U.S. Navy
Human Health Risk Assessment
Guidance

Prepared For:

Naval Facilities Engineering Command

Navy and Marine Corps Force Health Protection Command

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December 2008

U.S. Navy Human Health Risk Assessment Guidance

Chapter 1 – Introduction

Table of Contents

List of Figures

ACRONYMS AND ABBREVIATIONS

BHHRA	Baseline Human Health Risk Assessment
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COC	Chemical of Concern
CNO	Chief of Naval Operations
DQO	Data Quality Objective
ER	Environmental Response
HHRA	Human Health Risk Assessment
IR	Installation Restoration
MC	Munitions Constituents
MEC	Munitions and Explosives of Concern
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
RERA	Risk Evaluation of Remedial Alternatives
RPM	Remedial Project Manager
USEPA	United States Environmental Protection Agency

1.0 Introduction

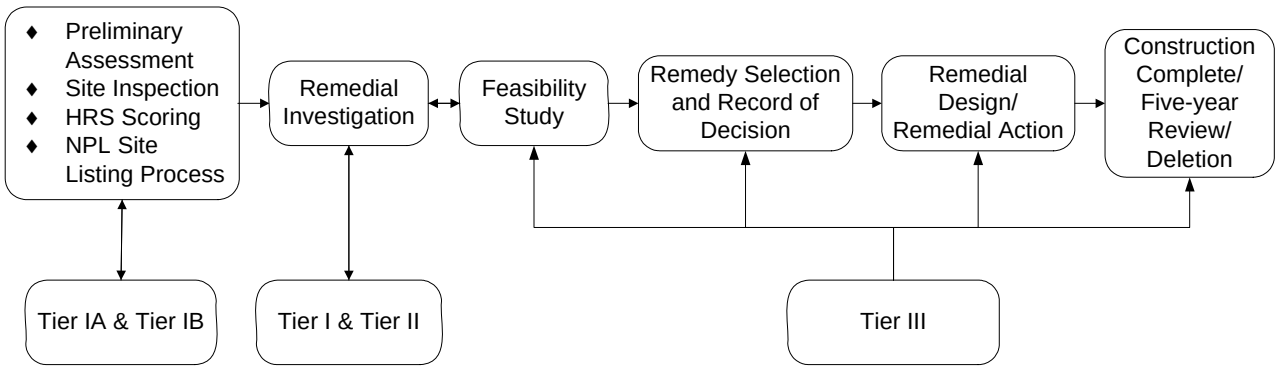
The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA, or "Superfund"), as amended, established a national program for responding to releases of hazardous substances to the environment. The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) is the regulation that implements CERCLA. Among other things, the NCP establishes the overall approach for determining appropriate remedial actions at Superfund sites. The overarching mandate of the Superfund program is to protect human health and the environment from current and potential threats posed by hazardous substances, and the NCP echoes this mandate (United States Environmental Protection Agency [USEPA], 1989). In order to comply with CERCLA, the Navy established the Installation Restoration (IR) Program, which is intended to develop and foster effective business practices that will provide outcomes that are consistent with CERCLA in an economically-effective manner (USNAVY, 2006). The IR Program was changed to the Environmental Response (ER) Program when the program was expanded to include explosive safety hazards associated with munitions and explosives of concern (MEC) and the human health and environmental risks associated with munitions constituents (MC).

Risk assessment is a key step in the ER process because it provides context for all of the information that is generated during the investigation process. Risk assessment results are used to evaluate site concentrations to determine if the risks are significant, whether or not further investigation or other actions are appropriate, and to help determine cleanup levels for remediating a site.

This guidance identifies a three-tiered risk assessment approach that should be utilized to evaluate sites. Figure 1.1 presents the relationship of the tiered approach to the remedial process. The tiered approach incorporates risk management into the decision-making process, minimizes the level of effort, and eliminates sites that are not of concern. The tiered approach ensures that the level of effort expended to evaluate sites is commensurate with the magnitude and complexity of the site-specific issues. At relatively simple sites, risk-based screening (Tier I) can be used to evaluate the potential risks. At complex sites (e.g., sites with multiple chemicals of concern (COCs) or exposure pathways), a baseline human health risk assessment (BHHRA) (Tier II) can be performed to evaluate site-specific exposure scenarios and receptors. The human health risks associated with remedial alternatives are evaluated in Tier III. The three-tiered approach allows Navy Remedial Project Managers (RPMs) to focus resources on those sites that could pose a significant risk to human health and/or the environment.

The guidance focuses on important general issues rather than on in-depth, technical risk assessment issues. Other resources (e.g., issue papers, case studies, discussion groups, and USEPA guidance) are available for RPMs who would like more detailed information. However, the underlying logic that is identified in this guidance should be used to guide the decision-making process.

Figure 1.1 – Relationship of the Tiered Approach to the Remedial Process



1.1 Purpose

The purpose of this guidance document is to present a framework for risk-based decision making at Navy sites by establishing sound and consistent risk evaluation practices for evaluating potential human health risks. Other objectives include:

1.) ensuring that RPMs are aware of current risk assessment requirements, policies, and tools;

2.) providing a mechanism to gather and share risk assessment and risk management information;

3.) identifying barriers to risk-based decision making and develop strategies to address these barriers;

4.) providing a basis for working toward consistent Navy-wide risk-based decision processes based on a three-tiered approach;

5.) reducing costs by matching the level of effort expended with the complexity of the site; and

6.) increasing the uniformity and efficiency of the IR process, while at the same time providing the flexibility to evaluate each site individually.

1.2 Document Organization

The topics addressed in this guidance, and the overall organization of this document, are summarized below.

- **Chapter 1 – Introduction** – Provides a general introduction to the human health risk assessment (HHRA) guidance.
- **Chapter 2 – Regulatory Framework** – Provides an overview of the regulatory requirements for conducting HHRAs.
- **Chapter 3 – Overview of the Human Health Risk Assessment Process** – Provides a brief overview of the HHRA process including the goals, tiered approach, risk communication, and risk management.
- **Chapter 4 – Strategically Managing the HHRA Process** – Provides a summary of the key issues that RPMs should consider in order to effectively manage the HHRA process.
- **Chapter 5 – Planning/Scoping** – Discusses risk assessment related issues that RPMs should consider when planning an environmental investigation.
- **Chapter 6 – Data Quality Objectives for Risk Assessment** – Presents the approach for using Data Quality Objectives (DQOs) as strategic planning tools that can be used to ensure that the type, amount, and quality of the data collected is appropriate to meet project objectives.
- **Chapter 7 – Tier IA and Tier IB – Risk-Based Screening** – Details the process for risk-based screening used to determine if the site may exit the HHRA process.
- **Chapter 8 – Tier II – Baseline Human Health Risk Assessment** – Presents the steps that comprise a BHHRA.

- **Chapter 9** – **Other Tools: Using Probabilistic Risk Assessment to Further Characterize Risks** – Presents an alternative technique for evaluating risk, and the uncertainty and variability associated with risks presented in a BHHRA.

- **Chapter 10 – Tier III – Risk Evaluation of Remedial Alternatives** – Provides RPMs with the steps used to conduct a Risk Evaluation of Remedial Alternatives (RERA), which is one component of the process used to choose a remedy that reduces, controls, or eliminates the risks to human health and the environment.

- **Chapter 11** – **Risk Communication Principles and Techniques** – Presents basic concepts and techniques for effective risk communication.

- **Chapter 12 – Risk Management** – Presents guidelines that risk managers should consider when evaluating risk assessment information in order to make risk management decisions at a site.

1.3 Navy Policy Statement

On 12 February 2001 the Office of the Chief of Naval Operations (CNO) issued the Navy Policy for Conducting Human Health Assessments under the Environmental Restoration Program (USNAVY, 2001). The purpose of this Policy was to provide clarification of the Navy's policy on HHRAs and the manner in which HHRAs are to be implemented for the Navy in the ER Program. The primary goal of the Navy Policy was that HHRAs conducted for the Navy should follow a three-tiered risk assessment process. This process was developed to ensure that HHRAs are scientifically based, defensible, and are performed in a manner that is cost effective and protective of human health.

1.4 Target Audience

Navy RPMs are the target audience of this guidance document. Therefore, the document focuses on issues that RPMs must understand and address in order to carry out their responsibilities and incorporate risk-based decision making into the IR process. This guidance focuses on important general issues rather than on in-depth, technical risk assessment issues. Other resources (e.g., the issue papers, case studies, discussion groups, and USEPA guidance) are available for RPMs who would like more detailed information.

Many of the recommendations and strategies presented in this guidance emphasize the fact that remedial decisions often require the integration of information from many technical disciplines. The RPM is often one of the primary “integrators” and is required to have a conceptual understanding of the theories used by each discipline involved in a remedial decision, including the protocols used in risk assessment. This is often critical to a project because the failure to understand or communicate any aspect of risk assessment (including protocol, results, uncertainties, or pitfalls), can lead to the improper use of risk assessment results in remedial decision making.

1.5 References

USEPA. 1989. Risk Assessment Guidance for Superfund: Human Health Evaluation Manual Part A. Interim Final. Office of Emergency and Remedial Response. Washington, D.C. 9285.701A. EPA/540/1-89/002. http:// www.epa.gov/oswer/riskassessment/ragsa/index.htm.

USNAVY. 2001. Chief of Naval Operations Memorandum: Conducting Human Health Risk Assessments Under The Environmental Restoration Program. Ser N453E/1U595168. February 12, 2001.

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U.S. Navy Human Health Risk Assessment Guidance

Chapter 2 – Regulatory Framework

Table of Contents

List of Figures

ACRONYMS AND ABBREVIATIONS

ARAR	Applicable or Relevant and Appropriate Requirements
BHHRA	Baseline Human Health Risk Assessment
CCL	Construction Completion List
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CERCLIS	Comprehensive Environmental Response, Compensation, and Liability Information System
DOD	Department of Defense
FS	Feasibility Study
HHRA	Human Health Risk Assessment
HRS	Hazard Ranking System
IAG	Inter-Agency Agreement
NAVFAC	Naval Facilities Engineering Command
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NFA	No Further Action
NPL	National Priorities List
O&F	Operational and Functional
O&M	Operation and Maintenance
PA	Preliminary Assessment
PRP	Potentially Responsible Party
RA	Remedial Action
RD	Remedial Design
RD/RA	Remedial Design/Remedial Action
RERA	Risk Evaluation of Remedial Alternatives
RI	Remedial Investigation
RI/FS	Remedial Investigation/Feasibility Study
ROD	Record of Decision
SARA	Superfund Amendments and Reauthorization Act
SI	Site Inspection
USEPA	United States Environmental Protection Agency

2.0 Introduction

This chapter describes the regulatory basis and framework for evaluating potentially contaminated sites and the role of human health risk assessment (HHRA) in the process. The key components of the regulatory framework are the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), and how Navy Lead Agency authority is implemented throughout the process.

A partial list of documents and web sites that identify and discuss the regulatory framework for evaluating hazardous waste sites is presented below.

- NCP (40 CFR 300), http://www.epa.gov/emergencies/content/lawsregs/ncpover.htm
- Department of the Navy Environmental Restoration Program Manual. August 2006. https://portal.navfac.navy.mil/portal/page/portal/navfac/navfac_ww_pp/navfac_nfesc_pp/environmental/erb/resourceerb/nerp_manual_2006(20070710).pdf
- Risk Assessment Guidance for Superfund: Human Health Evaluation Manual Part A. Interim Final. USEPA, Office of Emergency & Remedial Response, 1989. EPA/540/1-89/002 http://www.epa.gov/oswer/riskassessment/ragsa/index.htm.
- CERCLA – (U.S. House of Representatives, U.S. Code, Title 42, Chap. 103), http://www.epa.gov/superfund/policy/cercla.htm.
- Superfund Amendments and Reauthorization Act (SARA) – (U.S. House of Representatives, U.S. Code, Title 42, Chap. 103), http://www.epa.gov/superfund/policy/sara.htm.
- Superfund - http://www.epa.gov/superfund/programs/er/hazsubs/supers.htm.

2.1 Comprehensive Environmental Response, Compensation and Liability Act

CERCLA (or "Superfund") created a tax on the chemical and petroleum industries and provided broad federal authority to respond directly to releases, or threatened releases, of hazardous substances that may endanger public health or the environment. CERCLA established:

- prohibitions and requirements concerning closed and abandoned hazardous waste sites;
- liability of parties responsible for releases of hazardous waste at these sites; and
- a trust fund to provide for cleanup when no responsible party could be identified.

The law authorizes short-term removals and long-term remedial responses. Short-term removals may be performed to address releases, or threatened releases, which require prompt response. Long-term remedial responses are actions that permanently and significantly reduce the dangers associated with releases, or threatened releases, of hazardous substances that are serious but not immediately life threatening.

CERCLA also enabled the revision of the NCP. The NCP provides the guidelines and procedures needed to respond to releases and threatened releases of hazardous substances, pollutants, or contaminants. The NCP also established the National Priorities List (NPL). The NPL is a list that was created in response to the NCP requirement that a system be developed to "list" and "delist" hazardous

waste sites. SARA amended CERCLA on October 17, 1986 (U.S. House of Representatives, U.S. Code, Title 42, Chap. 103 (a)). The United States Environmental Protection Agency's (USEPA's) experiences in administering the complex Superfund program during its first six years resulted in SARA, which made several important changes and additions to the program. SARA did the following:

- stressed the importance of permanent remedies and innovative treatment technologies in cleaning up hazardous waste sites;
- required Superfund actions to consider the standards and requirements found in other state and federal environmental laws and regulations;
- provided new enforcement authorities and settlement tools;
- increased state involvement in every phase of the Superfund program;
- increased the focus on human health problems posed by hazardous waste sites;
- encouraged greater citizen participation in making decisions on how sites should be cleaned up; and
- increased the size of the trust fund to $8.5 billion.

