessment is completed, the risk assessor should review the assessment to determine whether significant changes in science or policy affecting the risk assessment have occurred. Ideally, a framework for accommodating these changes should be part of project planning and should balance the need for consistency and certainty within the regulated community and stakeholders with recognition that science and science policy are continually advancing.

Risk assessors may also be aware of soon-to-be-released information affecting certain facets of the risk assessment and can give the project managers notice regarding pending significant changes. For example, before toxicity values are updated in USEPA's IRIS, the chemical-specific risk assessments undergo external peer review and USEPA lists the projected schedule for finalizing these assessments. The risk assessor may let the project manager know that a draft IRIS assessment is expected to be finalized soon, and how the draft value could impact the risk characterization results.

8.2.1.2 Option – Perform a Qualitative or Semi-Quantitative Evaluation of the Updated Information

As indicated in Section 4.5.1.1 and Section 7.2, the human health risk assessment may require updates over time. However, an update to a toxicity value or an exposure parameter value does not necessarily mean that the risk assessment calculations must be revised and the assessment reissued. These changes may not be pertinent to the scenarios or chemicals that are driving a specific risk management decision. There may be opportunities to perform a qualitative or semi-quantitative

evaluation of the potential effect that the updated information would have on the risk characterization. For example, relatively small changes in assumptions regarding drinking water ingestion rates may not need to be updated in the risk assessment for a site where the remedial decision is based on direct-contact soil exposure pathways. Or, an oral reference dose may be revised to show a 10% increase in toxicity, but the existing risk assessment indicates that this chemical contributes only a small fraction to the hazard index. The risk assessor can quickly verify and document that the change in the toxicity value does not affect the results and conclusions of the risk assessment.

8.2.2 Issue – Full Consideration of the Uncertainty in Numerical Risk Estimates

When using the risk assessment results to support risk management decisions, a project manager may require that the risk characterization provide more than the upper-bound risk assessment results (for example, the RME cancer risk). Since risk assessments incorporate uncertainties and bias, sole reliance on the upper-bound risk estimate may provide adequate characterization of all relevant information and potential exposures to manage risks.

8.2.2.1 Option – Qualitatively Evaluate the Uncertainty in the RME Risk Results

Protective and appropriate risk management decisions for a site must account for the potential uncertainties and bias that are inherent in the quantitative risk estimates. Therefore, uncertainty surrounding risk drivers should be evaluated for the pertinent media, exposure pathways, and any assumptions inherent in the methods used. A project manager may request that the risk assessor include a clear discussion (or table) in the risk characterization, which lists each area of uncertainty in the risk assessment along with an estimate of the potential for this uncertainty to result in overestimating or underestimating risk. These estimates may be organized by the major components of a risk assessment as described in this guidance (data evaluation, toxicity, and exposure assessment).

While the numerical risk estimates are important factors in the management of the site, the uncertainty assessment is equally important in informing the risk management decision. A well-documented uncertainty assessment should address the major uncertainties in the risk estimates relative to the CSM, including the exposure scenarios and receptors. The relationship between uncertainty and conservative bias should be considered in applying the uncertainty assessment in risk management. For example, as discussed in Chapter 5, conservative assumptions and models used by USEPA in developing toxicity criteria for IRIS (USEPA 2013b) reflect science policy for managing uncertainties in chemical dose-response relationships for a range of possible human receptors based on imperfect data. The various uncertainties and their potential bias inherent in a risk assessment that should be considered in risk management are discussed in earlier chapters of this document.

8.2.2.2 Option – Calculate Both RME and Central Tendency Exposure Risk Results

Section 6.1 describes the concept of RME in the context of the exposure assessment as protective of public health and representing a plausible individual exposure. The risk assessment may also include an evaluation of central tendency exposure, as recommended in USEPA risk assessment guidance (USEPA 1992c). The central tendency exposure represents a median or average exposure concentration within the potentially exposed population. The purpose of calculating the central tendency exposure risk estimate is to provide a measure of the degree of conservatism associated with the RME result. If use of either the central tendency exposure or RME result supports the same risk management decision, then there may be a relatively high degree of confidence in that decision. However, if the target risk level lies between the central tendency exposure and RME result, then the risk management decision may be more difficult and the influence of other aspects of the uncertainty analysis should be integrated in the exposure assessment.

8.2.2.3 Option – Perform a Probabilistic Evaluation of the Uncertainty

Probabilistic risk assessment, as described in Section 7, is a technique in which single values for the input parameters to the risk assessment calculations are replaced with probability distributions for the parameter values. For example, rather than using a single estimate of the mean concentration of a chemical in an exposure medium, a probabilistic risk assessment would use a probability distribution for the mean concentration. The value of a probabilistic risk assessment in supporting the uncertainty analysis lies in its ability to identify the location of the RME risk estimate within the overall distribution of risk results. USEPA guidelines for exposure assessment place the RME between the 90th and 99.9th percentiles of the risk results for the exposed population (USEPA 1992c). By providing a distribution of risk results, a probabilistic risk assessment allows a project manager to determine whether the RME risk result falls within this range, or where it lies relative to another metric.

A project manager should be aware that a probabilistic risk assessment does not necessarily require the collection of additional data or other cost-intensive inputs. If there is sufficient information to estimate both central tendency and RME values for a parameter, then it is likely that a probability distribution can also be developed for that parameter.

8.3 Other Factors in Risk Management

8.3.1 Issue – Integrating Factors in Addition to the Risk Assessment to Support Risk Management Decisions

Project managers must understand and balance the results and recommendations from a risk assessment with other considerations and communicate how this information was used to form the basis of their decisions. Different states may have different inputs and policies for this process, particularly for identifying and selecting a remedial alternative.

8.3.1.1 Option – Use Available Guidance to Identify Other Factors

Social, economic, and ecological issues associated with the specific site should be considered along with the results of the risk assessment when making risk management decisions. At the federal level, USEPA has established nine criteria for helping project managers select among different remedial alternatives (USEPA 1988a; USEPA 1997f). These criteria may not be applicable in all circumstances or in a specific state, but they provide a general framework for identifying and integrating inputs other than human health risk and regulatory criteria in risk management decisions. These criteria include community acceptance, short-term and long-term effectiveness, reduction of toxicity or mobility, and cost.

More recently, USEPA has provided an overview of other considerations to integrate with risk assessment in the final *Framework for Human Health Risk Assessment to Inform Decision Making* (USEPA 2014f). This document includes discussions of environmental justice, sustainability considerations, and cost-benefit analysis that were not explicitly addressed in the earlier documents. A discussion of the changing definitions of risk assessment and risk management, and the relationship between them, is provided in ITRC's guidance (ITRC 2008).

8.3.1.2 Option – Apply Sustainability as the Organizing Principle for Risk Management

More recently, the concept of sustainability has been introduced as a specific attribute of effectiveness that seeks to maximize the benefits of remediation, rather than simply focusing on achieving minimal risk. Sustainability is described as the creation and maintenance of conditions under which humans and nature exist in productive harmony (NRC 2011). "The focus on [minimizing] risk sometimes includes risk-risk and risk-benefit trade-offs in management decisions, but does not" always include "the social (including health), ecological, or economic pillars of sustainability" (NRC 2011). ITRC's *Green and Sustainable Remediation: A Practical Framework* (ITRC 2011a) provides project managers with a process and tools to systematically consider relevant sustainability issues for a specific project.

8.3.1.3 Option – Facilitate Stakeholder Acceptance

Section 3.1 provides information on identifying and engaging stakeholders in the risk assessment. Beyond the regulatory context, environmental risk management often involves social, political, aesthetic, and economic considerations that project managers must balance accordingly. Although risk assessors tend to regard their work in technical terms and succeed in developing risk assessments that are compliant with regulatory requirements and scientifically correct, the methods and assumptions that form the basis of a risk assessment may ignore or discount other important factors of risk management described in Section 8.3.1.1 and Section 8.3.1.2. Facilitating stakeholder acceptance may involve integrating these other factors to acknowledge stakeholder concerns and risk perception. Risk communication issues relevant to this process are discussed in Chapter 9.

8.4 Resources and Tools

The following resources and tools were not cited in the sections above and are included here for further information.

Risk Assessment and Risk Management in Regulatory Decision -Making. Final Report (Commission 1997b)

Alternatives for Managing the Nation's Complex Contaminated Groundwater Sites (NRC 2013)

9.0 RISK COMMUNICATION

Risk communication is an integral part of the risk assessment process, which typically includes the processes of communication among the agencies and between the agencies and organizations responsible for site assessment and management. Risk communication also includes communication with the various parties who are potentially at risk from the site or are otherwise interested in the site. Different elements of the overall risk communication process can have varied purposes (ITRC 2008; USEPA 2007e). Overall, the risk communication process is designed to be iterative and to inform the risk assessment and risk management decisions. The goal of risk communication is for all stakeholders to have a common understanding of the processes and assumptions used in risk assessment. Often, however, risk communication issues can only be minimized, not avoided. Section 3.1.1.3 provides detail on how to identify and engage stakeholders.

Possible strategies and some available tools for supporting risk communication to the public are presented in this section. The level and type of risk communication vary depending on the complexity of the site and the level of potential risk and risk perception associated with the site. The list of resources at the end of this chapter contains additional references that address specifics on communication in greater detail. This chapter focuses on some of the key issues in risk communication. The key issues are organized around three general topic areas:

Soliciting Stakeholder Input

- When to Solicit Stakeholder Input

Recognizing Challenges in Risk Perception and Interpretation

- Risk Perception and Interpretation Create Challenges

Using Effective Presentation Strategies

- Identifying Effective Presentation Strategies

9.1 Soliciting Stakeholder Input

9.1.1 Issue – When to Solicit Stakeholder Input

Communication with stakeholders should be iterative and may support all stages of the risk assessment from scoping through the implementation of recommendations in risk management. Early and earnest involvement of stakeholders often improves the quality of the risk assessment, while also expediting the review and revision process (see Section 3.1).

9.1.1.1 Option –Timing and Level of Stakeholder Input is Site Specific

Although early stakeholder involvement is encouraged, the timing of engagement may vary for different stakeholders. For example, certain stakeholders might be involved only during development of the CSM for the purpose of identifying site-specific exposure activities. When stakeholders are not engaged until after the assessment is complete, communication is typically in one direction—from risk managers to the public—and often in the form of announcements of the results of completed assessments or of remedial action decisions. This approach risks a win-lose confrontation, in which some stakeholders may feel disempowered and present potential roadblocks to project completion for various reasons.

The appropriate level and scope of engagement is project-specific and depends on the interests and background of individual stakeholders and the scale and complexity of the risk assessment.