SARA also required the USEPA to revise the Hazard Ranking System ([HRS]; see section 2.3.4) to ensure that it accurately assessed the relative degree of risk to human health and the environment posed by sites being considered for placement on the NPL (U.S. House of Representatives, U.S. Code, Title 42, Chap. 103, (b)). Sites are listed on the NPL based on their HRS score and public comments.

2.2 National Oil and Hazardous Substances Pollution Contingency Plan

The NCP (40 CFR 300), is the regulation that implements CERCLA. The NCP is the federal government's blueprint for responding to both oil spills and hazardous substance releases. The NCP is the result of efforts to develop a national response capability and promote overall coordination among the hierarchy of responders and contingency plans. Among other things, the NCP establishes the overall approach for determining appropriate remedial action at Superfund sites (http://www.epa.gov/emergencies/content/lawsregs/ncpover.htm). The NCP identifies the following nine separate criteria for evaluating alternatives for viable remedial actions:

Threshold Criteria – Must be met for a remedial alternative to be acceptable

1.) overall protection of human health and the environment;

2.) compliance with applicable or relevant and appropriate requirements (ARARs) (unless a waiver is obtained);

Balancing Criteria – Additional criteria used to help rank the remedial alternatives that meet the Threshold Criteria

3.) long-term effectiveness and permanence;

4.) reduction of toxicity, mobility, or volume;

5.) short-term effectiveness;

6.) implementability;

7.) cost;

Modifying Criteria – Criteria that may result in the selection of a less desirable (i.e., less desirable in terms of the Threshold and Balancing Criteria) remedial alternative as the remedy for a site

8.) state acceptance; and

9.) community acceptance.

Risk information is required at various stages in the process so that each potential remedial alternative can be evaluated in relation to these nine criteria (USEPA, 1989).

2.3 Superfund Process

The Superfund cleanup process begins with site discovery or notification to the USEPA of possible releases of hazardous substances. Sites are discovered by various parties – including citizens, state agencies, and USEPA Regional offices. Once discovered, sites are entered into the Comprehensive Environmental Response, Compensation, and Liability Information System (CERCLIS), the USEPA's computerized inventory of potential hazardous-substance release sites. The USEPA uses an 11-step process to assess the threats posed by releases of hazardous substances and implement the appropriate response.

Step 1 – Preliminary Assessment (PA)

Step 2 – Site Inspection (SI)

Step 3 – HRS Scoring

Step 4 – NPL Site Listing Process

Step 5 – Remedial Investigation/Feasibility Study (RI/FS)

Step 6 – Record of Decision (ROD)

Step 7 – Remedial Design/Remedial Action (RD/RA)

Step 8 – Construction Completion

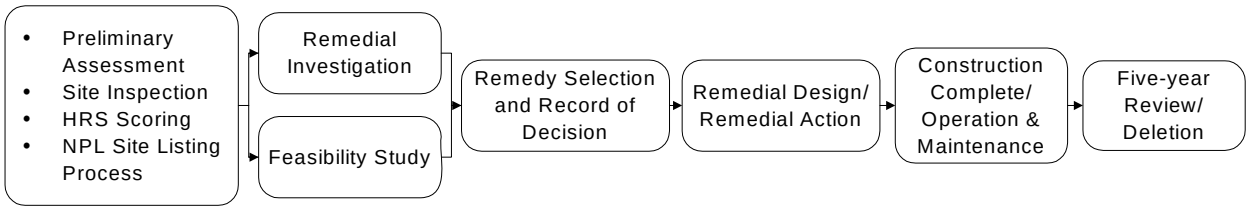
Step 9 – Operation and Maintenance (O&M)

Step 10 – Five-Year Review

Step 11– NPL Site Deletions

Figure 2.1 presents an overview of the Superfund process and how these steps are related. Releases that require immediate or short-term response actions are addressed under the Emergency Response program of Superfund (http://www.epa.gov/superfund/programs/er/hazsubs/supers.htm). A risk assessment is formally conducted as part of the RI.

Figure 2.1 – Overview of the Superfund Remedial Process



2.3.1 Step 1 – Preliminary Assessment

The PA is used to evaluate potential releases of hazardous substances from a site. The PA is a limited-scope investigation performed on every CERCLA site. PAs collect readily-available information about a site and its surrounding area. The PA is designed to distinguish, based on limited data, between sites that pose little or no threat to human health and the environment, and sites that may pose a threat, and therefore, require further investigation. The PA also identifies sites requiring assessment for possible emergency response actions. If the PA results in a recommendation for further investigation, a SI is performed. The USEPA publication *Guidance for Performing Preliminary Assessments Under CERCLA* (www.epa.gov/superfund/sites/npl/hrsres/pa/patoc.pdf) (USEPA, 1991), and the electronic scoring program (http://www.epa.gov/superfund/programs/npl_hrs/quickscore.htm) provide more information on conducting PAs (USEPA, 1991).

2.3.2 Step 2 – Site Inspection

The SI provides the data needed for HRS scoring and documentation. The SI provides more information for evaluating release or the potential for a release of hazardous substances at a site. SI investigators typically collect environmental and waste samples to determine what hazardous substances are present at a site. They determine if these substances are being released to the environment and, if so, assess if they have reached nearby populations. The SI can be conducted in one stage or two. The first stage (i.e., the focused SI) tests hypotheses developed during the PA and can yield information sufficient to prepare an HRS scoring package. If further information is necessary to document an HRS score, the second stage (i.e., the expanded SI) is conducted. The USEPA publication *Guidance for Performing Site Inspections Under CERCLA* (http://www.epa.gov/superfund/cleanup/pasi.htm) provides more information on conducting an SI (USEPA, 1992a).

2.3.3 Step 3 – Hazard Ranking System

The HRS is the principal mechanism the USEPA uses to place sites on the NPL. It is a screening system that uses information from the PA/SI to assess the potential of sites to pose a threat to human health or the environment. The HRS approach assigns numerical values to factors that relate to risk, based on conditions at the site. The factors are grouped into the following three categories:

- **Release Potential** – The likelihood that a site has released or has the potential to release hazardous substances into the environment.
- **Waste Characteristics** – The characteristics of the waste (e.g., toxicity and waste quantity).
- **Receptors** – The people or sensitive environments affected by the release.

In addition to the three factors identified above, there are four exposure pathways that can be scored under the HRS including groundwater migration (drinking water); surface water migration (drinking water, human food chain, sensitive environments); soil exposure (resident population, nearby population, sensitive environments); and air migration (population, sensitive environments). If all pathway scores are low, the site score is low. However, the site score can be relatively high even if only one pathway score is high. This is important for HRS scoring, because some extremely dangerous sites pose threats through only one pathway. For more information, please consult the USEPA publications, *The Hazard Ranking System Guidance Manual, Interim Final,* November 1992 *(USEPA, 1992b* [http://www.epa.gov/superfund/programs/npl_hrs/hrsint.htm]) and the December 14, 1990 *Federal Register*, Hazard Ranking System, Final Rule (55 FR 51532).

2.3.4 STEP 4 – NATIONAL PRIORITIES LIST SITE LISTING PROCESS

Sites are listed on the NPL based on their HRS score and public comments. The NPL is a management tool that publicly identifies sites or other releases that appear to warrant remedial actions. The NPL is updated periodically.

2.3.5 STEP 5 – REMEDIAL INVESTIGATION/FEASIBILITY STUDY

After a site is listed on the NPL, an RI/FS is performed at the site. The RI/FS is the approach established by the Superfund program to characterize the nature and extent of risks posed by sites, and for developing and evaluating remedial options. Remedies should protect human health and the environment, in addition to being cost-effective. The goal of the RI/FS is to gather information sufficient to support an informed risk-management decision regarding which remedy appears to be most appropriate for a given site (USEPA, 1989). The RI serves as the mechanism for collecting data to:

- characterize site conditions;
- determine the nature and extent of the waste;
- assess risk to human health and the environment; and
- conduct treatability testing to evaluate the potential performance and cost of the treatment technologies that are being considered in the FS.

The FS is the mechanism for the development, screening, and detailed evaluation of different remedial alternatives. The RI and FS can be conducted concurrently — data collected for the RI influences the development of remedial alternatives in the FS, which in turn affect the data needs and scope of treatability studies and additional field investigations (which are performed as part of the RI). This phased approach encourages the continual planning/scoping of the site characterization effort, which minimizes the collection of unnecessary data and maximizes data quality. The RI/FS should be viewed as a flexible process that should be tailored to specific circumstances and the information needs of individual sites (USEPA, 1989).

The HHRA is an integral part of the RI/FS process. The four different types of HHRAs that are used in the site remediation process are risk-based screening, baseline human health risk assessment (BHHRA), refinement of preliminary remediation goals, and the risk evaluation of remedial alternatives (RERA). In the RI, risk assessment results are used to determine if the site poses unacceptable threats to human health. In the FS, risk assessment information is used to evaluate the potential health impacts of remedial alternatives.

The RI/FS process is generally conducted in phases, which are often iterative. The phases include Scoping; Site Characterization; Development and Screening of Remedial Alternatives; Treatability Investigations; and Detailed Analysis. For more information, please consult the USEPA publication, *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA; Interim Final (*http://www.epa.gov/superfund/policy/remedy/pdfs/540g-89004-s.pdf) (USEPA, 1988).

2.3.6 STEP 6 – RECORD OF DECISION

The ROD is a public document that explains which cleanup alternatives will be used to clean up a Superfund site. In addition, the final cleanup levels are also identified in the ROD. The ROD for sites listed on the NPL is created from information generated during the RI/FS and remedy selection process (USEPA, 1988).

2.3.7 STEP 7 – REMEDIAL DESIGN/REMEDIAL ACTION

RD is the phase in a Superfund-site cleanup where the technical specifications for cleanup remedies (including engineering controls and/or institutional controls) and technologies are designed. RA follows the RD phase and involves the actual construction or implementation phase of Superfund-site cleanup. The RD/RA is based on the specifications described in the ROD (USEPA, 1988).

2.3.8 STEP 8 – CONSTRUCTION COMPLETION

The USEPA has developed a construction completion list (CCL) to simplify its system of categorizing sites and to better communicate the successful completion of cleanup activities. Sites qualify when:

- any necessary physical construction is complete, whether or not final cleanup levels or other requirements have been achieved;
- the USEPA has determined that the response action should be limited to measures that do not involve construction; or
- the site qualifies for deletion from the NPL.

Inclusion of a site on the CCL indicates that cleanup activities have been completed, although this does not necessarily mean that the overall process has been completed (USEPA, 1988).

2.3.9 STEP 9 – OPERATION AND MAINTENANCE

O&M activities maintain and ensure the integrity of the selected remedy for a site. O&M measures are initiated by a state after the remedy has achieved the remedial-action objectives and cleanup levels outlined in the ROD, and the remedy is determined to be operational and functional (O&F) based on state and federal agreement. For Superfund-lead sites, remedies are considered O&F either one year after construction is complete or when the remedy is functioning properly and performing as designed — whichever is earlier. Remedies requiring O&M measures include landfill caps, gas collection systems, groundwater extraction treatment, groundwater monitoring, and surface water treatment.

Once the O&M period begins, the state or Potentially Responsible Party (PRP) is responsible for maintaining the effectiveness of the remedy. O&M monitoring includes the following four components:

1.) inspection;

2.) sampling and analysis;

3.) routine maintenance; and

4.) reporting.

O&M activities are usually required for sites where cleanup proceeded through landfill/capping activities, groundwater activities, or through natural attenuation (USEPA, 1988).

2.3.10 STEP 10 – FIVE-YEAR REVIEW

Section 121(c) of CERCLA requires a periodic review of remedial actions, at least every five years after the initiation of such action, for as long as hazardous substances, pollutants, or contaminants that may pose a threat to human health or the environment remain at the site. If it is determined during a five-year

review that the action no longer protects human health and the environment, further remedial actions will need to be considered (USEPA, 1989).

2.3.11 Step 11 – National Priorities List Site Deletions

The USEPA may delete a site from the NPL if it determines that no further action (NFA) is required to protect human health or the environment. Under Section 300.425(e) of the NCP (55 FR 8845, March 8, 1990), a site may be deleted when NFA is appropriate, if the USEPA determines that one of the following criteria has been met:

1.) the USEPA, in conjunction with the state, has determined that responsible parties or other parties have implemented all appropriate response actions required;

2.) the USEPA, in consultation with the state, has determined that all appropriate Superfund-financed responses under CERCLA have been implemented, and that NFA by responsible parties is appropriate; or

3.) an RI has shown that the release poses no significant threat to public health or the environment and, therefore, remedial measures are not appropriate (USEPA, 1999).