9.2 Recognizing the Challenges in Risk Perception and Interpretation

9.2.1 Issue – Risk Perception and Interpretation Create Challenges

Even though stakeholders may be familiar with the risk assessment process, stakeholders often have different perspectives on the significance of the findings of the risk assessment and appropriate risk management actions. These differing perspectives affect the perception of risks by stakeholders.

As described in USEPA's *Risk Communication Handbook* (USEPA 2007e), risk perception involves the influence of subjective factors on how risks are understood and valued. Characteristics of a hazard and the subjective context of the perceiver (qualitative personal views) are as important as the objective (quantified) risk in influencing an individual's perception of risk. For example, while odors may present no physical risk, failure to address them in a timely manner may elevate other concerns about the credibility of the cleanup process. Risk communications must not underestimate the importance and validity of risk perception.

Typical influences on an individual's perception of a numerical risk estimate include:

- whether the individual is voluntarily or involuntarily placed at risk from the hazard (for example, cancer risks from smoking versus pesticide residue on produce)
- the degree to which the hazard represents a dreaded or catastrophic event (for example, cancer fatality risks from exposures to intense sunlight versus cancer risks from a nuclear power plant release).

Typical influences related to the personal context include:

- feelings of equity, fairness, or control in the distribution of cost, benefits, and potential secondary risks (for example, when pollution risks are borne by local residents and the benefits

of allowable emissions from a factory accrue to remote shareholders)
- levels of trust in the institution or industry generating the secondary risks (for example, radiation risks related to a medical products facility may be perceived more favorably than those from a nuclear power facility)
- the degree of familiarity with the potential risk (for example, risks from automobile travel versus risks from airline travel for someone who has never flown)

These influences correspond to the audience's cultures, traditions, and individual experiences and may play a greater or lesser role in risk communication depending on site-specific factors.

9.2.1.1 Option – Be Aware of, and Address, Possible Differences in Perceived Risks

Risk communication efforts should be attuned to the presence of these influences on relevant stakeholders. The Center for Risk Communication (Center for Risk Communication 2013) indicates that only five percent of public stress is driven by factual issues. The remaining 95% reflects perception. Risk communication must address not only the magnitude of the problem, but also the discrepancy between perceived and actual risks.

9.2.1.2 Option – Use Effective Risk Communication Methods

Risk communicators should recognize that they may be judged based on their role in the process. For example, a project manager has a professional interest in the outcome that may be perceived as a conflict of interest by some stakeholders. Be cognizant of how the risk communicator's role may be perceived. Stakeholder reactions may seem personally directed at the risk communicator, when the reactions are in fact directed at the role.

Effective presentation of the risk assessment can help to provide an informed perception of risks. Numerous publications address effective risk communication, including USEPA's succinct seven cardinal rules of risk communication (USEPA 1988b), as well as USEPA's *Risk Communication Handbook* (USEPA 2007e), and other guidance (Adler and Kranowitz 2005). The seven cardinal rules of risk communication can be incorporated into the presentation of the risk assessment by presenting the objectives and findings transparently, and acknowledging potential bias, error, and uncertainty. The concept of acceptable levels of risk and, if applicable, the role of media-specific levels (within the framework of federal or state regulations and guidance) should also be presented. The consistency of the information presented during risk communication should be maintained throughout the risk assessment process, balanced by stakeholder and public concerns. During planning for the risk assessment, effective risk communication streamlines discussion of results with stakeholders. As the project progresses and nears completion, effective risk communication should result in an outcome that most, if not all, consider reasonable.

USEPA's Seven Cardinal Rules for Risk Communication

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

Source: USEPA 1988b

Acknowledging potential differences in risk perceptions is a key to successful risk communication. The pros and cons of proposed risk management strategies to address objective risks must be discussed in a factual and understandable manner with stakeholders. These principles and plans should be presented in language that is appropriate for the audience. The guidance for the U.S. Plain Writing Act (PLAIN 2011) and subsequent executive orders is useful in framing risk communications in approachable language.

9.3 Using Effective Presentation Strategies

9.3.1 Issue – Identifying Effective Presentation Strategies

Successful risk presentation conveys the context, objectives, scope, assumptions, methods, and endpoints related to the risk assessment to both technical and nontechnical audiences.

9.3.1.1 Option – Develop an Appropriate Message for Communication with the Public

If DQOs (see Section 3.3.1.2) were developed during project planning, then they may be an effective tool for communicating information to stakeholders. When communicating to nontechnical audiences, the structure underlying the risk assessment must be conveyed clearly and succinctly before meaningful communication is possible. Crucial elements include the regulatory context and objectives, the CSM, the results of the risk assessment, and the risk management alternatives. If stakeholders were involved in the initial planning phases of the assessment, reviewing this information during the risk presentation is an excellent means of focusing comments within the constraints of the agreed-upon scope and purpose of the assessment.

USEPA's Steps for Message Mapping

Strategic message development through message mapping (USEPA 2007g) follows specific actions to:

1. *Identify stakeholders.*
2. *Elicit stakeholder concerns.*
3. *Identify common concerns.*
4. *Develop key messages.*
5. *Develop supporting information.*
6. *Test the message.*
7. *Plan for message delivery.*

The technical stakeholders involved in risk communication must have a common understanding of the key findings, biases, and uncertainties related to the risk assessment prior to presenting findings to nontechnical stakeholders. In presenting the risk results to stakeholders, the focus should be equally on the CSM, the numerical results of the risk calculations, the key analytes and pathways driving risk, and on the uncertainty and protective biases that may be associated with the results. If technical stakeholders appear to present different conclusions or judgments on these aspects of the assessment, then other stakeholders may conclude, rightly or wrongly, that the scientific integrity of the assessment has been compromised.

The primary elements of a strategic and effective message development and delivery for conveying risk assessment results to the general public are (1) succinct, relevant, accurate, and credible messages (images are most effective) and (2) timely incorporation of new information in messages as the project unfolds. Message mapping, a seven-step process useful in developing clarity in risk communication, can be considered for this task (USEPA 2007g).

Risk communication messages should generally be definitive, precise, and informational. A brief core message might be considered along the lines of:

Problem: Chemicals in environmental media are poorly contained and nearby residents may unwittingly be exposed to chemicals in environmental media during daily activities.

Proposed option: Responsible party will remove (or contain) chemicals in environmental media after defining a well-marked exclusion zone to minimize public exposures.

Discussion topics: For example:

- What are the scope and schedule of the planned approach?
- What additional concerns not currently identified in the DQOs or CSM should we plan to address?

Each statement can be broken down further; however, too many bullet points can lead to inefficiency and information overload.

9.3.1.2 Option – Use an Effective Delivery Method for Communication with the Public

For sites with a high level of public awareness, materials should be prepared for use in forums such as print, television, radio, websites, and social media. Be aware that news may travel by less formal methods, such as word of mouth, certain forms of social media, or biased outlets of various types. Individuals and biased organizations may omit relevant facts, provide slanted views, digitally alter visual materials, or fail to announce progress or important changes; hence, the need for consistent and effective communication from project stakeholders.

The use of bullet points is recommended for written communications. Storyboards, formal documents, and handouts should all contain the core message. The storyboard or handout message should fit on one page or, at most, one two-sided sheet. Details or elaborations would be provided only in longer, formal documents. Risk, and progress toward assessing and managing risk, can be communicated with both written and audiovisual materials. These materials may be shared with the media, and the team may also broadcast information themselves as webinars, podcasts, or recorded interviews. These materials may be presented on a dedicated website for general availability any time. A question and answer portal could be made available with more traditional forms, such as an address (or mail code), a fax number, or a dedicated phone line with voice mail.

Town hall meetings may or may not be necessary or requested for presenting the core message (the risk assessment objectives, status, and any updates) and receiving feedback and concerns. In these meetings, the speakers must be knowledgeable, earnest, articulate, and approachable. The presentation ideally consists of project news, especially milestones met, in the context of the core message. Clear answers to anticipated audience questions should be developed well in advance. When inaccurate and inflammatory accusations are likely to arise, audience members may be encouraged to submit questions before the meeting, to be vetted by those preparing for the meeting and answered during the meeting.

9.4 Resources and Tools

The following resources and tools were not cited in the sections above and are included here for further information.

Government-to-Citizen Communications: Utilizing multiple digital channels effectively (APHA 2009)

Public Sector Digital Communication Management Best Practices (ATSDR 2012)

Planning and Promoting Ecological Land Reuse of Remediated Sites; Chapter 8 (Community Stakeholders), ECO-2 (ITRC 2006)

Improving Risk Communication, National Research Council, Committee on Risk Perception (NRC 1989)

Twenty Things You Can Do To Help Environmental Stakeholder Groups Talk More Effectively About Science, Culture, Professional Knowledge, and Community Wisdom (Adler and Birkhoff 2000)

Applying Risk Communication Principles to Social Media Crisis. (Maltoni 2010)

The Determinants of Trust and Credibility in Environmental Risk Communication: An Empirical Study (Peters, Covello, and McCallum 1997).

10.0 TRIBAL AND PUBLIC STAKEHOLDER PERSPECTIVE

For the purpose of this document, the term "public stakeholder" means the citizen stakeholder, community, or environmental advocacy members, and members of the affected public. "Tribal" represents the Native American tribes, Pueblos, Nations and others, Native Hawaiians, and Native Alaskans (for example, Tlingit, Athabascan, Upik, and Inupiat).

Human health risk assessment is used to evaluate the probability that exposure to chemicals present in the soil, air, or water at a site can result in adverse human health effects. In order to effectively engage the public and tribal stakeholders in the decision-making process, all parties must reach a common understanding of what the potential risks are and what decisions and actions must be taken to reduce those risks and protect human health. This common understanding serves as the basis for the discussions needed to reach a fair and transparent risk management decision about the site.

Public and tribal stakeholders want to be assured that site investigation activities, whether for screening or cleanup, do no harm. When they share in the decision-making process, public and tribal stakeholders are more likely to feel invested and involved in the site characterization and may be more likely to support the proposed cleanup. During site investigations stakeholders will want to know:

- What are the chemicals to be evaluated and the associated human health risks?
- What type of sampling plan will be used to determine whether or not the chemicals are present in environmental media? Why did you choose that sampling method over another? Why is this area being sampled and not that area over there?
- If the chemical is present in an environmental medium, what is the concentration that makes the chemical harmful to human health? Who made that determination and what was the basis for that decision? Is that criterion being used as the basis for site cleanup? If not, why?
- If a site needs to be cleaned up, what technology or process will be used? Who makes that decision? What are the risks associated with the cleanup activity? What are the alternatives? How do you know that all of the chemical was removed?
- If the site is occupied, how will the residents and owners be affected by the risk assessment and subsequent cleanup? What type of compensation can they expect? What kind of legal issues or property restrictions must be considered?
- If a site is deemed to be safe, what is the assurance that chemical concentrations will not increase over time and pose a health hazard in the future? What kind of institutional or engineering controls will be put into place? How will those institutional or engineering controls be enforced over a long period of time? In the case of the tribes, this assurance may need to extend to seven generations, which for many tribes is the length of time that their stewardship of Mother Earth extends (ITRC 2012a, ITRC 2012b).