2.4 Navy Lead Agency Authority

Executive Order 12580, entitled Superfund Implementation, delegates the Department of Defense (DOD) "lead agency" authority to conduct removal actions, remedial actions, and "any other response measures" in a manner consistent with the NCP in the case of releases and threatened releases on or from DOD properties. The Department of the Navy Environmental Restoration Program Manual (USNAVY 2006), Section 2.2.9, delegates Naval Facilities Engineering Command (NAVFAC) with the responsibility of executing the ER program and providing NAVFAC-wide policy and guidance.

The exercise of such response authority must be consistent with the requirements of CERCLA section 120. CERCLA section 120 requires federal agencies to comply with all guidelines, rules, regulations, and criteria applicable to private facilities concerning preliminary assessments, "evaluations" under the NCP, listing on the NPL, and the conduct of remedial action. Section 120 also requires that inter-agency agreements (IAGs – also known as Federal Facility Agreements) be entered to govern remedial action at federal facilities. Such IAGs must provide that if the lead agency and USEPA are unable to reach an agreement on selection of a remedial action, USEPA gets to select the remedy. Such IAGs are required, however, only for facilities that are listed on the NPL. For facilities that are subject to an IAG, the roles and authority of Navy and USEPA will be defined, in part, by the terms of the agreement. For non-NPL facilities, the Navy has full response-action authority subject to the requirements of CERCLA and the NCP.

2.5 References

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U.S. House of Representatives, U.S.Code, Title 42, Chap.103,(b) http://www.epa.gov/superfund/policy/sara.htm.

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U.S. Navy Human Health Risk Assessment Guidance

Chapter 3 – Overview of the Human Health Risk Assessment Process

Table of Contents

List of Figures

ACRONYMS AND ABBREVIATIONS

BHHRA	Baseline Human Health Risk Assessment
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COPC	Chemical of Potential Concern
FS	Feasibility Study
HHRA	Human Health Risk Assessment
IC	Institutional Control
LUC	Land Use Control
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
ORNL	Oak Ridge National Laboratory
PRG	Preliminary Remediation Goal
RBSC	Risk-Based Screening Concentration
RERA	Risk Evaluation of Remedial Alternatives
RI/FS	Remedial Investigation/Feasibility Study
RPM	Remedial Project Manager
RSL	Regional Screening Level
USEPA	United States Environmental Protection Agency

3.0 Introduction

Risk assessment is an established approach to evaluate the potential for adverse health effects from exposures to toxic substances. Risk assessment is a tool that can be used to evaluate the potential effects of exposure to chemical/radiological concentrations in environmental media (e.g., groundwater, surface water, soil, sediment, air, biota, etc.). While it is a useful management-decision tool, it does not provide absolute statements about possible human health effects.

Human health risk assessments (HHRAs) typically focus on chemicals and exposure pathways directly related to a site (e.g., the incremental risks due to exposure to contaminated soil at a site). These assessments do not address risks from other sources of exposure (e.g., dietary exposures) or risks from naturally-occurring or anthropogenic chemicals that are not associated with the site under evaluation.

This chapter presents an overview of the HHRA evaluations that are performed as part of the site remediation process. Figure 3.1 presents an overview of the HHRA process. The four different types of Remedial Investigation/Feasibility Study (RI/FS) HHRA evaluations are:

1.) risk-based screening and development of preliminary remediation goals (PRGs) (Tier IA and Tier IB);

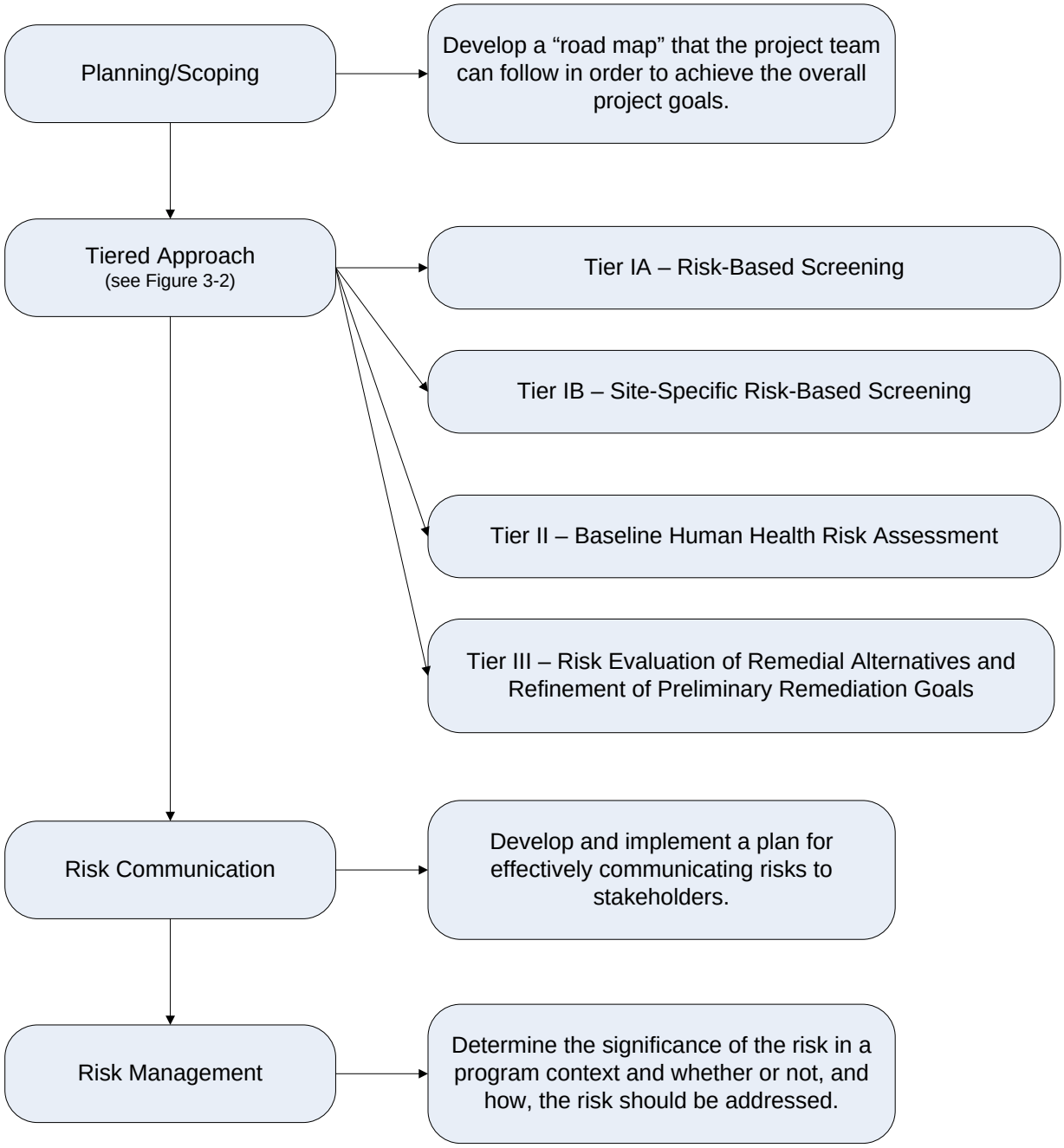
2.) baseline human health risk assessment (BHHRA) (Tier II);

3.) refinement of PRGs (Tier III); and

4.) risk evaluation of remedial alternatives (RERA) (Tier III).

Although the RI/FS process and related risk information activities are often presented in a fashion that makes the steps appear sequential and distinct, in practice the process is highly interactive. The RI/FS should be viewed as a flexible process that can and should be tailored to specific circumstances and to the informational needs of individual sites, not as a rigid approach that must be conducted identically at every site (USEPA, 1989).

Figure 3.1 – Human Health Risk Assessment Process



Each topic that is presented in this chapter of the guidance is also discussed in greater detail in other chapters of the guidance. Additional sources with more detailed information are as follows:

- ORNL (2008). Screening Levels for Chemical Contaminants. http://epa-prgs.ornl.gov/chemicals/
- USEPA (1989). Risk Assessment Guidance for Superfund: Human Health Evaluation Manual (Part A). Interim Final. 1989. Office of Emergency and Remedial Response. Washington, D.C. 9285.701A. EPA/540/1-89/002. http://www.epa.gov/oswer/riskassessment/ragsa/index.htm.
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3.1 Goals and Use of a Human Health Risk Assessment

The goal of an HHRA is to determine the magnitude and immediacy of potential threats to human health associated with exposure to hazardous substances. Deciding whether or not actions are warranted to mitigate a potential threat and selecting appropriate remedial goals and alternatives are considered risk management activities, and are distinct from risk assessment activities. In general, the objectives of an HHRA include:

1.) providing an analysis of baseline risks (i.e., current exposure conditions) and potential risks (based on future land use) in order to help determine the need for action at sites;

2.) providing a basis for determining levels of chemicals that can remain onsite and still be adequately protective of public health;

3.) providing a basis for comparing potential health impacts of various remedial alternatives; and

4.) following a consistent approach that facilitates evaluation and documentation of potential public health threats.

The HHRA process is an integral part of the remedial response process defined by Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) and the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The results of the HHRA are used for decision making at remedial sites (USEPA, 1989).

3.2 Exiting the Human Health Risk Assessment Process

3.2.1 Exit Criteria

Exit criteria are quantitative expressions of acceptable risks that may be used in conjunction with institutional controls (ICs) and land use to determine if a site can exit the HHRA process (i.e., no further action will be taken or a proposed plan with ICs will be implemented) or whether or not it warrants further evaluation. Exit criteria should not be considered until the nature and extent of contamination is well understood. The following criteria should be used to determine whether or not a site may exit the HHRA process.

1.) **Incomplete Exposure Pathways** – If chemicals present on site are not accessible to humans (e.g., non-volatile chemicals under a building foundation, no human populations present, etc.) then there is no possibility for human exposure, no risk, and the site may exit the HHRA process.

2.) **Background** – If there are no chemical concentrations present on site that are greater than background concentrations, then the site may exit the HHRA process. The Navy Policy on the Use of Background Chemical Levels should be followed for evaluation of background (USNAVY, 2004). *Note: This applies to all chemicals that are present in background samples. If a chemical was not detected in background samples, then it should not be screened out and should be evaluated further, using risk-based approaches. In states that require that risks be calculated including chemicals present at or below background concentrations, risks may be presented with and without contribution from background.*

3.) **Risk-Based Screening** – If there are no chemicals present on site that are greater than default risk-based regional screening levels (RSLs) in Tier IA or site-specific risk-based screening concentrations (RBSCs) in Tier IB then the site may exit the HHRA process. *Note: This comparison should also include chemicals detected at concentrations that are not representative of background concentrations. Essential nutrients (i.e., calcium, magnesium, potassium, and sodium) should be eliminated from consideration in the risk assessment because they are not associated with toxicity in humans under normal circumstances. Also, chemicals that are detected infrequently and at low concentrations (e.g., less than five percent frequency of detection and at concentrations slightly above the detection limit) may be eliminated from further consideration in the risk assessment process (USEPA, 1989). In addition, if analysis has determined that a chemical is present in a form that is not bioavailable, the chemical may be eliminated from further consideration. See the Framework for Metals Risk Assessment (USEPA, 2007) for guidance on evaluating the potential bioavailability of chemicals.*

4.) **Baseline Human Health Risk Assessment (BHHRA)** – If a BHHRA determines that the chemicals present at a site pose an acceptable risk then the site may exit the HHRA process.

Note: If an "Interim Removal Action" is performed (i.e., if all, or some, of the contamination is removed) then the site should be re-evaluated using the exit criteria identified above to determine whether or not it may exit the HHRA process.

Regardless of the initial exit criteria that are selected, it is important for Remedial Project Managers (RPMs) to continually re-evaluate their site throughout the process, with regard to the exit criteria, to determine if it may exit the HHRA process.

Note: If a site exits the HHRA process, Maximum Contaminant Levels [MCLs] or non-zero Maximum Contaminant Level Goals [MCLGs] and ecological risks should still be considered. In addition, the exit criteria presented in this section should not be viewed as discrete values. RPMs should evaluate each site on a case-by-case basis to determine if the risks are considered acceptable or unacceptable (USEPA, 1991c). In some situations, risks that are acceptable at one site may not be considered

acceptable at another site. This may be due to a variety of site-specific factors, such as the uncertainty associated with characterizing exposure or the uncertainties associated with the toxicity values of chemicals responsible for the majority of the risk.

3.2.2 DEVELOPMENT OF EXIT CRITERIA

Exit criteria are developed based on regulatory benchmarks and cancer and noncancer health risks. They may also take into account land use or ICs. The regulatory benchmarks and land use are discussed below. For more information on cancer and noncancer risks see Chapter 8 – Tier II Baseline Human Health Risk Assessments.

Regulatory Benchmarks

The USEPA has typically used a hazard index (i.e., the cumulative noncancer risks for all chemicals) of 1 or greater, or a hazard index for a target organ/critical effect of 1 or greater as a benchmark for evaluating noncarcinogenic hazard indices. For carcinogenic risk, the USEPA's approach emphasizes the use of one chance in one million [i.e., 1×10^{-6}] as the point of departure while allowing site or remedy-specific factors, including potential future uses, to enter into the evaluation of what is appropriate at a given site. As risks increase above one chance in one million, they become less desirable, and the risk to individuals generally should not exceed one in ten thousand (i.e., 1×10^{-4}) (USEPA, 1991c). The USEPA recommends that "where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 1×10^{-4} and the non-carcinogenic hazard index is less than 1, action generally is not warranted unless there are adverse environmental impacts. However, if MCLs or non-zero MCLGs are exceeded, action generally is warranted" (USEPA, 1991c).