Early and effective communications with public and tribal stakeholders to address these concerns is a crucial component of the risk management and decision-making process. It is unrealistic to expect citizen stakeholders or tribal members to be familiar with the science and statistical methods used in the calculation of toxicity values and the exposure assessment, but it is imperative that the underlying assumptions and values used for the basis of the risk assessment are transparent and communicated in a clear, concise, and understandable manner. At times, public and tribal stakeholders may need a better understanding of how sampling is done and why sample locations are selected. Sampling plans should aid the stakeholder in a better understanding of these approaches. (ITRC 2012a)

Public and tribal stakeholders must be identified and engaged during the project planning phase and should participate in the planning and implementation of the risk assessment. Public and tribal stakeholders may have information, knowledge, resources, or positions that may be affected by or may influence the risk assessment process (ITRC 2008). This information may be crucial in the development of the CSM.

Public and tribal stakeholders must also understand how the technical aspects of a risk assessment relate to them on a personal level. In addition, one person's perception of what is important in terms of risk may not necessarily be the same as another's. Individuals or groups may vary in how they evaluate the significance of risk and levels of uncertainty within their value systems and culture.

Differing value systems and cultural backgrounds are especially important when tribal stakeholders are present. Many tribes have treaties or other pacts with the federal government that grant them fishing, hunting, or cultural access rights in places that are not necessarily near their present-day reservations (ITRC 2011b). These tribes may have legal rights to the contaminated site or property. The special tribal access rights must be recognized and the appropriate tribal agencies included in the decision-making process.

Tribes have a government-to-government relationship with regulatory agencies, whereas public stakeholders do not. Many tribes enforce their own USEPA-approved water quality standards. Some tribes are developing tribal risk assessments that incorporate pathways and scenarios based on traditional and cultural routes of exposure, which in some cases are profoundly different from traditional risk assessments. Also, current state or federal geographical boundaries do not define boundaries to tribal ancestral homelands. For example, a major Department of Energy facility in New Mexico is located entirely on the ancestral homeland of a neighboring tribe. DOE has honored the government-to-government relationship and has partnered with the tribe in monitoring efforts and any proposed actions which may affect tribal members and resources. Any risk assessment that affects tribal stakeholders must be in compliance with tribal regulatory limits and should be a process that respects the tribe's government-to-government status (ITRC 2012a).

Identifying affected public and tribal stakeholders early in the planning process and including the key stakeholders in the planning and implementation of the risk assessment is vital to the success of a risk management decision. For example, fish, game, or vegetation grown or present on or near

the site may be a significant source of sustenance for Native Americans, Asians and Pacific Islanders. Understanding the specific species, the amount consumed, and their location on and in the area of the site is important to developing a risk assessment that accurately reflects the activities and potential exposure pathways for these receptors. Public and tribal stakeholder participation in defining the risk assessment and cleanup criteria and selecting the sampling and monitoring plans allows for a more open, transparent, and understandable decision-making process for risk management.

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APPENDIX A. SOURCES OF TOXICITY VALUES

Section 5.1.1 discusses choosing among toxicity values from multiple sources and references this table. In addition, Section 5.2.1 discusses understanding uncertainty in the toxicity values and references this table.

Table A-1. Sources of toxicity values

Name	Regulatory Agency	Available Toxicity Value				Review Process	Additional Notes
		Noncancer Oral	Noncancer Inhalation	Cancer Oral	Cancer Inhalation		
Federal							
The Integrated Risk Information System (IRIS) (USEPA 2013b)	USEPA	RfD	RfC	SF	UR	Rigorous review process which includes: internal agency review, inter-agency science consultation, independent external review, public comment, inter-agency science discussion, and final approval by the Office of Research and Development	Intended for use by all USEPA programs

Table A-1. Sources of toxicity values (continued)

Name	Regulatory Agency	Available Toxicity Value				Review Process	Additional Notes
		Noncancer Oral	Noncancer Inhalation	Cancer Oral	Cancer Inhalation		
Provisional Peer Reviewed Toxicity Values (PPRTVs) (USEPA 2013f)	USEPA (Superfund Health Risk Technical Support Center for the USEPA Superfund Program)	RfD	RfC	SF	UR	Internal review by USEPA scientists followed by external peer-review by independent scientific experts	Revised Health Effects Assessment Summary Table (HEAST) values are values that have been derived as per the request of Regional Superfund Offices for chemicals that are not covered under IRIS In 2009, for certain PPRTV assessments, screening toxicity values were appended. While these values have utility for screening purposes, caution should be taken when using these screening toxicity values to support final remedial action decisions. Similar to IRIS assessment but does not go through as rigorous review.
Agency for Toxic Substances and Disease Registry (ATSDR) (ATSDR 2013)	US Department of Health and Human Services	MRL[1,2]	MRL[1,3]	--	--	Rigorous review process which includes: Human Health Effects/MRL workgroup within the Division of Toxicology & Environmental Medicine; expert panel of peer reviewers; agency wide MRL workgroup (participation from other federal agencies)	MRLs set below levels that may cause adverse human health effects in sensitive subpopulations Not intended to define clean-up or action levels Serve as screening values Does not provide cancer toxicity values

Table A-1. Sources of toxicity values (continued)

Name	Regulatory Agency	Available Toxicity Value				Review Process	Additional Notes
		Noncancer Oral	Noncancer Inhalation	Cancer Oral	Cancer Inhalation		
Health Effects Assessment Summary Tables (HEAST) (USEPA 1997d)	USEPA (Superfund and RCRA) hazardous waste programs	RfD	RfC	SF	UR	Updated regularly from the early to mid-1990s; known as the Quarterly; Last update was 1998	Historical database of human health toxicity values
State							
Toxicity Criteria Database (CalEPA 2013)	Cal EPA	ChRFD; PHG[4]	REL	SF[5]	UR[5]	Submitted for public comments and external peer-review	Developed by the Office of Environmental Health Hazard Assessment (OEHHA) under SB32, the California Land Environmental Restoration and Reuse Act
Energy and Environmental Affairs Risk Assessment Web Site (MADEP 2014)	Mass DEP					Peer-reviewed within the Office of Research and Standards	
Health Risk Values & Health Risk Limits (MPCA 2014)	Minnesota Pollution Control Agency	HRL/RfD (non-cancer)	HRV/RfC (non-cancer)	HRL/SF (cancer)	HRV/UR (cancer)	Have adopted the USEPA guidelines for derivation and review	For air and water; derived with stakeholder involvement
Toxicity Values (used to develop Soil Cleanup Objectives) (NYDEC 2014)	New York State DEC	RfD	RfC	SF	UR	Selected from values published by established regulatory agencies; acute internally and externally reviewed	

Table A-1. Sources of toxicity values (continued)

Name	Regulatory Agency	Available Toxicity Value				Review Process	Additional Notes
		Noncancer Oral	Noncancer Inhalation	Cancer Oral	Cancer Inhalation		
Toxicity Factors (TCEQ 2014)	Texas Commission on Environmental Quality	RfD	ReV	SF	URF	Developed and reviewed by TCEQ toxicologists; posted for public review and comment and internally revised prior to finalizing the toxicity factors.	
International							
WHO/ International Programme on Chemical Safety's (IPCS) Concise International Chemical Assessment Documents (CICADs) (WHO 2013)	WHO	TDI	TC	--	--	Document is first reviewed by IPCS followed by international peer-review which is then proceeded by final review by the Review Board	Can be used in conjunction with the Environmental Health Criteria documents
National Institute of Public Health and Environmental Protection, Netherlands provides Maximum Permissible Risk (MPR) (Netherlands National Institute for Public Health and the Environment 2013)	RIVM	TDI	TCA	CR	CR	International committee of experts has reviewed the existing toxicological reviews for substances for which an MPR is to be developed	Provisional and temporary values presented

Table A-1. Sources of toxicity values (continued)

Name	Regulatory Agency	Available Toxicity Value				Review Process	Additional Notes
		Noncancer Oral	Noncancer Inhalation	Cancer Oral	Cancer Inhalation		
Toxicological Reference Values (Health Canada 2010)	Health Canada	TDI; ADI	TC	SF	UR	Sources of TRVs include: Health Canada Water Quality; Health Canada Priority Assessments Program; US USEPA IRIS; Cal EPA; WHO; ATSDR	--

--No Value Provided
1. Acute, sub-chronic and chronic duration values available
2. Oral MRLs analogous to RfDs
3. Inhalation MRLs analogous to RfCs
4. Derived for drinking water only and are not intended to be used as target levels for other environmental media
5. Cancer Potency Values
USEPA- United States Environmental Protection Agency
RfD- Reference Dose
RfC- Reference Concentration
SF- Slope Factor
UR- Unit Risk
MRL- Minimal Risk Level
Cal EPA- California Environmental Protection Agency
ChRfD- Child-specific Reference Dose
PHG- Public Health Goal
REL- Reference Exposure Level
Mass- Massachusetts
DEP- Department of Environmental Protection
DEC- Department of Environmental Conservation
ReV- Reference Value
URF- Unit Risk Factor
TCEQ- Texas Commission on Environmental Quality
WHO- World Health Organization
TC- Tolerable Concentration
TDI- Total Daily Intake
RIVM- National Institute of Public Health and the Environment
TCA- Tolerable Concentration in Air
CR- Cancer Risk
ADI- Acceptable Daily Intake

APPENDIX B. TOXICITY ASSESSMENT OVERVIEW

Toxicity values for many chemicals have been developed by USEPA and other regulatory or public health agencies (for example, ATSDR, WHO). As a result, in the process of conducting a risk assessment, a risk assessor is generally not charged with the task of conducting toxicity assessments. More often, toxicity values for most if not all chemicals of potential concern at a site are available from readily accessible sources.

The risk assessor should, however, understand the basis, assumptions, and uncertainties that underlie the derivation of toxicity values. This understanding can help appropriately characterize and communicate the risks from a particular exposure scenario and assist risk managers in making informed risk management decisions.

Toxicity values have many descriptors and qualifiers: cancer and noncancer, oral and inhalation, and chronic, subchronic, and acute. The toxicity values used to evaluate a particular exposure scenario should be consistent with the calculation being performed (cancer risk versus noncancer risk), the exposure routes of interested (oral, dermal contact, inhalation) and, in the case of noncancer risk, the exposure period being evaluated (chronic, subchronic, or acute exposure).

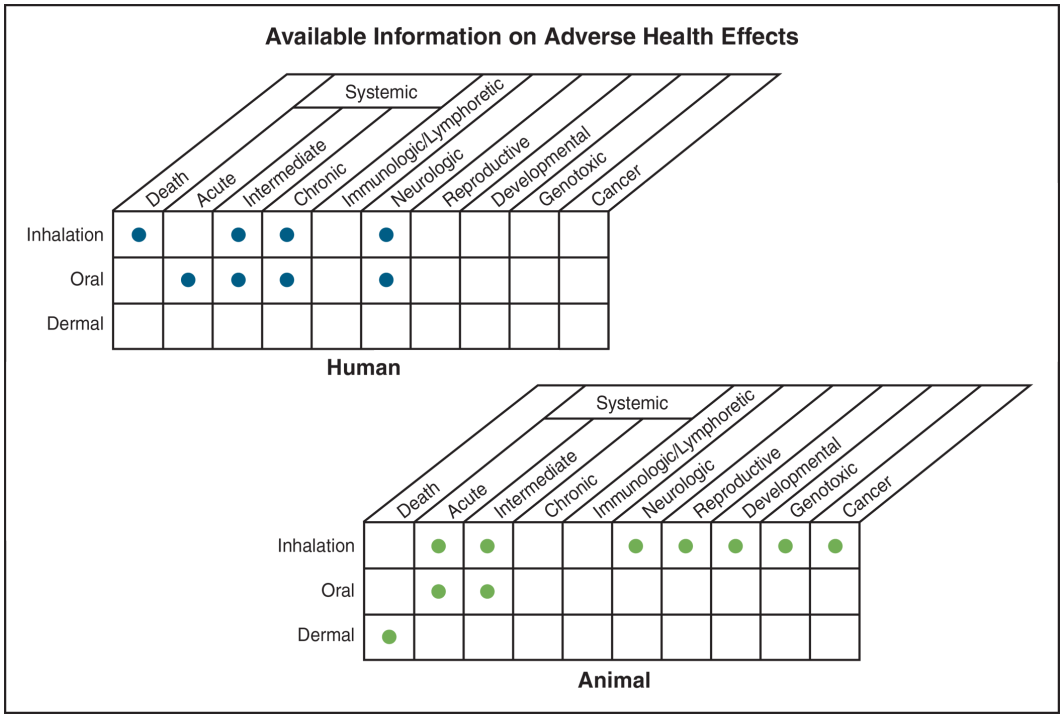

Figure B-1. Consideration of adverse effect (endpoint), route of exposure, and relevance to human health in toxicity assessment.

Source: Figure 3-4 of ATSDR 2006.

The toxicity assessment component of a risk assessment considers the types of adverse health effects associated with chemical exposures (Figure B-1), the relationship between the magnitude of exposure and adverse effects (Figure B-2), and related uncertainties such as the weight of evidence of a particular chemical's carcinogenicity in humans (USEPA 1989a).

The toxicity assessment commonly involves two steps: hazard identification and dose-response assessment (USEPA 2012c). Figure B-2 illustrates multiple adverse health effects and related dose response relationships for the same chemical. The outcome of a toxicity assessment is usually expressed as a toxicity value, such as a reference dose (RfD) or cancer slope factor (CSF), which incorporates the findings of the hazard and dose-response assessments and safety factors that address uncertainties in the assessment. A toxicity assessment may also conclude that a toxicity value cannot be developed because of inadequate data.

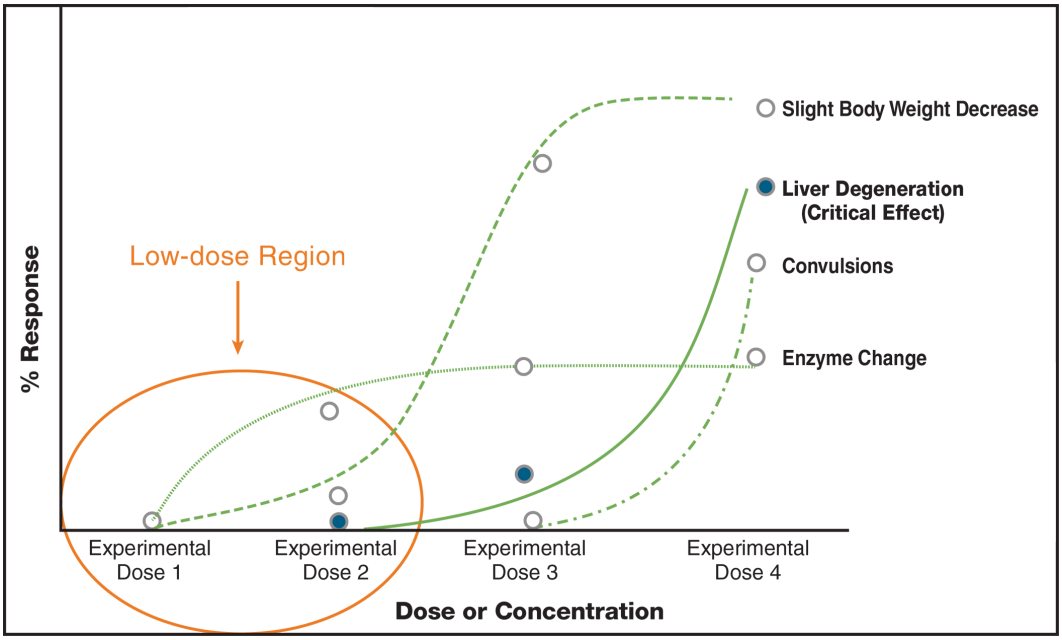

Figure B-2. Multiple adverse health effects and related dose-response relationships for the same chemical.

Source: NCEA, USEPA (USEPA 2010b).

B.1 Toxicity Assessment of Noncarcinogens

Chemicals with known or assumed noncancer effects are presumed to have a dose below which no adverse effects occur, because of the body's ability to eliminate or detoxify the chemical. The dose at which this effect occurs is known as the threshold dose. In laboratory experiments, the highest nonzero tested dose at which no adverse effects occur is called the "no observed adverse effect level" (NOAEL) and the lowest dose where an adverse effect does occur is known as the "lowest observed adverse effect level" (LOAEL). The threshold dose in the experimental model lies between the NOAEL and LOAEL. The value of the NOAEL and LOAEL depends on the design of the experiment: an experiment with more or fewer animals, or with a difference selection of test

doses, will have a different NOAEL and LOAEL. Some toxicity studies fail to identify a NOAEL as a result of dose selection or lack of statistical significance in increased effect (Figure B-4).

The benchmark dose (BMD) corresponding to a lower limit of a one-sided 95% confidence interval on the BMD, is USEPA's preferred approach to using NOAEL/LOAEL approach because it is determined using all data from a dose-response curve and is not limited by dose selection. (Figure B-3) The BMD is selected as the dose level that produces a predetermined change in adverse response. With a degree of certainty, noncancer effects are not expected to occur if the dose is below the threshold, regardless if the exposure occurs daily for the span of a lifetime. Figure B-4 illustrates how points of departure within individual toxicity studies can differ.

Noncancer toxicity values are in units of milligrams of compound per kilogram of body weight (mg/kg-day) for oral/dermal exposure and micrograms of compound per meter cubed of inhaled air ($\mu g/m^3$) for inhalation exposure.

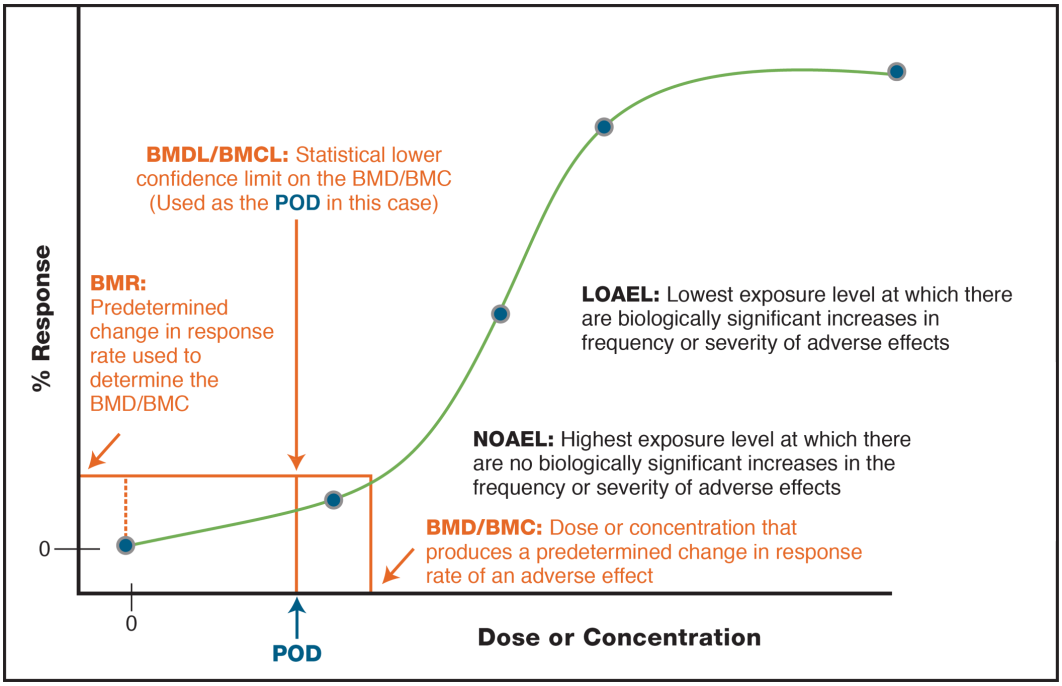

Figure B-3. Dose-response curve showing various options for points of departure for a noncancer endpoint.

Source: NCEA, USEPA (USEPA 2010b).

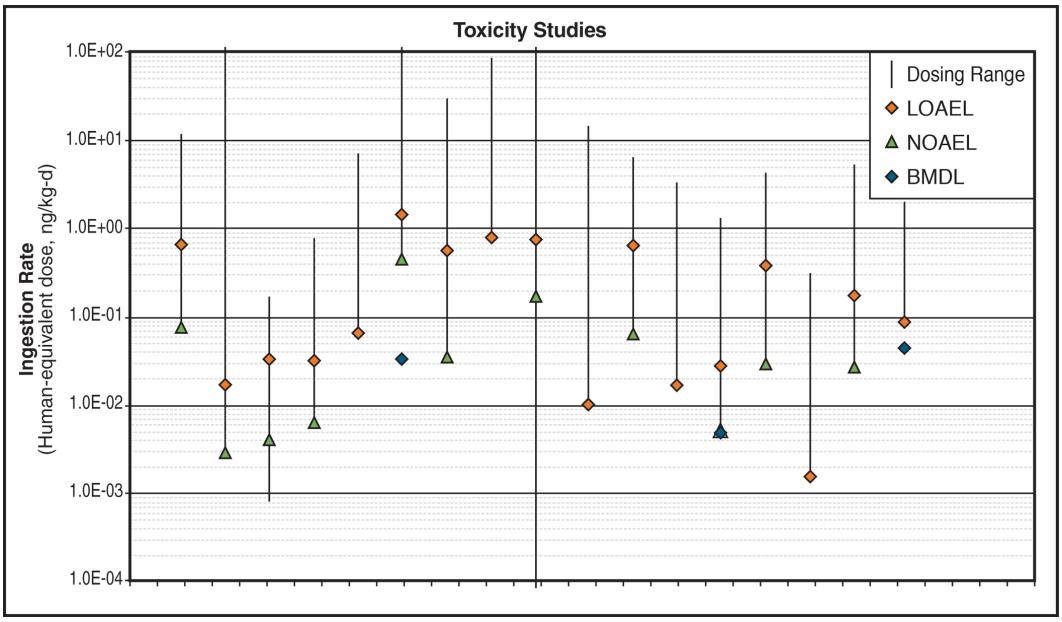

Figure B-4. Comparison of points of departure derived across studies for various adverse effects from same chemical. More than an order of magnitude difference in possible points of departure within studies is shown, with implications for reference value determination.