Impact of Land Use and Institutional Controls on Exit Criteria

It is important to understand the benefits of land use controls (LUCs), as well as the restrictions that accompany them. Implementing LUCs for a site can be beneficial because they allow the risk assessment to reflect actual future land use, which can lower the cost of the remediation if a land use other than residential is specified. This is due to the fact that exit criteria for land uses other than residential (e.g., industrial) are typically less stringent. Although LUCs may present a viable option as part of a remedy, it is important to consider the long-term, life-cycle, costs of LUCs (e.g., long-term monitoring). The implementation of LUCs is a risk-management decision and the long-term costs of LUCs should be weighed against the additional costs of cleanup to unrestricted use. Additional information about monitoring and enforcing LUCs is available from the Department of the Navy (USNAVY, 2003).

3.3 Project Planning/Scoping

HHRAs can take on many different forms that require varying types and amounts of information, depending on the characteristics of the site. Consequently, in some cases, the HHRA might consist of risk-based screening, while in other cases it might consist of complete baseline and future land use assessments. The purpose of the planning/scoping process is to develop a "road map" that the project team can follow in order to achieve the overall project goals. Planning/scoping also allows for the development of a comprehensive sampling and analysis plan that will satisfy the needs of each RI/FS component, while helping to ensure that time and budget constraints are met (USEPA, 1989).

Risk assessors should be included early in the planning/scoping process to ensure that the type, amount, and quality of data collected will be suitable for the HHRA. Including risk assessors early in the planning/scoping process achieves the following objectives:

- minimizes the cost of obtaining the information;

- maximizes the amount of information that can be used in the risk assessment;
- identifies all of the information that will be needed to complete the risk assessment; and
- identifies stakeholders' concerns about the risk assessment in order to address them, to the extent possible, during the RI/FS process.

Changing regulatory and political factors, stakeholder concerns, and results from different phases of the RI/FS process will result in different project risk assessment and data needs. As a result of these changes, project planning/scoping will occur throughout the project.

See Chapter 5 – Planning/Scoping for more detailed information about planning and scoping HHRAs.

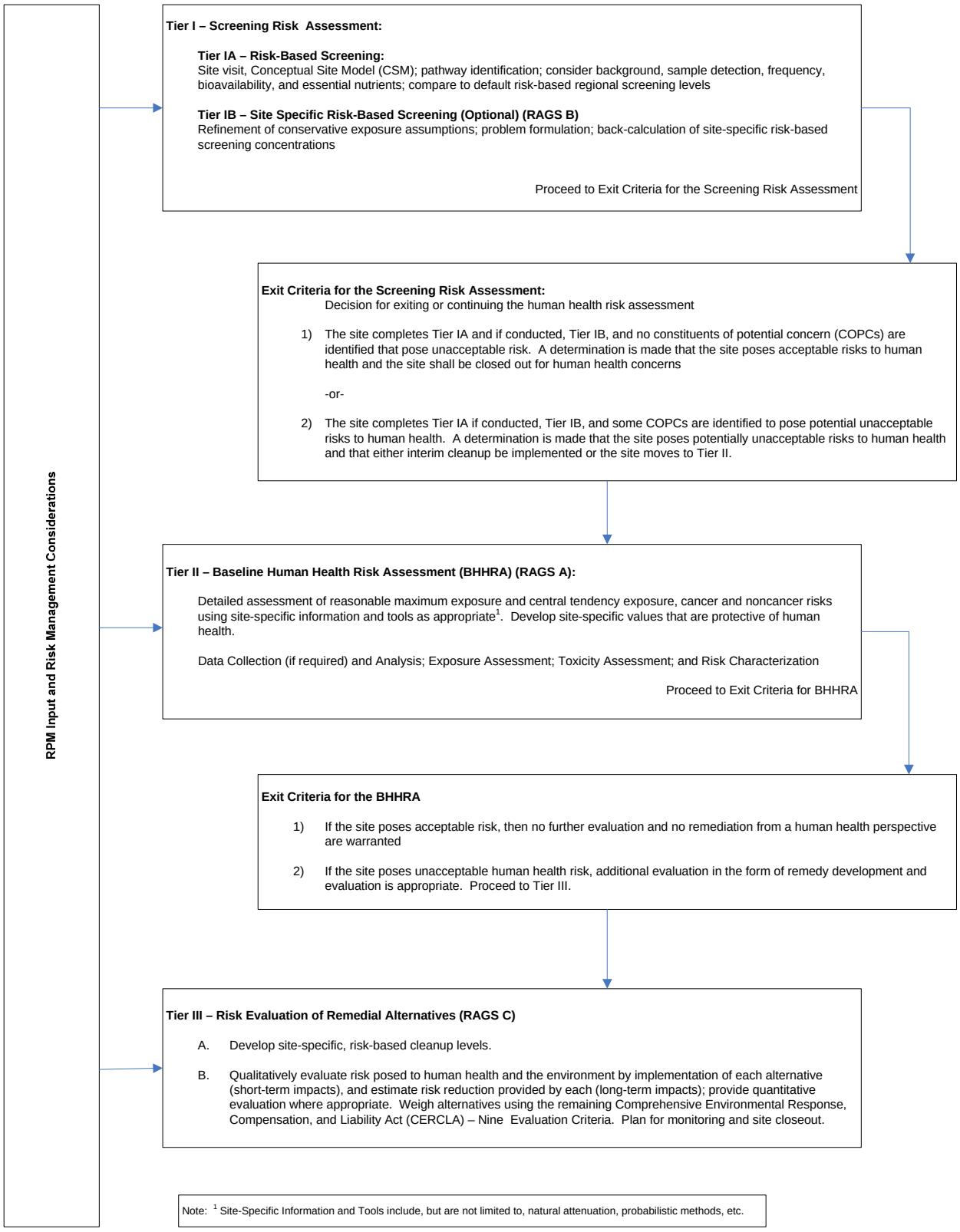
3.4 Tiered Approach

The three-tiered HHRA approach is a framework for integrating risk assessment information into the process of evaluating and remediating sites. Sites vary greatly in terms of complexity, physical and chemical characteristics, and in the risk that they may pose to human health and the environment. The tiered approach recognizes this diversity, and uses a multi-leveled approach to tailor remedial activities to site-specific conditions and risks.

Figure 3-2 presents an overview of the tiered approach. Tiers IA and IB are risk-based screening approaches that, with minimal effort, are used to quickly determine whether or not sites warrant further consideration. Tier IA uses RSLs, which are based on conservative, default exposure assumptions (e.g., residential scenario). Tier IB uses RBSCs based on site-specific exposures. Tier II involves a much more detailed risk assessment that may evaluate the current baseline risks, as well as risks associated with future land use at a site. Tier III evaluations focus on the risks associated with different remedial alternatives. All three tiers result in cost-effective actions that protect human health and the environment.

Note: If there are no chemical concentrations present on site that are greater than background concentrations then the site may exit the HHRA process. This applies to all chemicals that are present in background samples. The Navy Policy on the Use of Background Chemicals should be followed for evaluation of background (USNAVY, 2004). If a chemical was not detected in background samples, then it should not be screened out and should be evaluated further, using risk-based approaches.

Figure 3.2 – Navy Tiered Human Health Risk Assessment Process (USNAVY, 2001)



3.5 Tier IA – Risk-Based Screening

The purpose of Tier IA risk-based screening is to determine whether or not a site poses acceptable or unacceptable risks, using conservative default assumptions. Risk-based screening is a useful step in the overall site evaluation process because a site will either be eliminated from further consideration, or a subset of chemicals at the site will be identified as a potential concern and will become the focus of subsequent site investigation and evaluation steps.

Risk-based screening compares site chemical concentrations to RSLs. RSLs are concentrations of chemicals in soil, air, and water that are calculated using "risk" levels that are considered protective of human health for default exposure scenarios and exposure pathways. RSLs are determined by performing a reverse risk assessment, where standard risk assessment equations are rearranged to solve for media concentrations rather than risk. Default residential and industrial exposure scenarios are combined with USEPA toxicity values and target risk goals (e.g., a cancer risk of one in one million or 1×10^{-6}) to determine acceptable concentrations of chemicals in each media.

Risk-based screening has become a standard part of the risk assessment process. The USEPA has increasingly emphasized this approach, because it saves time and money while protecting human health. The Oak Ridge National Laboratory (ORNL), working under contract with the USEPA, has prepared default RSLs, which are available at http://epa-prgs.ornl.gov/chemicals/. The outcomes of risk-based screening are consistent with what would occur if a complete HHRA was performed (USEPA, 1993). PRGs for the FS are often developed based on the RSLs.

See Chapter 7 – Tier IA and Tier IB Risk-Based Screening for more detailed information about risk-based screening.

3.6 Tier IB – Site-Specific Risk-Based Screening

Tier IB is similar to Tier IA in that site media concentrations are compared with risk-based concentrations to determine if concentrations pose an acceptable risk. However, the RBSCs used in Tier IB are calculated using site-specific exposure assumptions. Some situations where it might be beneficial to develop site-specific RBSCs instead of using default RSLs are:

- areas with extreme climates (e.g., Alaska) where standard chemical exposure factors such as exposure duration and frequency are not appropriate (e.g., RBSCs could be developed based on Alaska-specific residential and industrial exposure scenarios).
- land uses with plausible exposure scenarios that are different than the generic industrial worker scenario (e.g., a construction worker exposure scenario, in which workers are working directly in contaminated subsurface soil).
- a facility where there are numerous sites and specific-future land use is known (e.g., if a large parcel of property is going to be developed for commercial purposes, then it may be appropriate to develop site-specific RBSCs that reflect the future exposure scenarios).

It is important to note that, unlike a Tier 1A evaluation, a Tier IB evaluation may not be necessary at every site. In some instances it may be appropriate to proceed directly from Tier IA to Tier II, depending on the complexity of the site. Developing site-specific RBSCs involves some effort, but will result in more sites being screened out from further consideration than if default RSLs are used.

See Chapter 7 – Tier IA and Tier IB Risk-Based Screening for more detailed information about risk-based screening.

3.7 Tier II – Baseline Human Health Risk Assessment

The Tier II BHHRA is a quantitative analysis of the potential adverse health effects (current or future) caused by exposure to site-related chemicals. The BHHRA contributes to the site characterization and subsequent development, evaluation, and selection of appropriate response alternatives. The carcinogenic risks and noncarcinogenic hazards calculated in the BHHRA are used to:

- document the magnitude of risk at a site, and the primary causes of that risk;
- assist in determining whether or not additional response action is necessary at the site;
- modify PRGs; and
- support selection of the "no-action" remedial alternative, where appropriate.

BHHRAs are site-specific and, therefore, may vary in both detail and the extent to which qualitative and quantitative analyses are used, depending on the complexity and particular circumstances of the site (USEPA, 1989).

See Chapter 8 – Baseline Human Health Risk Assessment for more detailed information about conducting BHHRAs.

3.8 Tier III – Risk Evaluation of Remedial Alternatives

The purpose of Tier III, RERAs, is to evaluate the potential human health risks associated with remedial alternatives that are being considered for a site. This process begins in the development and screening stages of the FS and extends to Site Closeout/Long-Term Monitoring. The goal of these evaluations is to provide decision makers with information on the short-term and long-term risks associated with each alternative to assist in selecting a remedy for a site (USEPA, 1991b). Short-term risks are those that occur during implementation of a remedial alternative (e.g., risk associated with inhalation of fugitive dust during excavation of impacted soil at a site). Long-term risks include those that remain after the remedial action has been completed. The evaluations also consider the alternative's ability to provide protection over time. Long-term risks are often called "residual" risks. As part of the evaluation, PRGs are recalculated and refined based on the selected remedial actions.

The complexity of RERAs should be commensurate with the complexity of the remedial alternatives and the concentrations and relative toxicity of the chemicals being remediated (USEPA, 1991b). RERAs are often qualitative and the level of effort will vary with each remedial alternative and with each site being evaluated. For example, in some instances only a qualitative evaluation of the risks may be necessary. In other instances a quantitative evaluation of risks using PRGs or a deterministic risk assessment may be necessary.

See Chapter 10 – Risk Evaluations of Remedial Alternatives for more detailed information about conducting RERAs.

3.9 Risk Communication

Effective risk communication at a site is often vital to the overall success of a site remediation project. With heightened public awareness of hazardous chemicals (e.g., dioxin) and exposure routes (e.g., vapor intrusion), it is very important to consider developing a risk communication plan for each site. At many sites there are a variety of stakeholders who have different objectives and concerns. This may lead to a difficult and lengthy remedial process. Risk communication is an interaction between the groups responsible for site remediation and the stakeholders, each group recognizing and responding to the legitimate concerns of the other. Effective risk communication helps streamline the remedial process by gaining stakeholder acceptance. The Navy and Marine Corps Public Health Center (NMCPHC) has prepared a Risk Communication Primer to assist RPMs with risk communication (http://www-nmcphc.med.navy.mil/HERC/Products/primer.pdf.

See Chapter 11 – Risk Communication Principles and Techniques for more detailed information about risk communication.