Source: NCEA, USEPA (USEPA 2010b).

Typically, animal dose-response toxicity studies provide data for hazard identification and toxicity values. This approach presents an uncertainty or knowledge gap in comparing how humans might respond relative to the animals models used. To account for this uncertainty, USEPA and other agencies apply uncertainty factors (UFs) when an oral reference dose (RfD) or inhalation reference concentration (RfC) is derived from animal studies. The RfD/RfC value is derived by dividing the point of departure (NOAEL, LOAEL or BMD) by the overall UFs. The UFs are generally applied, when appropriate, to account for:

- the uncertainty in extrapolating from the LOAEL in the absence of the NOAEL;
- the use of the NOEL obtained from a subchronic study an extrapolating to a chronic exposure;
- confidence in the adequacy of the overall database;
- interspecies extrapolation (animal to human);
- intra-species variation in sensitivity.

Application of UFs to a study's point of departure is intended to produce a health-protective estimate of threshold that is lower than the actual threshold.

B.2 Toxicity Assessment of Carcinogens

For chemicals with known or assumed cancer effects, it is typically presumed in the absence of sufficient evidence that no threshold dose for effects exists (in other words, some incremental level of

risk is associated with any dose above zero). To assess carcinogenic effects, a two-step process is used. First, a chemical is assigned a weight-of-evidence classification based on the likelihood that a chemical is a human carcinogen (for example, "known", "probable", "suggestive evidence"). If the chemical drives the risk estimate at a site, then this classification may factor into a site management decision, such as response urgency.

Next, if a chemical is a known or probable human carcinogen, then a CSF is calculated. Various models may be used to calculate the CSF, but all assume that there is no threshold and use both animal and human data to calculate the CSF, with a 95% upper confidence bound on the slope (the actual unit risk is likely lower); see Figure B-5. The CSF is expressed as the rate of cancer per unit of dose $(mg/kg\text{-}day)^{-1}$ or as an inhalation unit risk factor (IUR) as the rate of cancer per unit of concentration of inhaled air ($\mu g/m^3$).

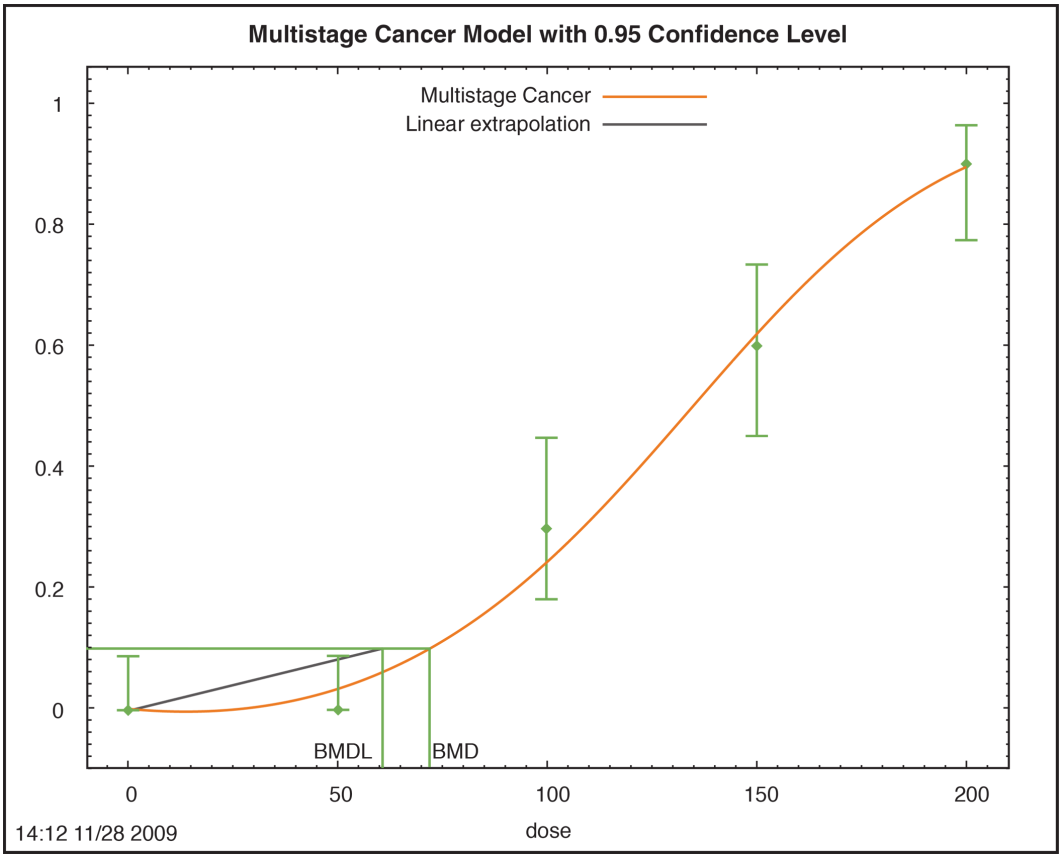

Figure B-5. Determination of a cancer slope factor.

Source: Environ, used with permission.

B.3 Summary

Toxicity assessment of chemicals entails its own practices of accounting for uncertainty to generate values adequately protective of human health in risk management informed by risk assessment. These practices include assumptions made regarding the potential for health effects in humans

based on animal studies, as well as adoption of uncertainty factors and upper confidence limits to quantify reference values and potency factors. The criteria for chemicals of concern at sites change as new toxicity studies become relevant and adequate or improved data quality becomes available. Risk managers must be aware of these issues and how they may affect decision making in risk management and communication. Alternatively, a toxicologist should be included on the project team for support regarding these issues.

B.4 Additional Resources

USEPA provides general guidance for conducting cancer and noncancer risk assessments, including the development and review of reference and risk values for health effects in humans. The following resources were not cited in the sections above and are included here for further information.

USEPA Cancer Guidelines (USEPA 2005b)

USEPA RfC Guidelines (USEPA 1994b)

Review of RfD and RfC Derivation Process (USEPA 2002d)

USEPA Science Policy Council Guidelines (USEPA 2000b) and (USEPA 2015b)

National Center for Environmental Assessment Guidelines for Peer Review (NCEA 2009)

NIH Introduction to Toxicology and Dose-Response (NIH 2010)

APPENDIX C. MODELS ROUTINELY USED TO ESTIMATE EXPOSURE CONCENTRATIONS FOR DIFFERENT EXPOSURE SCENARIOS AND EXPOSURE PATHWAYS

Section 6.2.2.2 discusses using models to estimate EPCs.

Table C-1. Models routinely used to estimate exposure concentrations for different exposure scenarios and exposure pathways

Exposure pathways	Models
Vapor Intrusion into Buildings	Generic empirical attenuation factors developed by USEPA (2012i) may be useful as a screening tool for predicting potential indoor air concentrations due to the migration of subsurface volatile chemicals into buildings through building foundations.
	Indoor air concentrations from the volatilization and migration of soil gas (from soil, groundwater or LNAPL) into a building can be estimated using the model described by Johnson and Ettinger (1991), which USEPA and other agencies recommend for screening evaluations (USEPA 2004c; ITRC 2007c; ITRC 2007d; NJDEP 2013; DTSC 2011b).
Vapor Emission from Exposed Water	Vapor emissions from exposed water surfaces in excavations can be modeled using the mass transfer coefficients recommended by USEPA (1995a).
Vapor Emission from Exposed Soil	Vapor emissions from exposed soil can be estimated using the Jury model (Jury, Spencer, and Farmer 1983; USEPA 1996b) based on depletion over time assuming that chemicals are present in the soil from the ground surface to an infinite depth. This model can be modified to estimate average vapor emissions over time assuming that chemicals are present in soil to a finite depth.
Air Dispersion	Average air concentrations can be estimated using empirical correlations presented in USEPA's Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites (USEPA 2002f).
	"Worst-case" ambient air concentrations due to vapor emission from outdoor areas can be estimated using USEPA's AERSCREEN (USEPA 2011a).
Dust Emissions and Dust Concentrations	Emission of respirable soil particulates (PM10) from outdoor soil can be calculated using the wind erosion model recommended by USEPA (1996b).
Residential Garden Vegetable Uptake	The uptake of chemicals in soil by homegrown produce can be estimated using the methods outlined in USEPA guidance (2005c; 2005d). The uptake of chemicals in soil by homegrown produce can be calculated assuming that chemical concentrations are present in the entire root zone and the chemical concentrations do not deplete or deplete over time (Jury, Spencer, and Farmer 1983).

APPENDIX D. COMMON RISK ASSESSMENT DEFAULTS AND POTENTIAL SITE-SPECIFIC OPTIONS

Section 7.1.1.1 includes discussion of alternatives to default assumptions for values in risk assessment calculations.

Table D-1. Common risk assessment defaults and site-specific options

Component of Risk Assessment	Route of Exposure	Chemicals	Common Default	Options
Characterization	All	All	Maximum detected or UCL on biased samples	Soil/sediment - perform Outlier test, address hot spot separately, calculate EPC that is true to the data distribution (area-weighted averages) Groundwater - use more reasonable/average EPC, use data from most recent rounds (where stabilized)
Characterization	All	PAHs, dioxins, pesticides, metals (commonly As)	All concentrations are presumed site-related	Use site-specific or literature values to quantitatively account for background contribution. Determine whether site-related using lines of evidence approach.
Exposure	All	All	Residential exposure may be possible anywhere	Selection of future land use through access planning documents or interview planners, evaluate feasibility of deed restrictions, identify areas of relatively lower concentrations
Exposure	All	All	Deterministic risk numbers	Probabilistic risk assessment may help bound the uncertainties and ranges of values
Exposure	Dermal absorption	Semivolatile organic compounds (SVOCs)	Pharmacokinetic properties– not from soil	Use literature based value from soil
Exposure	Fish consumption	All	Sport fish or subsistence fishers	Obtain site-specific/region-specific exposure data (creel study), camera observations for fishing activities
Exposure	Garden produce pathway	All	High bias, especially with elevated soil concentrations, deterministic plant:soil ratios	Use regression models where available (Bechtel Jacobs Company LLC 1998); sample existing vegetation or develop a test plot; compare modeled intakes of metals to background intakes published by USDA and ATSDR (USDA 2014; ATSDR 2014).