3.10 Risk Management

The USEPA makes a very clear distinction between risk management and risk assessment. Risk management is the process of evaluating risks and other considerations (e.g., applicable statutes), to make and justify regulatory decisions at a site (USEPA, 1995). Risk managers are responsible for determining the significance of the risks at a site and whether or not and how the risk should be addressed (USEPA, 1989). Risk assessment is the process of selecting, evaluating, and presenting scientific information, without considering issues such as cost, feasibility, or how the scientific analysis might influence the regulatory or site-specific decision. Risk assessors are responsible for:

- generating a credible, objective, realistic, and scientifically-balanced analysis;
- presenting information on hazards, dose-responses, exposures and risks; and
- explaining confidence in each assessment by clearly delineating strengths, uncertainties and assumptions, along with the impacts of these factors (e.g., confidence limits, use of conservative/non-conservative assumptions) on the overall assessment.

Risk assessors should not make decisions on the acceptability of any risk level for protecting public health or selecting procedures for reducing risks (USEPA, 1995). In practical terms, this means that risk assessment reports should clearly present the risks in a way that can be used by risk managers, while avoiding making value judgments about what actions should be taken.

See Chapter 12 – Risk Management for more detailed information about the relationship between risk management and risk assessment.

3.11 References

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U.S. Navy Human Health Risk Assessment Guidance

Chapter 4 – Strategically Managing the Human Health Risk Assessment Process

Table of Contents

List of Figures

ACRONYMS AND ABBREVIATIONS

BHHRA	Baseline Human Health Risk Assessment
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COPC	Chemical of Potential Concern
CSM	Conceptual Site Model
DOD	Department of Defense
DQO	Data Quality Objective
ER	Environmental Restoration
HHRA	Human Health Risk Assessment
IAG	Inter-Agency Agreement
IC	Institutional Control
LUC	Land Use Control
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
NAVFAC	Naval Facilities Engineering Command
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NMCPHC	Navy and Marine Corps Public Health Center
NPL	National Priorities List
PRG	Preliminary Remediation Goal
RBSC	Risk-Based Screening Concentration
RI/FS	Remedial Investigation/Feasibility Study
RPM	Remedial Project Manager
RSL	Regional Screening Level
SAP	Sampling and Analysis Plan
UFP	Uniform Federal Policy
USEPA	United States Environmental Protection Agency

4.0 Introduction

This chapter provides a summary of the key issues that Remedial Project Managers (RPMs) should consider in order to effectively manage the human health risk assessment (HHRA) process. These issues include:

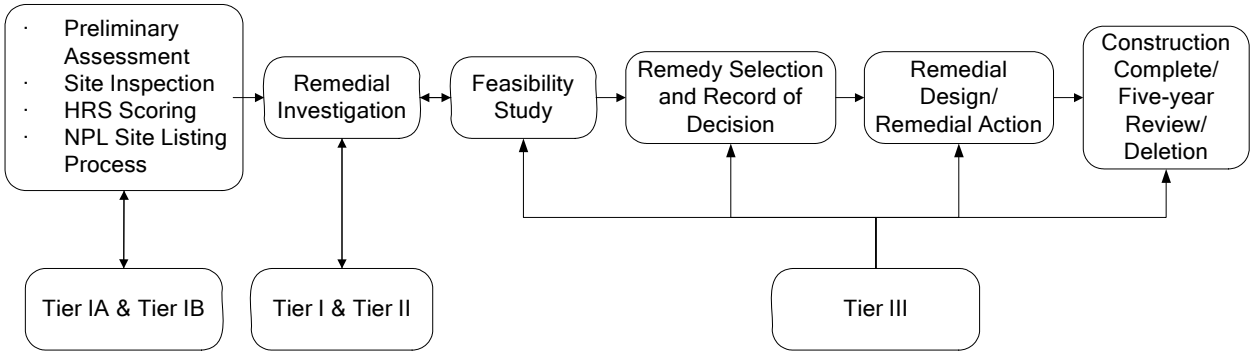
- Tiered Risk Assessment Approach;
- Lead Agency Authority;
- Project Planning;
- Conceptual Site Model (CSM) Development;
- Data Quality Objectives (DQOs) for Risk Assessment;
- Impact of Ecological Risk Assessment on the Process;
- Exiting the HHRA Process;
- Risk Communication; and
- Risk Management.

More in-depth discussions of each of these topics are presented in other chapters of this guidance.

4.1 Tiered Risk Assessment Approach

Risk assessment is a key step in the Environmental Restoration (ER) process because it provides context for all of the information that is generated during the investigation process. Risk assessment results are used by RPMs to evaluate site concentrations to determine if the risks are significant, whether or not further investigation or other actions are appropriate, and to help determine cleanup levels for remediating a site. Figure 4.1 presents the relationship of the three-tiered risk assessment approach to the remedial process. The tiered approach incorporates risk information into the decision-making process, minimizes the level of effort, and eliminates sites that are not of concern. The tiered approach also ensures that the level of effort expended to evaluate sites is commensurate with the magnitude and complexity of the site-specific issues. At relatively simple sites, risk-based screening (Tier I) can be used to evaluate the potential risks. At complex sites, a baseline human health risk assessment (BHHRA) (Tier II) can be performed to evaluate site-specific exposure scenarios and receptors. The human health risks associated with remedial alternatives are evaluated in Tier III. Finally, the three-tiered approach allows Navy RPMs to focus resources on those sites that pose a significant risk to human health and/or the environment.

Figure 4.1 – Relationship of the Tiered Approach to the Remedial Process



4.2 Lead Agency Authority

Executive Order 12580, entitled Superfund Implementation, delegates the Department of Defense (DOD) "lead agency" authority to conduct removal actions, remedial actions, and "any other response measures" in a manner consistent with the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) in the case of releases and threatened releases on or from DOD properties. The Department of the Navy Environmental Restoration Program Manual (USNAVY 2006), Section 2.2.9, delegates the Naval Facilities Engineering Command (NAVFAC) with the responsibility of executing the ER program and providing NAVFAC-wide policy and guidance.

The exercise of such response authority must be consistent with the requirements of Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) section 120. CERCLA section 120 requires federal agencies to comply with all guidelines, rules, regulations, and criteria applicable to private facilities concerning preliminary assessments, "evaluations" under the NCP, listing on the National Priorities List (NPL), and the conduct of remedial action. Section 120 also requires that inter-agency agreements (IAGs) (also known as Federal Facility Agreements) be entered to govern remedial action at federal facilities. Such IAGs must provide that if the lead agency and the United States Environmental Protection Agency (USEPA) are unable to reach an agreement on selection of a remedial action, USEPA gets to select the remedy. Such IAGs are required, however, only for facilities that are listed on the NPL. For facilities that are subject to an IAG, the roles and authority of Navy and USEPA will be defined, in part, by the terms of the agreement. For non-NPL facilities, the Navy has full response-action authority subject to the requirements of CERCLA and the NCP.

4.3 Project Planning/Scoping

The purpose of the project planning/scoping process is to develop a "road map" that the project team can follow in order to achieve the overall project goals. As a general rule, it is wise to include risk assessors early in the process in order to help develop the CSM and provide input concerning potentially-exposed populations, exposure routes, and likely risks at the site. In addition, risk assessors can identify data needs "up front" thus avoiding data gaps that may require costly re-sampling and analysis. Planning for a risk assessment at the beginning of the process should be done in order to achieve the following objectives:

- minimize the cost of obtaining the information;
- maximize the amount of information that can be used in the risk assessment;
- identify all of the information that will be needed to complete the risk assessment; and

- identify stakeholders' concerns about the risk assessment in order to address them, to the extent possible, during the Remedial Investigation/Feasibility Study (RI/FS) process.

Project planning/scoping also allows for the development of a comprehensive sampling and analysis plan that will satisfy the needs of each component of the project, while helping to ensure that time and budget constraints are met (USEPA, 1989). The Navy Policy on Sediment Site Investigations and Response Actions also provides guidance on development of comprehensive sampling and analysis plans (USNAVY, 2002).

4.4 Conceptual Site Model Development

The purpose of a CSM is to provide an understanding of the potential for exposure, under current and future land use, to chemicals at a site based on the source(s) of contamination, the release mechanism(s), the exposure pathway(s), and the receptor(s). Based on a CSM, a data-collection strategy can be developed to prioritize field sampling activities and reduce uncertainty in risk characterization. A CSM may also provide sufficient information to allow for development of a strategy for early-response actions to address exposure pathways that are considered complete and that pose an imminent risk to public health (USDOE, 1997). The CSM is critical to developing sampling and other work plans, because the process of creating the CSM results in a thorough compilation and evaluation of known information, and identifies key questions that should be addressed during the site investigation. The CSM can also be used as an effective tool in the planning/scoping process to communicate site conditions to regulators and stakeholders.

4.5 Data Quality Objectives for Risk Assessment

DQOs are qualitative and quantitative statements established prior to data collection, which specify the quality and quantity of the data required to support decisions during remedial response activities. DQOs should be viewed as strategic planning tools that help to ensure that the type, quality and quantity of data collected at a site are appropriate to meet project goals. They are particularly important since the analytical data collected during environmental investigations typically serve numerous purposes (e.g., site characterization, risk assessment, design of remedial alternatives, etc.). Three key risk assessment DQO issues are as follows.

1.) **Adequate Site Characterization** – The foundation of a credible risk assessment is analytical data, which are used to develop representative exposure point concentrations. In addition to sampling density and coverage considerations, it is important that all media of concern are sampled at likely exposure points, in order to provide a consistent basis for evaluating site risks.

2.) **Detection Limits** – Analytical methods should be selected so that the detection limits are less than default risk-based regional screening levels (RSLs) (used in Tier IA) or site-specific risk-based screening concentrations (RBSCs) (calculated in Tier IB). For some analytical methods, the detection limits for non-detected data may exceed the RSLs and RBSCs. A chemical would be considered a chemical of potential concern (COPC), even though the chemical may not be present. Risk assessors should provide risk-based detection limits to the RPM during the DQO planning process, to ensure that appropriate analytical methods are selected.

3.) **Background Samples** – The purpose of a site risk assessment is to estimate the incremental risks associated with exposure to contamination present at the site due to Navy activities rather than background contamination. The purpose of background screening is to focus the risk assessment on COPCs that are related to site activities and to eliminate chemicals that are present at background concentrations. Consequently, background or reference samples should be obtained at sites.

Note: While DQOs should be identified for every project, the need for formal DQO planning sessions varies, based on project needs and project complexity. In some cases, the project objectives and data needs are so clear (or so prescriptive) that the DQOs are easily established by the RPM alone, and the

documentation for the DQO process fits on a single sheet of paper. In other cases, the DQO process may require a considerable investment of time and resources, as well as input from technical experts (e.g., risk assessors, geologists, and engineers). DQOs are part of the systematic planning process, and should be documented in the Uniform Federal Policy- Sampling and Analysis Plan (UFP-SAP) prior to field sampling.

4.6 Impact of Ecological Risk Assessment on the Process

Potential impacts to the environment should also be considered when evaluating a site, because ecologically-based preliminary remediation goals (PRGs) may be lower (i.e., more protective) than their corresponding human health-based PRGs (e.g., copper). It is important to note that remedies based on ecologically-based PRGs should consider the "Net Environmental Benefit" of the alternative. That is, RPMs should assess the damage that will occur to the environment at a site as a result of implementing the remedy versus the damage to the environment resulting from "No Further Action." See the Navy Guidance on Performing Ecological Risk Assessments for more information on ecologically-based PRGs: http://web.ead.anl.gov/ecorisk/.

Note: The concepts presented above also apply to "risks" or "impacts." For example, a site that may be considered "No Further Action," based on the results of an HHRA, may be an "Action Site," based on the results of an ecological risk assessment. Consequently, both human health and environmental impacts should be assessed, when appropriate, at remedial sites.

4.7 Exiting the Human Health Risk Assessment Process

4.7.1 Exit Criteria

Exit criteria are quantitative expressions of acceptable risks that may be used in conjunction with institutional controls (ICs) and land use to determine if a site can exit the HHRA process (i.e., no further action will be taken or a proposed plan with ICs will be implemented) or whether or not it warrants further evaluation. Exit criteria should not be considered until the nature and extent of contamination is well understood. The following criteria should be used to determine whether or not a site may exit the HHRA process.

1.) **Incomplete Exposure Pathways** – If chemicals present on site are not accessible to humans (e.g., non-volatile chemicals under a building foundation, no human populations present, etc.) then there is no possibility for human exposure, no risk, and the site may exit the HHRA process.

2.) **Background** – If there are no chemical concentrations present on site that are greater than background concentrations then the site may exit the HHRA process. The Navy Policy on the Use of Background Chemical Levels should be followed for evaluation of background (USNAVY, 2004). *Note: This applies to all chemicals that are present in background samples. If a chemical was not detected in background samples, then it should not be screened out and should be evaluated further, using risk-based approaches. In states that require that risks be calculated including chemicals present at or below background concentrations, risks may be presented with and without contribution from background.*

3.) **Risk-Based Screening** – If there are no chemicals present on site that are greater than RSLs or RBSCs then the site may exit the HHRA process. *Note: This comparison should also include chemicals detected at concentrations that are not representative of background concentrations. Essential nutrients (i.e., calcium, magnesium, potassium, and sodium) should be eliminated from consideration in the risk assessment because they are not associated with toxicity in humans under normal circumstances. Also, chemicals that are detected infrequently and at low concentrations (e.g., less than five percent frequency of detection and at concentrations slightly above the detection limit) should be eliminated from further consideration in the risk assessment*

process (USEPA, 1989). In addition, if analysis has determined that a chemical is present in a form that is not bioavailable, the chemical may be eliminated from further consideration. See the Framework for Metals Risk Assessment (USEPA, 2007) for guidance on evaluating the potential bioavailability of chemicals.