Table D-1. Common risk assessment defaults and site-specific options (continued)

Component of Risk Assessment	Route of Exposure	Chemicals	Common Default	Options
Exposure	Soil contact	All	Exposure to all depths may be assumed	Use a physically realistic mixing model if you assume deeper soil can be moved to the surface by excavation, use data relevant to receptors, implement institutional or engineering controls
Fate and Transport	Fish/biota uptake	All	Default/conservative bioaccumulation and uptake factors	Develop site-specific uptake factors, identify relevant region-/species-specific factors
Fate and Transport - Leaching to groundwater	Ingestion, dermal contact	Lead	Assumes default values for bioavailability and levels in background environmental media	Run IEUBK model (USEPA 2010a) with site-specific values, obtain in vitro or in vivo site-specific bioavailability data, use published % bioavailability
Fate and Transport - Leaching to groundwater	Ingestion, dermal contact	Metals, pesticides and dioxins	Assumes 100% bioavailability	Determine % bioavailable and reestimate risk/hazard impacts (major issue for As due to conservative toxicity)
Fate and Transport - Partitioning from solid to liquid matrices	Ingestion, dermal contact	All	Default partitioning coefficient (Kd)	Obtain site-specific data, use relevant literature data
Fate and Transport - Partitioning from solid to liquid	Ingestion, dermal contact	All	Equilibrium partitioning and infinite mass	Use finite mass, Synthetic Precipitation Leaching Procedure (SPLP)-type leaching from Soil Screening Guidance (soil to groundwater) (USEPA 1996b)
Fate and Transport - Partitioning from solid to air matrices	Inhalation	All	Equilibrium partitioning and infinite mass	Use finite mass, Synthetic Precipitation Leaching Procedure (SPLP)-type leaching from Soil Use finite mass Jury model (soil to air) (Jury, Spencer, and Farmer 1983)
Fate and Transport - Vapor intrusion	Inhalation	Volatile organic compounds (VOCs)	Use models such as: Johnson and Ettinger, empirical, 3-D.	Consistent with other routes of exposure in the risk assessment, use all available data and good science to evaluate the relevance/significance of this inhalation pathway.
Toxicity	All	Chromium	Conservatively use hexavalent	Analytical speciation and application of appropriate toxicity

Table D-1. Common risk assessment defaults and site-specific options (continued)

Component of Risk Assess-ment	Route of Exposure	Chemicals	Common Default	Options
Toxicity	All	Emerging Chemicals	Chromium toxicity For chemicals with no standards or evolving standards, there is no default, which makes site decisions challenging	value(s) for all environmental media Identify emerging chemicals as early in the process as possible and get team agreement on how to evaluate and make decisions on these chemicals.
Toxicity	All	Non-carcinogens	For screening, and sometimes baseline assessments, sum all hazard quotients	Calculate separate hazard indexes for different toxic effects
Toxicity	All	Non-carcinogens	Treat all values identically for risk management	• Focus on chemicals driving the risk estimates • Focus on chemicals with low uncertainty factors incor-porated into the noncancer toxicity values • Focus on most realistic exposure scenarios
Toxicity	All	All	Appendix values from Provisional Peer Reviewed Toxicity Value (PPRTV) in screening and iden-tification of risk-drivers (USEPA 2013f)	per PPRTV - do not use Appendix values for cleanup decisions, use literature values to provide ranges of outcomes
Toxicity	All - Inges-tion	PCBs	Quantitatively evaluate non-cancer hazards for exposure to Aroclors that do not have RfDs	Choose appropriate surrogate or evaluate qualitatively

APPENDIX E. EXAMPLE RISK PRESENTATION TABLE

Section 7.2.1.1 explains how to present risk results in a clear and organized manner. The following table offers an example of the clear presentation of risk results.

Table E-1. Risk Results Table: Incremental cumulative cancer risk and noncancer hazard index results, On-site, Area 1

Exposure to Soil					Outdoor Worker		Indoor Worker		Construction Worker	
Chem Group	Chemical	CASRN	Class	Exposure Conc. (mg/kg)	Soil Exposure		Indoor Air Exposure		Soil Exposure	
					Risk	HQ	Risk	HQ	Risk	HQ
VOC	Benzene	71-43-2	A	0.15	1E-08	0.0002	2E-06	0.02	3E-09	0.0003
VOC	Bromodichloromethane	75-27-4	B2	0.1	8E-10	0.000002			1E-10	0.0003
VOC	Chloroform	67-66-3	B2	0.341	9E-08	0.0002	1E-05	0.02	2E-08	0.001
VOC	Chloromethane	74-87-3	D	103		0.07		**4**		0.08
VOC	Cumene	98-82-8	D	2.12		0.00007		0.008		0.0003
VOC	1,2-Dichlorobenzene	95-50-1	D	0.083		0.000002		0.0001		0.000001
VOC	1,1-Dichloroethane	75-34-3	SC	7.64		0.0005		0.05		0.0003
VOC	1,2-Dichloroethane	107-06-2	B2	2	4E-07	0.005	**4E-05**	**0.7**	7E-08	0.003
VOC	1,1-Dichloroethene	75-35-4	C	1.12		0.0004		0.02		0.002
VOC	Trichloroethene	79-01-6	HC	203	9E-06	**3**	**1E-03**	**400**	2E-06	**10**
VOC	Vinyl Chloride	75-01-4	A	1.36	3E-07	0.002	8E-06	0.05	6E-08	0.007
VOC	Xylenes (total)	1330-20-7	ID	7.33		0.001		0.1		0.002

Table E-1. Risk Results Table: Incremental cumulative cancer risk and noncancer hazard index results, On-site, Area 1 (continued)

Exposure to Soil					Outdoor Worker		Indoor Worker		Construction Worker	
Chem Group	Chemical	CASRN	Class	Exposure Conc. (mg/kg)	Soil Exposure		Indoor Air Exposure		Soil Exposure	
					Risk	HQ	Risk	HQ	Risk	HQ
SVOC	Benzo(a)pyrene	50-32-8	B2	0.069	2E-07		5E-13		2E-08	
SVOC	Chrysene	218-01-9	B2	0.16	4E-10		4E-13		3E-11	
SVOC	Dibenz(a,h)anthracene	53-70-3	B2	0.22	6E-07		1E-15		5E-08	
SVOC	Fluoranthene	206-44-0	D	0.11		0.000003				0.0000006
SVOC	Fluorene	86-73-7	D	0.046		0.000001				0.0000002
SVOC	Indeno(1,2,3-cd)pyrene	193-39-5	B2	0.1	3E-08		3E-14		2E-09	
SVOC	Naphthalene	91-20-3	C	0.717	1E-08	0.0004	2E-07	0.005	2E-09	0.002
SVOC	Phenanthrene	85-01-8	D	0.32		0.00001				0.000002
SVOC	Pyrene	129-00-0	NL	0.11		0.000004				0.0000007
INORG	Arsenic	7440-38-2	A	7	2E-06	0.01			2E-07	0.006
INORG	Cadmium	7440-43-9	B1	3	4E-11	0.002			6E-10	0.005
INORG	Mercury	7439-97-6	D	0.06		0.0002		0.0009		0.0005
				Cumulative Cancer Risk or Hazard Index (HI):	1E-05	**3**	**1E-03**	**405**	2E-06	**10**

Notes:
Chem Group - chemical group
CASRN - Chemical abstracts service registry number

Class - USEPA Weight-of-Evidence Cancer Classification. Original classifications were (A, B1, B2, C, D, E), these are being replaced with "carcinogenic to humans," "likely to be carcinogenic to humans," "suggestive evidence of carcinogenic potential," "inadequate information to assess carcinogenic potential" and "not likely to be carcinogenic to humans." (USEPA 1986, 2005a)
HC - Human carcinogen
ID - inadequate data to classify as a human carcinogen|
NL - Not likely to be carcinogenic to humans
SC - Suggestive evidence of carcinogenicity but not sufficient to assess human carcinogenic potential
Grey shaded results indicate a cancer risk greater than 10^{-4} or noncancer HQ greater than 1.
Bold results indicate a cancer risk greater than 10^{-5} or noncancer HQ greater than 0.1
Soil exposure pathways consist of incidental ingestion of soil, dermal contact with soil, and inhalation of fugitive dusts and outdoor vapors
Indoor air pathway considers building occupants exposed to vapors from soil gas infiltrating a hypothetical building

APPENDIX F. ENDNOTES

NOTE 1. MAKING RESOURCES ACCESSIBLE

The appropriate technical expertise and resources may be located in house, but because of organizational structure, may not be readily accessible to a project manager. For example, this was the case in Texas. To support consistent implementation of risk-based corrective action programs and to maintain high caliber technical expertise, the technical experts housed in the various remediation programs were consolidated into one organizational unit so they could provide support to the project managers on an as-needed basis.

This effort achieved the goals of providing consistent and predictable expert support to the project managers via focused training, mentoring, and direct project support; allowed the agency to provide technical expertise and resources, but at the same time contain the expenses; fostered ongoing program development and refinement; and helped to retain the technical experts over the long term.

See Section 3.1.1.2.

NOTE 2. TERMS DESCRIBING LEVELS BELOW WHICH CONCENTRATIONS ARE REPORTED

Various terms are used to describe the level below which concentrations are reported (for example reporting limit, detection limit, method detection limit, sample quantitation limit, instrument detection limit). There are differences in technical meanings, as presented in Section 5 of RAGS Part A (USEPA 1989a) and Section 5.7 of ITRC's *Groundwater Statistics and Monitoring Compliance* (ITRC 2013). For a specific chemical, the value can vary by different characteristics (for example, laboratory, sample moisture content, other chemicals present in the sample).

See Section 4.5.4.1.

NOTE 3. WHEN IS ROUTE-TO-ROUTE EXTRAPOLATION FROM ORAL TOXICITY VALUES NOT APPROPRIATE?

As stated in USEPA guidance (2009a), the following circumstances, included in the Inhalation Dosimetry Methodology (USEPA 1994b), are specific examples of situations when route-to-route extrapolation from oral toxicity values might not be appropriate, even for use during screening:

- Groups of chemicals are expected to have different toxicity by the two routes – for example, metals, irritants, and sensitizers.
- A first-pass effect by the respiratory tract is expected.
- A first-pass effect by the liver is expected.
- A respiratory tract effect is established, but a dosimetry comparison cannot be clearly established between the two routes.
- The respiratory tract was not adequately studied in the oral studies.

- Short-term inhalation studies, dermal irritation, in vitro studies, or characteristics of the chemical indicate the potential for portal-of-entry effects at the respiratory tract, but studies themselves are not adequate for inhalation toxicity value development.

USEPA guidance (2009a) also provides more information about route-to-route extrapolation.

See Section 5.1.2.4.

NOTE 4. PAH RESOURCES

Polycyclic Aromatic Hydrocarbons

- Toxicological Profile for Polycyclic Aromatic Hydrocarbons (PAHs) (ATSDR 1995).
- Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons (USEPA 1993b).

See Section 5.1.3.2.

NOTE 5. USING THE RPF APPROACH FOR CUMULATIVE RISK ASSESSMENTS

- Organophosphorus Cumulative Risk Assessment – 2006 Update (USEPA 2006d).
- Triazine Cumulative Risk Assessment (USEPA 2006g).
- Cumulative Risk from Chloroacetanilide Pesticides (USEPA 2006a).
- Revised N-Methyl Carbamate Cumulative Risk Assessment (USEPA 2007d).
- Pyrethrins/Pyrethroid Cumulative Risk Assessment (USEPA 2011e).

See Section 5.1.3.2.

NOTE 6. RESOURCES FOR DIOXINS/FURANS

- Recommended Toxicity Equivalence Factors (TEFs) for Human Health Risk Assessments of 2,3,7,8-Tetrachlorodibenzo-p-dioxin and Dioxin-Like Compounds (USEPA 2010d).
- Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds (van den Berg et al. 2006).
- Adoption of Revised Toxicity Equivalency Factors (TEFWHO-05) for PCDDs, PCDFs, and Dioxin-like PCBs (CalEPA 2011).

See Section 5.1.3.3.

NOTE 7. RESOURCE FOR PCBS

Polychlorinated biphenyls (PCBs)

- PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures (USEPA 1996a).

See Section 5.1.3.3.

NOTE 8. CDC CONCURRENCE STATEMENT

The CDC defined this as: "We agree, but we do not have the funding, staff, or control over the means to implement the recommendation. The response highlights strategies that have been shown to be effective; however a commitment to implement actions cannot be made due to our lack of control over available resources" (CDC 2012a).

See Section 5.1.5.1.

NOTE 9. RANGE OF ACCEPTABLE LEAD CONCENTRATIONS FOR ADULT EXPOSURE

As explained in USEPA (2003a) guidance, this range of soil lead concentrations derives from USEPA's recommended default ranges for baseline BLL (PbB_0 from 1.7 to 2.2 µg/dL) and geometric standard deviation (GSD_i from 1.8 to 2.1), as summarized on Table 1 of the guidance. Specifically, USEPA derived the low end of the range (750 mg/kg) by using a GSD_i of 2.1 and PbB_0 of 2.2 µg/dL, and the high end of the range (1,750 mg/kg) by using a GSD_i of 1.8 and PbB_0 of 1.7 µg/dL.

See Section 5.1.5.2.

NOTE 10. USEPA WEIGHT-OF-EVIDENCE CLASSIFICATIONS

USEPA (2005b) presents the following classifications:

- carcinogenic to humans
- likely to be carcinogenic to humans
- suggestive evidence of carcinogenic potential
- inadequate information to assess carcinogenic potential
- not likely to be carcinogenic to humans

See Section 5.2.1.

NOTE 11. EXPERT CONSENSUS

In the case of some chemicals, consensus may not exist within the scientific and regulatory community regarding chemical classification. If consensus is not present, note this lack of agreement among experts in the Risk Characterization.

See Section 5.2.1.

NOTE 12. DOSE CALCULATION

Where:

dose = mg chemical per kg body weight per day

C = chemical concentration (mg/L or mg/kg)

IR = intake rate (L/day or kg/day)

FC = fraction contacted (unitless)
AF = adsorbed fraction (unitless)
EF = exposure frequency (days/year)
ED = exposure duration (years)
BW = body weight (kg)
AT = averaging time (days)

Based on the equation in Exhibit 6-14 in Chapter 6 of USEPA's risk assessment guidance (USEPA 1989a).

See Section 6.1.

NOTE 13. CALCULATION OF INHALATION EXPOSURE CONCENTRATION

Where:
EC = time-weighted average concentration (mg/m^3)
C = chemical concentration (mg/m^3)
ET = exposure time (hours/day)
EF = exposure frequency (days/year)
ED = exposure duration (years)
AT = averaging time (hours)

Based on the equation in Exhibit 6-16 in Chapter 6 of USEPA's risk assessment guidance (USEPA 1989a).

See Section 6.1.

NOTE 14. DOSE CALCULATION WITH BIOAVAILABILITY EXPOSURE FACTOR

Where:
dose = mg chemical per kg body weight per day
C = chemical concentration (mg/L or mg/kg)
IR = intake rate (L/day or kg/day)
FC = fraction contacted (unitless)
AF = adsorbed fraction (unitless)
BA = bioavailability factor (unitless)
EF = exposure frequency (days/year)
ED = exposure duration (years)
BW = body weight (kg)
AT = averaging time (days)

Based on the equation in Exhibit 6-14 in Chapter 6 of USEPA's risk assessment guidance (USEPA 1989a and USEPA 2007c).

See Section 6.1.3.1.

NOTE 15. GIS SOFTWARE FOR POLYGONS

An example of software that can be used to create Thiessen polygons is ESRI ARCGIS. In the ESRI ARCGIS software the Thiessen polygons can be generated by selecting **ArcToolbox > Analysis Tools > Proximity > Create Thiessen Polygons** (ESRI 2012).

See Section 6.2.4.2.

NOTE 16. CALCULATION OF AREA-WEIGHTED AVERAGE CONCENTRATIONS

Where:

C_i = concentration at each individual sampling location

A_i = surface area (for example, acres) of the polygonal subarea constructed for each individual sampling location

See Section 6.2.4.2.

NOTE 17. STATES WITH PUBLISHED METALS AND PAH BACKGROUND DATA

Several states, including California, Illinois, Maine, Massachusetts, Michigan, New York, Ohio, and Washington have published background data for metals or PAHs in soil.

See Section 6.2.5.

NOTE 18. SEGREGATION OF HAZARD INDICES

For noncancer hazard indices, segregation of hazard indices by effect and mechanism of action may be appropriate (USEPA 1989a). This process can be complex and time-consuming because it is necessary to identify all of the major effects and target organs for each chemical and then to classify the chemicals according to target organ(s) or mechanism of action. This analysis is not simple and should be performed by a toxicologist. If the segregation is not carefully done, an underestimate of true hazard could result.

See Section 7.1.2.1.

NOTE 19. EXAMPLE FORWARD AND BACKWARD CALCULATION

Basic Equation – Ingestion of Arsenic in Drinking Water - Adult

Where:

$Risk_{WI}$ = cancer risk for water ingestion (probability)
SF_o = oral slope factor (1.5 [milligrams per kilogram-day]$^{-1}$ or [mg/kg-day]$^{-1}$ for arsenic)
C_W = concentration of chemical in water (milligrams per liter [mg/L])
IR_W = ingestion rate (2 liters [L] per day for adults)
EF = exposure frequency (350 days/year)
ED = exposure duration (24 years for adult)
BW= body weight (70 kilogram [kg] adult)
AT = averaging time (70 years x 365 days/year; or 25,550 days)

Based on linear low-dose cancer risk equation presented in Section 8.2.1 and the equation in Exhibit 6-11 in Chapter 6 of USEPA's risk assessment guidance (USEPA 1989a).

Forward Risk Calculation

What is the risk of exposure to a specified arsenic concentration in groundwater?

- Assume arsenic concentration in groundwater, or C_W is 0.001 mg/L. The only unknown in the equation is cancer risk which is calculated.
- For this example, cancer risk equals 1 x 10^{-5}.

Backward Risk Calculation

What chemical concentration in groundwater (under the scenario above) would correspond to a cancer risk of one in a million or 1 x 10^{-6}?

- Assume the cancer risk is 1 x 10^{-6}. The only unknown in the equation is chemical concentration.
- For this example, the arsenic concentration in groundwater corresponding to a cancer risk of 1 x 10^{-6} is 0.000071 mg/L.

See Section 2.1.

NOTE 20. LIFETIME AVERAGE DAILY DOSE CALCULATION FOR DRINKING WATER

Where:
Dose = mg chemical per kg body weight per day
C_w = contaminant concentration (mg/L)
IR = ingestion rate (L/day)
EF = exposure frequency (days/year)
ED = exposure duration (years)

BW = body weight (kg)

AT = averaging time (days)

Based on the equation in Exhibit 6-11 in Chapter 6 of USEPA's risk assessment guidance (USEPA 1989a).

See Section 6.1.1.3.

APPENDIX G. TEAM CONTACTS

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APPENDIX H. ACRONYMS

ADAF	age-dependent adjustment factors
ALM	adult lead methodology
ATSDR	Agency for Toxic Substances and Disease Registry
BLL	blood lead level
BMD	benchmark dose
CDC	Center for Disease Control
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CSF	cancer slope factor
CSM	conceptual site model
DQA	data quality assessment
DQOs	data quality objectives
DTSC	California Department of Toxic Substances Control
ECOS	Environmental Council of States
EPC	exposure point concentration
IEUBK	integrated exposure uptake biokinetic
ITRC	Interstate Technology and Regulatory Council
IRIS	Integrated Risk Information System
ISM	incremental sampling methodology
LADD	lifetime average daily dose
LOAEL	lowest observed adverse effect level
MOA	mode of action
NCEA	National Center for Environmental Assessment
NOAEL	no observed adverse effect level
OEHHA	California Office of Health Hazard Assessment
PAH	polycyclic aromatic hydrocarbons
PCB	polychlorinated biphenyl
QA/QC	quality assurance/quality control
RBCA	risk-based corrective action
RCRA	Resource Conservation and Recovery Act
RfC	reference concentration
RfD	reference dose
RME	reasonable maximum exposure
RPF	relative potency factor
RSL	regional screening levels
STSC	Superfund Health Risk Technical Support Center

SVOC	semivolatile organic compound
TCE	trichloroethylene
TEF	toxicity equivalence factor
TIC	tentatively identified compound
UCL	upper confidence limit
USEPA	United States Environmental Protection Agency
VOC	volatile organic compound

APPENDIX I. GLOSSARY

A

activity patterns

The activity or activities in which the receptor is assumed to be engaged involving details regarding where they are, when they were there, how long they were there, and over what area.

acute toxicity

Any poisonous effect produced within a short period of time following an exposure, usually 24 to 96 hours (USEPA 2013).

adverse human health effects

Typically defined as an incremental lifetime cancer risk (for example, exceeding a range of 1E-4 to 1E-6) or a hazard quotient or hazard index (for example, one).

antagonism

A chemical interaction that influences the toxicity of a chemical when one chemical interferes or inhibits the effect of the other chemical; for example, 4 + 6 = 8 (USEPA 2015h).