4.) **Baseline Human Health Risk Assessment (BHHRA)** – If a BHHRA determines that the chemicals present at a site pose an acceptable risk then the site may exit the HHRA process.

Note: If an "Interim Removal Action" is performed (i.e., if all, or some, of the contamination is removed) then the site should be re-evaluated using the exit criteria identified above to determine whether or not it may exit the HHRA process.

Regardless of the initial exit criteria that are selected, it is important for an RPM to continually re-evaluate their site throughout the process, with regard to the exit criteria, to determine if it may exit the HHRA process.

Note: If a site exits the HHRA process, Maximum Contaminant Levels [MCLs] or non-zero Maximum Contaminant Level Goals [MCLGs] and ecological risks should still be considered. In addition, the exit criteria presented in this section should not be viewed as discrete values. RPMs should evaluate each site on a case-by-case basis to determine if the risks are considered acceptable or unacceptable (USEPA, 1991). In some situations, risks that are acceptable at one site may not be considered acceptable at another site. This may be due to a variety of site-specific factors (e.g., the uncertainty associated with characterizing exposure or the uncertainties associated with the toxicity values of chemicals responsible for the majority of the risk).

4.7.2 Regulatory Benchmarks and Institutional Controls

Exit criteria are developed based on regulatory benchmarks and cancer and noncancer health risks. They may also take into account land use or ICs. The regulatory benchmarks and land use are discussed below. For more information on cancer and noncancer risks see Chapter 8 – Tier II Baseline Human Health Risk Assessment.

Regulatory Benchmarks

The USEPA has typically used a hazard index (i.e., the cumulative noncancer risks for all chemicals) of 1 or greater, or a hazard index for a target organ/critical effect of 1 or greater as a benchmark for evaluating noncarcinogenic hazard indices. For carcinogenic risk, the USEPA's approach emphasizes the use of one chance in one million [i.e., 1×10^{-6}] as the point of departure while allowing site or remedy-specific factors, including potential future uses, to enter into the evaluation of what is appropriate at a given site. As risks increase above one chance in one million, they become less desirable, and the risk to individuals generally should not exceed one in ten thousand (i.e., 1×10^{-4}) (USEPA, 1991). The USEPA recommends that "where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 1×10^{-4} and the non-carcinogenic hazard index is less than 1, action generally is not warranted unless there are adverse environmental impacts. However, if MCLs [Maximum Contaminant Levels] or non-zero MCLGs [Maximum Contaminant Level Goals, which are used to evaluate drinking water] are exceeded, action generally is warranted" (USEPA, 1991).

Impact of Land Use and Institutional Controls on Exit Criteria

It is important to understand the benefits of land use controls (LUCs), as well as the restrictions that accompany them. Implementing LUCs for a site can be beneficial because they allow the risk assessment to reflect actual future land use, which can lower the cost of the remediation if a land use other than residential is specified. This is due to the fact that exit criteria for land uses other than residential (e.g., industrial) are typically less stringent. Although LUCs may present a viable option as part of a remedy, it is important to consider the long-term, life-cycle costs of LUCs (e.g., long-term monitoring). The implementation of LUCs is a risk management decision and the long-term costs of LUCs should be weighed against the additional costs of cleanup to unrestricted use. Additional

information about monitoring and enforcing LUCs is available from the Department of the Navy (USNAVY, 2003).

4.8 Risk Communication

The success of an environmental restoration (ER) project may depend on the ability to effectively communicate with all interested parties. It is critical that the project team include risk communication from the beginning of the project. Each ER project will likely present its own risk communication challenges due to site-specific conditions. The Navy and Marine Corps Public Health Center (NMCPHC) has prepared a *Risk Communication Primer* to assist RPMs with risk communication (http://www-nmcphc.med.navy.mil/HERC/Products/primer.pdf).

Risk communication is communicating with any stakeholder, internal or external, on any issue that could impact your organization's mission. As a result, risk communication requires capabilities in the process of building, maintaining, and repairing relationships with stakeholders that impact your mission. This requires significant communication skills. Risk communication:

- is not public speaking.
- is not spinning or embellishing messages.
- requires being open, honest, genuine, and sincere
- requires applying the required communication skills (verbal and nonverbal) in a variety of situations.
- requires an ongoing commitment to practice and preparation before interacting with stakeholders.

Important Principles of Risk Communication are the following:

A. Identify stakeholders that impact your mission, favorably (supporters), neutrally (straddlers) or unfavorably (splenetics).

B. Determine where your stakeholders are primarily coming from (emotions, agendas, perception of risk).

C. Utilize third party supporters that can informally or formally help you.

D. Get in front of issues. If it's a crisis issue:

-tell people what you do know,
-tell them what you don't know and,
-update them as you learn more

E. Ensure your communicators are properly trained.

F. Learn the media communication process and build professional relationships with the media.

G. Have a flexible communication planning process. The action steps in the process such as message development and meeting planning should support your mission.

Chapter 11 provides additional guidance on effective risk communication.

4.9 Risk Management

The USEPA makes a very clear distinction between risk management and risk assessment. Risk management is the process of evaluating risks and other considerations (e.g., applicable statutes) to make and justify regulatory decisions at a site (USEPA, 1995). Risk managers are responsible for determining the significance of the risks at a site and whether or not, and how, the risk should be addressed (USEPA, 1989). Risk assessment is the process of selecting, evaluating, and presenting scientific information, without considering issues such as cost, feasibility, or how the scientific analysis might influence the regulatory or site-specific decision. Risk assessors are responsible for:

- generating a credible, objective, realistic, and scientifically-balanced analysis;
- presenting information on hazards, dose-responses, exposures and risks; and
- explaining confidence in each assessment by clearly delineating strengths, uncertainties and assumptions, along with the impacts of these factors (e.g., confidence limits, use of conservative/non-conservative assumptions) on the overall assessment.

Risk assessors should not make decisions on the acceptability of any risk level for protecting public health or selecting procedures for reducing risks (USEPA, 1995). In practical terms, this means that risk assessment reports should clearly present the risks in a way that can be used by risk managers, while avoiding making value judgments about what actions should be taken.

The ultimate goal of the remedial process is to identify and remediate sites that pose a threat to human health and the environment. The results of risk assessments are used by RPMs, in conjunction with a variety of other information (e.g., uncertainty, stakeholder concerns, etc.) to make risk management decisions.

4.10 References

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U.S. Navy Human Health Risk Assessment Guidance

Chapter 5 – Planning/Scoping

Table of Contents

List of Tables

List of Figures

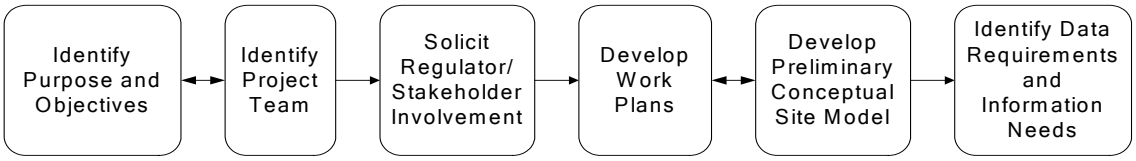
ACRONYMS AND ABBREVIATIONS

CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COPC	Chemical of Potential Concern
CSM	Conceptual Site Model
DOD	United States Department of Defense
DOE	United States Department of Energy
ER	Environmental Restoration
FFA	Federal Facilities Agreement
GIS	Geographic Information System
HHRA	Human Health Risk Assessment
IDQTF	Intergovernmental Data Quality Task Force
NAVFAC	Naval Facilities Engineering Command
NIRIS	Naval Installation Restoration Information Solution
PAH	Polycyclic Aromatic Hydrocarbon
QAPP	Quality Assurance Project Plan
RI/FS	Remedial Investigation/Feasibility Study
RPM	Remedial Project Manager
UFP	Uniform Federal Policy
USEPA	United States Environmental Protection Agency

5.0 Introduction

Human health risk assessments (HHRAs) can take on many different forms that require different types and amounts of information, depending on the needs of the site. This chapter discusses risk assessment related issues that Remedial Project Managers (RPMs) should consider when planning an environmental investigation. The general focus of this chapter is on risk assessments that are part of a Remedial Investigation/Feasibility Study (RI/FS) investigation, although much of the information is pertinent to other risk assessment situations as well. Figure 5.1 presents an overview of the planning/scoping process.

Figure 5.1 – Overview of the Planning/Scoping Process



5.1 Purpose and Objectives

The purpose of the planning/scoping process is to develop a "road map" that the project team can follow in order to achieve the overall project goals. Planning/scoping also allows for the development of a comprehensive sampling and analysis plan that will satisfy the needs of each component of the project, while helping to ensure that time and budget constraints are met (United States Environmental Protection Agency [USEPA], 1989); (Intergovernmental Data Quality Task Force [IDQTF], 2005). Planning for a risk assessment at the beginning of the process should be done to achieve the following objectives:

- minimize the cost of obtaining the information;
- maximize the amount of information that can be used in the risk assessment;
- identify all of the information that will be needed to complete the risk assessment; and
- identify stakeholders' concerns about the risk assessment in order to address them, to the extent possible, during the RI/FS process.

Changing regulatory and political factors, stakeholder concerns, and results from different phases of the RI/FS process will result in different project risk assessment and data needs. As a result of these changes, project planning/scoping should occur throughout the project.

5.2 Team Identification

When developing a team for a project, it is important to consider the scope of the project and the activities that will most likely occur during the process. The complexity of the site is dictated by many factors such as the number of impacted media, the types of chemicals of potential concern (COPCs), the extent of contamination, the number and types of currently-exposed populations, future land use considerations, and political considerations. The more complex a project, the more important that a multidisciplinary team (e.g., geologists, hydrogeologists, risk assessors, engineers, etc.) be assembled early in the process, to comprehensively address the technical issues posed by the site.

As a general rule it is wise to include risk assessors early in the process, to help develop the conceptual site model (CSM) and provide input concerning potentially-exposed populations, exposure routes, and likely risks at the site. For example, if there are some preliminary data available, risk-based screening could be performed to get a sense of what media or chemicals are of potential concern. This can greatly

increase the effectiveness of the project team. In addition, risk assessors can identify data needs "up-front" and avoid key data gaps and costly re-sampling and analysis.

5.3 Regulator and Stakeholder Involvement

Early in the process, RPMs should get to know who the stakeholders are, what their concerns are, how they perceive risk, and whom they trust. The following is a partial list of potential stakeholders:

- area residents;
- elected officials;
- civic organizations;
- health care providers;
- media;
- national, regional, state, tribal and local governmental organizations;
- environmental activists;
- business and industry;
- contractors;
- co-workers; and
- others.

The participation of stakeholders in a site remediation project depends on their concerns, attitudes, levels of interest, levels of involvement, histories, levels of knowledge, opinions, reasons for interest, and types of involvement (ATSDR, 2000). The likelihood of achieving a successful relationship with regulators and stakeholders increases with your knowledge of those with whom you are interacting.

Involving stakeholders early in the process allows them to voice their concerns, and potentially helps shape the remedial action process. In addition, frank and open discussions with stakeholders can often result in stakeholders feeling that they have ownership in the project. Stakeholders who have ownership in the project are more likely to look for ways to improve the process rather than trying to find ways to stop the process.

Regulator involvement should also occur early in the process, and should be conducted in accordance with the provisions outlined in the Federal Facilities Agreement (FFA) (USEPA, 1988). The provisions in the FFA deal primarily with policy issues that must be agreed upon between the Navy and USEPA before site-specific agreements can be finalized. The goal of the FFA is to ensure national consistency in dealing with Navy facilities that involve Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) activities, and requires negotiation between local USEPA regions and the Navy.

Inevitably, regulators and stakeholders have different concerns and ideas about how a risk assessment should be performed and how the information should be used in the decision-making process. The planning/scoping process provides an excellent opportunity to interact with regulators and stakeholders in a constructive manner and to identify risk assessment related concerns and issues early in the process. This helps streamline the process by addressing stakeholders' concerns before the HHRA is initiated, rather than responding to comments after the document is completed. In addition, involving stakeholders may create a climate where coalitions can be developed and may change the dynamics of negotiations

that occur with regulatory agencies. The USEPA is more likely to agree to a certain remedial alternative at a site if key stakeholder groups are supportive.

5.4 Develop Work Plans

One mechanism for formally including regulators and stakeholders in the process is to develop a work plan document that identifies the methodology that will be used to conduct the risk assessment. Risk assessment work plans vary significantly depending on the regulatory context, site complexity, and needs of the project team. Meetings should be conducted during the planning stages of the project to discuss and resolve stakeholders' and regulators' concerns regarding the approach to the HHRA presented in the work plan. Agreements regarding HHRA work plans should be documented in correspondence, and comment and response records.

Key elements of an HHRA work plan include:

- a CSM that identifies the receptors of concern, exposure scenarios, and exposure pathways to be evaluated;
- how background data will be used in the risk assessment;
- the COPC selection process;
- the source of the toxicity criteria (cancer slope factors, reference doses) to be used in the risk assessment;
- the exposure scenarios, exposure assumptions, and algorithms to be used to quantify exposure; and
- the methodology that will be used to characterize the risk and the uncertainties.

For instances when the HHRA work plan includes collection of additional environmental data, the Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP) format (IDQTF, 2005) should be used for the work plan according to Department of Defense (DOD) policy (DOD, 2007) and Chapter 29 of OPNAV Instruction 5090.1C (DON, 2007). This DOD policy supports the use of the UFP-QAPP for environmental sampling or testing services procured by, or on behalf of, the DOD.

The HHRA work plan should identify when a proposed approach varies significantly from that suggested by federal, regional, or state guidance, and provide an explanation as to why the variation is appropriate for the site under investigation. The RPM should be aware that USEPA and state requirements can differ significantly. Consequently, from a budget and schedule standpoint, it is prudent to discuss the risk assessment work plan with the stakeholders and regulators prior to the commencement of work.

If regulatory concurrence with a risk assessment work plan is desired, the RPM should emphasize to the reviewers that the involvement of a risk assessor from the regulatory community is important. At a minimum, Navy risk assessor(s) and risk assessor(s) from the regulatory agencies should be communicating with each other regarding risk assessment issues.

5.5 Development of a Preliminary Conceptual Site Model

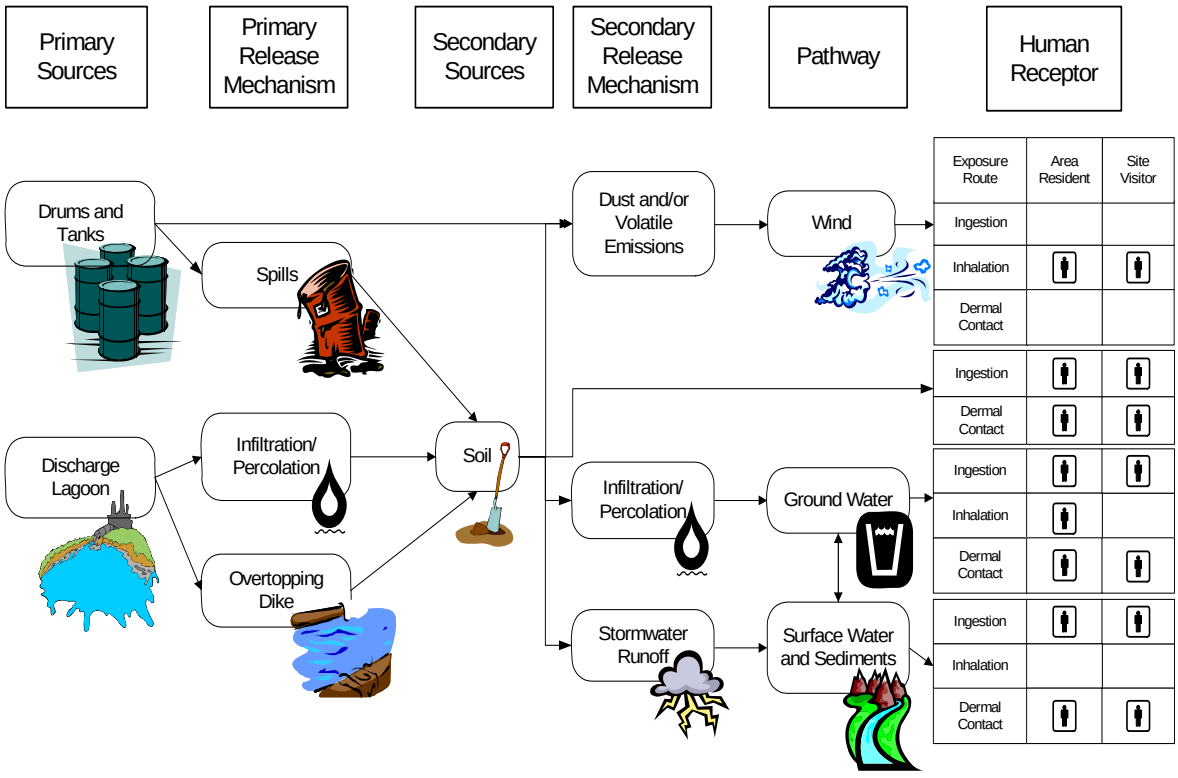
A CSM generally includes a graphical depiction of how people come into contact with sources of contamination. Figure 5.2 presents an example of a CSM. The CSM can be presented as a flow chart that depicts sources of contamination, migration pathways, exposed populations, and exposure routes. Alternatively, a CSM may consist of a picture of site conditions that conveys what is known or suspected at a discrete point in time about the sources, releases, release mechanisms, contaminant fate and transport, exposure pathways, potential receptors, and potential risks. The CSM can also be used as an

effective tool in the planning/scoping process to communicate site conditions to regulators and stakeholders.

The purpose of a CSM is to provide an understanding of the potential for exposure, under current and future land use, to chemicals at a site based on the source(s) of contamination, the release mechanism(s), the exposure pathway(s), and the receptor(s). Exposure pathways considered should include both direct pathways (e.g., soil ingestion, dermal contact with soil), and indirect exposure pathways (e.g., vapor intrusion and subsequent inhalation; transport of contaminants from soil to groundwater and subsequent ingestion), which have received increased attention in recent years. If vapor intrusion is a potential pathway of concern, the *Tri-Services Handbook for the Assessment of the Vapor Intrusion Pathway* (USAF et al., 2008) may be consulted.

Based on a CSM, a data-collection strategy can be developed to prioritize field sampling activities and reduce uncertainty in risk characterization (e.g., contaminant release/transport mechanisms, spatial variability, presence of hot spots, etc.). A CSM may provide sufficient information to allow for development of a strategy for early response actions to address exposure pathways that are considered complete and pose an imminent risk to public health (USDOE, 1997). The *Navy Policy on Sediment Site Investigation and Response Action* (USNAVY, 2002) should be consulted if sediment is a medium of concern. The development of a CSM is critical to developing sampling and other work plans because the process of creating the CSM results in a thorough compilation and evaluation of known information, and identifies key questions that should be addressed during the site investigation.

Figure 5.2 – Example of a Conceptual Site Model



5.6 Data Requirements and Information Needs

The data needed for risk assessment purposes for a site will be identified through the CSM development and scoping process. A risk assessor should be consulted since the data needs for risk assessment may be different and more extensive than those required for characterizing the nature and extent of contamination. The types of information that are needed for risk assessment purposes include information about general site history, site data, geographical information, physical parameters, fate and transport model inputs, and background data. Data are collected to characterize the site conditions, determine the nature of the wastes, assess the potential human health risks, and support treatability testing. Each of these components involves the collection, collation, and evaluation of information, which ultimately leads to specific risk management decisions.

5.6.1 Site History

Historical data about a site provides crucial information that serves as the cornerstone of the planning/scoping process. Historical information about the site's land use, such as industrial chemical processing and disposal practices, can focus the planning/scoping process by providing key information about the probable nature and extent of contamination. Information about activity patterns at the site can be used to develop current exposure scenarios. Information about site processes, such as how a manufacturing process worked, provides insight about what chemicals were probably used and in what quantities.

5.6.2 Site Data

There are several types of data that are collected during site investigations that have associated uses in the risk assessment. For example:

- analytical data collected to identify COPCs and their associated concentrations in potentially-impacted media (e.g., soil, groundwater, surface water, etc.);
- data representing spatial distribution of COPCs used to identify complete exposure pathways, determine representative exposure point concentrations, and to help identify locations where people may come into contact with chemicals;
- source-characterization data used to evaluate releases that are continual or have the potential to result in further contamination;
- environmental-setting data used to evaluate the fate, transport, and persistence of the contaminants. This may include chemical transformation information, such as degradation or attenuation rates.
- fate and transport model inputs (e.g., particle size distributions, organic carbon content, flow rates for streams, etc.) used to evaluate the extent to which a contaminant is transported and where it will be deposited, and
- data representing background concentrations of chemicals (present due to naturally-occurring or anthropogenic sources) for various media used to identify COPC concentrations that are related to site activities.

While these types of data will be used in the risk assessment, it is also likely that other members of the project team will use them for different purposes, such as site characterization.

5.6.3 Geographical Information Systems/Surveys/Base Maps

Geographical Information Systems (GIS) are important tools for performing risk assessments. This is especially the case for complex sites where there are large quantities of data. At many complex sites, it

is difficult to understand the spatial and chemical variability of COPCs and associated risks without GIS to help visualize the data. The following information will likely be needed for risk assessment purposes for complex sites where GIS is employed:

- spatial delineation of former land use activities, especially for land that was used for activities that resulted in potential contamination;
- spatial delineation of current land use activities;
- accurate sample location coordinates;
- spatial delineation of planned future land use activities (this is especially important for land that is going to be subdivided or used for different purposes); and
- the location of other geographic features (e.g., creeks, lakes, etc.).

These data should be maintained as part of the project data management system and typically are widely used by the project team to perform a variety of tasks such as calculating volume estimates, analyzing the analytical data for spatial trends, and communicating risks to others. The Naval Installation Restoration Information Solution (NIRIS) can be used to manage, view, map and access Navy and Marine Corps Environmental Restoration (ER) Program information. NIRIS is hosted centrally on the Naval Facilities Engineering Command (NAVFAC) portal at https://portal.navfac.navy.mil/pls/portal/url/page/niris. Instructions for accessing and using NIRIS are available from the NIRIS Workgroup.

5.6.4 Physical Parameter Data

In addition to analytical data, there is other site information that may also be obtained to better characterize potential exposure pathways. In some cases, plausible exposure pathways can be eliminated from further consideration if site-specific information is available that demonstrates that it is very unlikely that exposure will ever occur. For example, it is important to understand groundwater parameters such as turbidity and salinity. If groundwater at a site is brackish or if there are high amounts of suspended solids then it is unlikely that it will be used as a primary drinking water source. Depending on the site, there may be other physical parameters that should be measured for the purposes of the risk assessment.

5.6.5 Fate and Transport Model Parameter Needs

Fate and transport models are used to predict how chemicals will move in the environment (e.g., how chemicals in soil migrate to groundwater). Fate and transport models are often used in HHRAs to predict the concentration of chemicals in different media. Site-specific information is collected in order to increase the site-specificity of fate and transport models. Examples of site-specific information that may be useful for risk assessment purposes are presented in Table 5.1.

Table 5.1 – Examples of Modeling Data Needs (USEPA, 1989)

Type of Modeling	Modeling Parameters
Source Characteristics	Geometry, physical/chemical conditions, emission rate, emission strength, geography.
Soil	Particle size, dry weight, pH, redox potential, mineral class, organic carbon and clay content, soil porosity.
Groundwater	Head measurements, hydraulic conductivity (pump and slug test results), saturated thickness of aquifer, hydraulic gradient, pH, redox potential, soil-water partitioning, turbidity, salinity.
Air	Prevailing wind direction, wind speeds, stability class, topography, depth of waste, contaminant concentration in soil and soil gas, fraction organic content of soils, site content of soils, percent vegetation, bulk density of soil, soil porosity.

Table 5.1 – Examples of Modeling Data Needs (USEPA, 1989)

Type of Modeling	Modeling Parameters
Surface water	Hardness, pH, redox potential, dissolved oxygen, salinity, temperature, conductivity, total suspended solids, flow rates and depths for rivers/streams, estuary and embayment parameters such as tidal cycle, saltwater incursion extent, depth and area, lake parameters such as area, volume, depth, depth to thermocline.
Sediment	Particle size distribution, organic content, pH, benthic oxygen conditions, water content.
Biota	Dry weight, whole body, specific organ, and/or edible portion chemical concentrations, percent moisture, lipid content, size/age, life history stage.

Note: Many of the parameters may also be pertinent to other media.

Some of the information presented in Table 5.1 may be useful in the risk assessment process because it provides data to support the exposure scenarios developed for the risk assessment.

5.6.6 Background Sampling

A base- or site-specific background data set is often needed to distinguish site-related contamination from naturally-occurring or anthropogenic, background concentrations. This is particularly true for inorganics, but may also be significant for organics such as pesticides, polycyclic aromatic hydrocarbons (PAHs), and radionuclides. The size and quality of the site and background data sets greatly affect the ability to determine whether or not chemical concentrations reflect background conditions or are elevated above background conditions.

Background samples are typically collected from each medium of concern at or near the hazardous waste site in areas not influenced by site contamination. Ideally, background samples would be collected from areas that could not have received contamination from the site, and that have the same basic characteristics as the media of concern at the site (USEPA, 1989).

Screening out chemicals based on site-specific background or reference-area concentrations is an important step in the identification of COPCs. The purpose of background screening is to focus the risk assessment on COPCs that are related to site activities and to eliminate COPCs that are present at background or reference-area concentrations. Background is defined in the Navy Guidance as "either naturally occurring (nonanthropogenic) or anthropogenic (ambient), which are unrelated to Navy activities or operations" (USNAVY, 2004). Medium-specific approaches for determining background concentrations in soil, sediment, and groundwater are contained in the *NAVFAC Guidance for Environmental Background Analysis* documents (NAVFAC, 2002, 2003, 2004).

The importance of background to site-specific, remedial decisions and the sophistication and limitations of the statistical tests that will be used to compare site and background concentrations should be considered during the planning/scoping stages of a project. Consequently, "up-front" planning to collect a representative data set is often necessary and may require the technical assistance of a statistician, geologist, and a risk assessment specialist.