B

bioavailability

The fraction of an ingested dose that crosses the gastrointestinal epithelium and becomes available for distribution to internal target tissues and organs (USEPA 2007c).

biokinetics

Movement of a chemical (for example, absorbed lead) throughout the body by physiologic or biochemical processes.

C

chronic toxicity values

Toxicity values used for repeated or persistent exposures (durations exceeding 10% of a lifetime [7 years or longer] and for exposures by children ages 0-6).

cleanup

The assessment and reduction, removal, or control of chemicals in environmental media. Cleanup is synonymous with other terms such as "corrective action" and "remediation" used in various state, local, and federal programs.

conceptual site model

Describes the potential chemical sources, release mechanisms, fate and transport pathways, impacted environmental media, receptors, and exposure pathways for current and reasonably anticipated future activities and land uses. This model documents current site conditions and serves to conceptualize the relationship between chemicals in environmental media, sources, and receptors through consideration of potential or actual migration and exposure pathways (ITRC 2012a).

cumulative risk

The combined risks from aggregate exposures (combined exposure of an individual (or defined population) to a single chemical via relevant exposure routes, exposure pathways, and exposure media) to multiple chemicals (USEPA 2003c).

D

data gaps

Missing data or information needed to answer questions or allow a more refined analysis to be completed.

data quality assessment (DQA)

The scientific and statistical evaluation of data to determine whether data obtained from environmental operations are of the right type, quality, and quantity to support their intended use (USEPA 2006b).

data quality objectives (DQOs)

The qualitative and quantitative statements derived for the DQO process that clarify the study's technical and quality objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity (USEPA 2006).

deterministic risk assessment

A quantitative estimate of risk using single-point estimates for input parameters such as exposure factors.

distribution

A distribution describes the probability or likelihood of any potential value.

dose-response assessment

The relationship between exposure level (amount of chemical in an environmental media that is inhaled, absorbed, or ingested by a receptor) and the incidence of adverse effects (adapted from Commission 1997a).

E

engineering controls

Engineered and constructed physical barriers to contain, prevent, or mitigate exposure to chemicals in an environmental medium. Examples of engineering controls include engineered caps and subslab depressurization systems, mitigation barriers, and fences. Similar to activity and land use restrictions, engineering controls also typically require a specific mechanism for noticing the presence of engineering control and related restrictions, as well as long-term maintenance and management of the control. The timing of a decision to use an engineering control, and the specific mechanism to be used, may be based on criteria outlined in statute, regulation, policy, or guidance.

environmental medium

Soil, surface water, groundwater, indoor air, outdoor air, sediment, and other parts of the environment that may be impacted by the release of a chemical.

exposure

Contact of a receptor with a chemical. Exposure is quantified as the amount of the chemical available at the exchange boundaries of the organism (for example, skin, lungs, gut) and available for absorption (USEPA 1989a).

exposure area

A geographic area over which a receptor is reasonably assumed to move at random and equally likely to come into contact with an environmental medium (for example, soil) both spatially and temporally. An exposure area is further defined on the basis of observed or assumed patterns of receptor behavior, historic activity, and the nature and extent of chemicals in environmental media (USEPA1989a). An exposure area may also be called an exposure unit.

exposure assessment

The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure (USEPA 1989a).

exposure factor

Factors related to human behavior and characteristics that define the time, frequency, and duration of exposure; and help determine an individual's exposure to a chemical (USEPA 2011b).

exposure medium

Environmental medium containing concentrations of a chemical that may be contacted by a receptor.

exposure pathway

The course a chemical takes from a source to a receptor. An exposure pathway describes a unique mechanism by which an individual or population is exposed to chemicals at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, a transport/exposure medium (for example, air) or media (in cases of intermedia transfer) also is included (USEPA 1989a).

exposure point

A location of potential contact between a receptor and a chemical (USEPA 1989a).

exposure route

The way a chemical comes in contact with an organism (for example, by ingestion, inhalation, dermal contact (USEPA 1989a).

exposure scenario

A set of facts, data, assumptions, and professional judgment about how an exposure occurs or does not occur. An exposure scenario addresses the (1) chemicals in environmental media and their sources; (2) exposed populations (or receptors); (3) migration of chemicals in environmental media from sources to receptors; and (4) routes of exposure (ingestion, dermal contact, inhalation).

H

hazard identification

The process of determining whether exposure to a chemical in environmental media by a receptor can cause an increase in the incidence of an adverse human health effect (for example, incremental lifetime cancer risk) (USEPA 2012b).

hazard index

The sum of more than one hazard quotient for multiple substances and/or multiple exposure pathways. The hazard index is calculated separately for chronic, subchronic, and shorter-duration exposures (USEPA 1989a).

hazard quotient

The ratio of a single substance exposure level over a specified time period (for example, subchronic) to a reference dose for that substance derived from a similar exposure period (USEPA 1989a).

hot spots

Hot spots are considered to be soil volumes with relatively high concentrations that could be present at a site but whose locations and dimensions cannot be anticipated prior to sampling (ITRC 2012a).

I

institutional controls
Non-engineered instruments that help minimize the potential for human exposure to contamination and/or protect the integrity of the remedy (USEPA 2001c). Examples include deed restrictions on land use, groundwater use restrictions, and city ordinances prohibiting private well installations. The use of these controls typically require a specific mechanism for placing the restriction and future compliance with the restriction. The timing of the decision to use an institutional control, as well as, the specific mechanism to be used may be based on criteria outlined in statute, regulation, policy or guidance.
M
mode of action
The way in which a chemical elicits toxicity; does not complete characterization of the mechanisms of action (USEPA 2005b).
Monte Carlo simulation
A technique for characterizing the uncertainty and variability in exposure estimates by repeatedly sampling the probability distributions of the exposure equation inputs and using these inputs to calculate a range of exposure values (USEPA2001c).
mutagenic carcinogen
The capacity of either a carcinogen or its metabolite to react with or bind to DNA in a manner that causes mutations (USEPA2007b).
P
permanent data gaps
Data gaps that cannot be resolved due to lack of information such as lack of information concerning the site history, future land uses, or from site-specific sampling information.
pharmacokinetic
Study of the absorption, distribution, metabolism, and excretion of chemicals and the genetic, nutritional, behavioral, and environmental factors that modify these parameters (Commission1997a).
potentiation
A chemical interaction that influences the toxicity of a chemical. One chemical increases the effect of another chemical (USEPA 2014m) (for example, 1 + 2 = 10).
probabilistic risk assessment
A technique that uses statistically derived distributions of input values (for example, exposure factors) to calculate a range of risk.
professional judgment
Decisions made based on knowledge gained through education and experience.
project manager
An individual from a regulatory agency (for example, federal, state, or local), or a consulting company, or responsible party company, who is coordinating the site cleanup including the risk assessment.
project risk
Project risks include any uncertain events or conditions that have the potential to adversely affect a project's objectives, scope, time, cost, or targeted primary outcomes, or to result in unintentional adverse outcomes.
R
reasonable maximum exposure

The highest exposure that is reasonably expected to occur at a site (USEPA 1989a).

receptor

An individual (for example, residential adult, residential child, worker, trespasser, or recreator) who has the potential to be exposed to a chemical in environmental media.

reference concentration (RfC)

A concentration specified by USEPA to limit human inhalation exposure to potentially hazardous levels of chemicals in air (Commission 1997a).

reference dose (RfD)

A dose specified by USEPA to limit human oral and dermal exposure to potentially hazardous levels of chemicals that are thought to have thresholds for their effects, such as noncarcinogens (Commission 1997a).

relative potency factor

A scaling factor that represents the relative toxicity of a chemical based on the toxicological dose-response data of an index chemical.

risk assessment

An organized process used to describe and estimate the likelihood of adverse health outcomes from environmental exposures to chemicals. The four steps are hazard identification, dose-response assessment, exposure assessment, and risk characterization (Commission 1997a).

risk characterization

The risk characterization integrates information from the preceding components of the risk assessment and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers (USEPA 2000c).

risk communication

Risk communication is the formal and informal process of communication among and between regulatory agencies and organizations responsible for site assessment and management, and the various parties who are potentially at risk from or are otherwise interested in the site.

risk management

The process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations (Commission 1997a).

S

slope factor

An upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime exposure to an agent. This estimate, usually expressed in units of proportion (of a population) affected per mg/kg-day, is generally reserved for use in the low-dose region of the dose-response relationship, that is, for exposures corresponding to risks less than 1 in 100 (USEPA 2013).

stakeholders

A stakeholder is anyone who has a “stake” in the development, outcome or decisions made as a result of a risk assessment. A stakeholder can be a person, a group, or an organization that is either affected, potentially affected, or has any interest in the project

or in the project's outcome, either directly or indirectly (Commission1997a; Commission 1997b; NRC 1996; NRC 2009).

subchronic toxicity values

Toxicity values typically used for exposure durations ranging from 2 weeks to 7 years, and are not used for children ages 0-6.

synergistic effects

Effects from exposure to multiple chemicals that lead to an increased response that exceeds what would be estimated for exposure to each chemical independently (USEPA 2014e) (for example, 2 + 2 = 20).

systematic planning

A planning process that is based on the scientific method. It is a common-sense approach designed to ensure that the level of detail in planning is commensurate with the importance and intended use of the data, as well as the available resources. Systematic planning is important to the successful execution of all activities at hazardous waste sites, but it is particularly important to dynamic field activities because those activities rely on rapid decision-making. The data quality objective (DQO) process is one formalized process of systematic planning. All dynamic field activities must be designed through the use of systematic planning, whether using DQO steps or some other system. See also Data Quality Objective (USEPA 2015h).

T

tessellation

The covering of a surface with a pattern of flat shapes so that there are no overlaps or gaps.

toxicity assessment

The combination of the hazard identification and the dose response assessment.

toxicity values

Derived values (for example, reference doses and slope factors) that can be used to estimate the incidence or potential for adverse human health effects in receptor (USEPA 2015h).

U

uncertainty

The lack of perfect knowledge of values or parameters used in a risk assessment. Uncertainty may be reduced by collection of additional data.

upper confidence limit (UCL)

The upper boundary of a range of values. The range of values is referred to as a confidence interval.

V

variability

A population's natural heterogeneity or diversity, particularly that which contributes to differences in exposure levels or in susceptibility to the effects of chemical exposures (Commission 1997a). For example, workers may perform different functions that may affect time, frequency, and duration of contact with an environmental medium). Variability cannot be reduced by collection of additional data.