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U.S. Navy Human Health Risk Assessment Guidance

Chapter 6 – Data Quality Objectives for Risk Assessment

Table of Contents

List of Tables

List of Figures

ACRONYMS AND ABBREVIATIONS

COPC	Chemical of Potential Concern
CSM	Conceptual Site Model
DQO	Data Quality Objective
GC/MS	Gas Chromatography/Mass Spectroscopy
HHRA	Human Health Risk Assessment
RBSC	Risk-Based Screening Concentration
RPM	Remedial Project Manager
RSL	Regional Screening Level
TAL	Target Analyte List
TCL	Target Compound List
USEPA	United States Environmental Protection Agency

6.0 Introduction

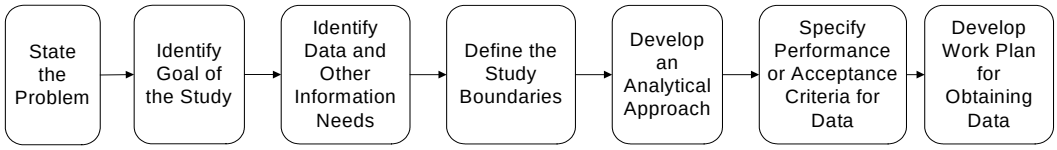
This chapter presents the approach for using Data Quality Objectives (DQOs) as strategic planning tools that can be used to ensure that the type, amount, and quality of the data collected is appropriate to meet project goals. This issue is particularly important since the analytical data collected during environmental investigations typically serve numerous purposes (e.g., site characterization, risk assessment, design of remedial alternatives, etc.). Figure 6.1 presents an overview of the United States Environmental Protection Agency's (USEPA's) DQO process.

Important benefits of the DQO process are that it provides investigators with a reliable approach for clarifying how decisions about a site will be supported by environmental data and that it establishes site-specific performance criteria for these decisions. In general, the DQO process also:

- increases efficiency by generating the appropriate type (i.e., using appropriate data collection and analysis methods) and appropriate amount of data necessary to answer site-specific, study questions;
- addresses the right questions early in the investigation by obtaining better knowledge of the chemicals involved;
- improves the application and interpretation of sampling designs by using statistical and scientific principles for optimization;
- helps investigators conserve resources by determining which data collection and analysis methods are most appropriate for the data quality needs of the study; and
- provides investigators with cutoff criteria – a way for the planning team to determine when enough data of sufficient quality have been collected to make site decisions with the desired level of confidence (USEPA, 2000).

The following sections describe the purpose of DQOs and how DQOs are considered as part of sampling methods, sample analysis issues, risk-based detection limits, data validation procedures, and data management.

Figure 6.1 – Overview of the Data Quality Objectives Process



6.1 Purpose

DQOs are qualitative and quantitative statements established prior to data collection, which specify the quality and quantity of the data required to support decisions during remedial response activities. The DQOs for a particular site vary according to the end use of the data (USEPA, 1989). While DQOs should be identified for every project, the need for formal DQO planning sessions varies based on project needs and project complexity. In some cases the project goals and data needs are so clear (or so prescriptive) that the DQOs are easily established by the Remedial Project Manager (RPM) alone, and the documentation for the DQO process fits on a single sheet of paper. In other cases, the DQO process may require a considerable investment of time and resources, as well as input from technical experts (e.g., risk assessors, geologists, engineers, chemists, etc.).

USEPA Guidance defines the DQO process as a seven-step iterative planning approach for environmental data-collection activities. It provides a systematic approach for defining the criteria that a data-collection design should satisfy, including when, where, and how to collect samples or measurements; determination of tolerable decision error rates; and the number of samples or measurements that should be collected (USEPA, 2000 & USEPA, 2006).

Table 6.1 – USEPA DQO Process, Steps and Activities

Step	Activities
1. State the Problem	Identify and involve the project manager/decision makers and the project personnel. Identify the project schedule, resources, milestones, and requirements.
2. Identify the Goal(s) of the Study	Describe the study goals and objectives.
3. Identify Data and Other Information Needs	Identify the information needed to meet the study goal(s).
4. Define the Study Boundaries	Identify any constraints to data collection.
5. Develop an Analytical Approach	Determine the quality of the data needed and the procedures necessary to attain it.
6. Specify Performance or Acceptance Criteria	Specify acceptable limits on decision errors.
7. Develop a Work Plan for Obtaining Data	Determine the quality and quantity of data needed. Describe how, when, and where the data will be collected and analyzed.

The outputs of the DQO process are qualitative and quantitative statements that are developed in the first six steps of the DQO process. DQOs define the purpose of the data-collection effort, clarify what the data should represent to satisfy this purpose, and specify the performance requirements for the quality of information to be obtained from the data. These outputs are then used in the seventh and final step of the DQO process to develop a data-collection design, typically presented in a work plan that meets all performance criteria and other design requirements and constraints. The DQO process is iterative and is allowed to terminate when the DQO outputs are acceptable to the RPM with respect to potential decision error rates and expenditure of resources. Numerous USEPA DQO procedural and guidance documents can be found at http://www.epa.gov/quality/qa_docs.html#5360-1.

Note: The data generated during site investigations serve as the foundation for all of the decisions that are made concerning the site. Data management though, is often an overlooked or de-emphasized aspect of environmental investigations. It is important to have a data management plan that results in a logical and systematic approach for electronic data collection. The data management plan should take into account what information the end users need, how the users will retrieve the information, and how to ensure and to document the accuracy of the data management system. The data management plan should encompass the activities from sample collection through data validation and use of the data by risk assessors and others. Involving a data manager early in the process will ensure that electronic data of known quality are readily available, which will reduce the level of effort for the rest of the project team.

6.2 Sampling

6.2.1 Sampling DQOs

In general, there is a limited budget and different objectives being pursued by the project team, regulators, and other stakeholders. These differences typically result in negotiations that shape the resulting sampling plans. Consequently, it is important to include regulators and stakeholders in the sampling design process. The following considerations should be taken into account when developing DQOs for sampling plans:

- objectives of the study;

- cost-effectiveness of alternative sampling designs;
- patterns of environmental contamination and variability; and
- practical considerations – such as convenience, site accessibility and availability, security of sampling equipment, and political considerations (Gilbert, 1997).

While it is important to carefully consider all four criteria when developing sampling plans for sites, risk assessors are primarily focused on patterns of environmental contamination and variability.

The primary DQO for environmental sampling, from a risk assessment point of view, is to determine exposure point concentrations for chemicals of potential concern (COPC) that are representative of conditions that people encounter. Usually site sampling plans focus on primary and secondary source areas, modes of contaminant transport, and potential human exposure points as identified in the conceptual site model (CSM). In other cases, sites are subdivided first based on exposure scenarios (e.g., industrial area vs. open space), and then data are gathered or grouped together accordingly.

6.2.2 SAMPLING METHODOLOGIES

There are a number of different ways to collect samples at sites – including the purposeful, systematic, and random sampling methodologies that are summarized below:

- **Purposeful** sampling involves using knowledge about a site (e.g., historical information, contamination information, or disposal practices) to select sample locations. Purposeful sampling might be performed in an area where the maximum impacts at a site might be expected (e.g., immediately adjacent to a spill area) to provide initial information on the nature and extent of contamination;
- **Systematic** sampling consists of collecting samples at locations and times according to spatial or temporal patterns. The most common systematic sampling approach is to overlay a grid on an area and then collect a sample at each grid node; and
- **Random** sampling involves collecting samples from locations at a site in a manner such that each location has an equal probability of being sampled (Gilbert, 1997).

In some cases these approaches may be combined. For example, a systematic grid might be developed and then samples could be randomly collected within each grid cell. Specific sampling considerations may be required for characterizing certain exposure pathways. One example is the evaluation of the vapor intrusion pathway, for which specific sampling guidance has been written (see the *Tri-Services Handbook for the Assessment of the Vapor Intrusion Pathway* (USAF et al., 2008).

6.2.3 DISCRETE VS. COMPOSITE SAMPLES

A discrete sample, or grab sample, is a single sample obtained from a single location and time. A composite sample represents the mixing of two or more discrete samples. Multi-incremental sampling is a specific type of compositing strategy that involves the mixing of numerous discrete samples from a single decision unit. Composite samples may introduce sampling errors through inadequate mixing, and provide less information about the nature and extent of contamination than discrete samples. If extreme values are a concern, compositing may result in diluting the higher samples (e.g., combining one high sample with four low samples) and masking the presence of a hot spot. The degree that samples are diluted depends on how many discrete samples are included in the composite sample and how the sub-sampling locations were selected.

In general, discrete samples are preferable because they provide more information about the nature (including variability) and extent of contamination. Discrete sampling data can also be statistically evaluated in order to estimate an average concentration.

From a risk assessment perspective, composite sample results may be useful because, in general, people are exposed to the average concentration in an area. For example, it might make sense to take a composite sample in a relatively small exposure area (e.g., an individual residence) in order to ensure that the average exposure point concentration is less than the site-specific project goals. Compositing samples is most useful in situations where sampling or analytical costs are high, (e.g., when dioxins are involved).

6.3 Sample Analysis

6.3.1 Selection of Target Analytes

An important DQO at every site is to determine which chemicals are likely to be present in the media of concern. Historical information (e.g., previous sampling results, chemical processes, disposal practices) should be used to focus the analytical program on chemicals that are known, or suspected to be present at the site. This means that not every sample should be analyzed for the full Target Compound List (TCL) and Target Analyte List (TAL). In fact, chemicals should be eliminated from consideration if there are compelling data – such as the case when chemicals have not been detected during multiple rounds of sampling. The USEPA recommends to, in general, "eliminate those chemicals that have not been detected in any samples of a particular medium" (USEPA, 1989). This principle should be applied when possible.

Reducing the number of chemicals being analyzed can have a positive impact on the budget, because potentially costly analytical methods can be eliminated from the sampling and analysis plan. This may also allow for more sampling focused on the COPCs that are likely to be responsible for the majority of the risk.

Note: It is important that the rationale for excluding chemicals from consideration is well documented, because COPC identification is a key step in the risk assessment process and will likely be scrutinized by regulators and stakeholders.

There are some types of data that are potentially unsuitable for a quantitative risk assessment, examples of which are presented in Table 6.2. These types of data though, may be very useful for site characterization and field-screening purposes.

Table 6.2 – Examples of the Types of Data Potentially Unsuitable for a Quantitative Human Health Risk Assessment (HHRA)

Analytical Instrument or Method	Purpose of Analysis	Analytical Result
HNu Organic Vapor Detector	Health and Safety, Field Screen	Total organic vapor
Organic Vapor Analyzer	Health and Safety, Field Screen	Total organic vapor
Combustible Gas Indicator	Health and Safety	Combustible vapors, oxygen-deficient atmosphere
Field Gas Chromatography[(a)]	Field Screen/Analytical Method	Specific volatile and semi-volatile organic chemicals

[(a)] Depending on the detector used, this instrument can be sufficiently sensitive to yield adequate data for use in a quantitative risk assessment; however, a confirming analysis by gas chromatography/mass spectroscopy (GC/MS) should be performed on a subset of the samples in a laboratory prior to use.

6.3.2 Detection Limits

Typically, one step in the risk assessment process is to compare chemical concentrations in environmental media to default risk-based regional screening levels (RSLs), other site-specific risk-based

screening concentrations (RBSCs), standards, or other criteria. Consequently, analytical methods should be selected so that the detection limits are less than the concentration of interest. For example, in the absence of appropriate analytical methods, non-detected data may exceed the RSLs, and a chemical would be considered a COPC even though the chemical may not be present. This is especially the case for highly toxic chemicals, such as dioxins. Risk assessors should provide risk-based detection limits to the RPM during the DQO planning process in order to ensure that the appropriate analytical methods are selected.

Note: Only analytical labs and analytical methods approved by the Navy can be used as a source of primary data, as specified in Chapter 8.1.2.4 of the Navy Environmental Restoration Program Manual (USNAVY, 2006).

6.4 Data Validation

Data validation is an important step in the data evaluation process and helps to determine whether or not the analytical DQOs have been achieved. Data validation is the process of evaluating field and laboratory data quality for precision, accuracy, representativeness, completeness, and comparability as well as overall data usability. The data validation process provides quality assurance information that is used in the data analysis steps of the risk assessment. Specifically, data validation ensures that chemicals are properly identified and quantified, and determines the overall usability of the data relative to the project objectives. Data validation consists of the following steps:

- assigning qualifiers to individual data values based on whether or not the chemical in question is detected, and the associated degree of variability, with consideration given to the level of deviation from performance standards;
- assessing the relevancy of certain performance criteria used to make decisions on the observed data, given information obtained during the course of the project; and
- determining whether or not the data can proceed to Data Quality Assessment (and the evaluation of whether or not DQOs were satisfied) (USEPA, 2002).

The data validation level of effort depends on the complexity of the site and the overall project needs. In general, some percentage of the data (e.g., 5-10%) should undergo data validation (or some form of review) in order to ensure that the laboratory is correctly identifying, quantifying, and qualifying the analytical results. In special circumstances (e.g., instances where there are legal concerns), it may be necessary to validate a higher percentage of the data.

Note: State and USEPA Regional Guidance should be consulted to identify if any specific data validation requirements should be utilized to evaluate analytical data.

6.5 References

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U.S. Navy Human Health Risk Assessment Guidance

Chapter 7 – Tier IA and Tier IB Risk-Based Screening

Table of Contents

List of Tables

List of Figures

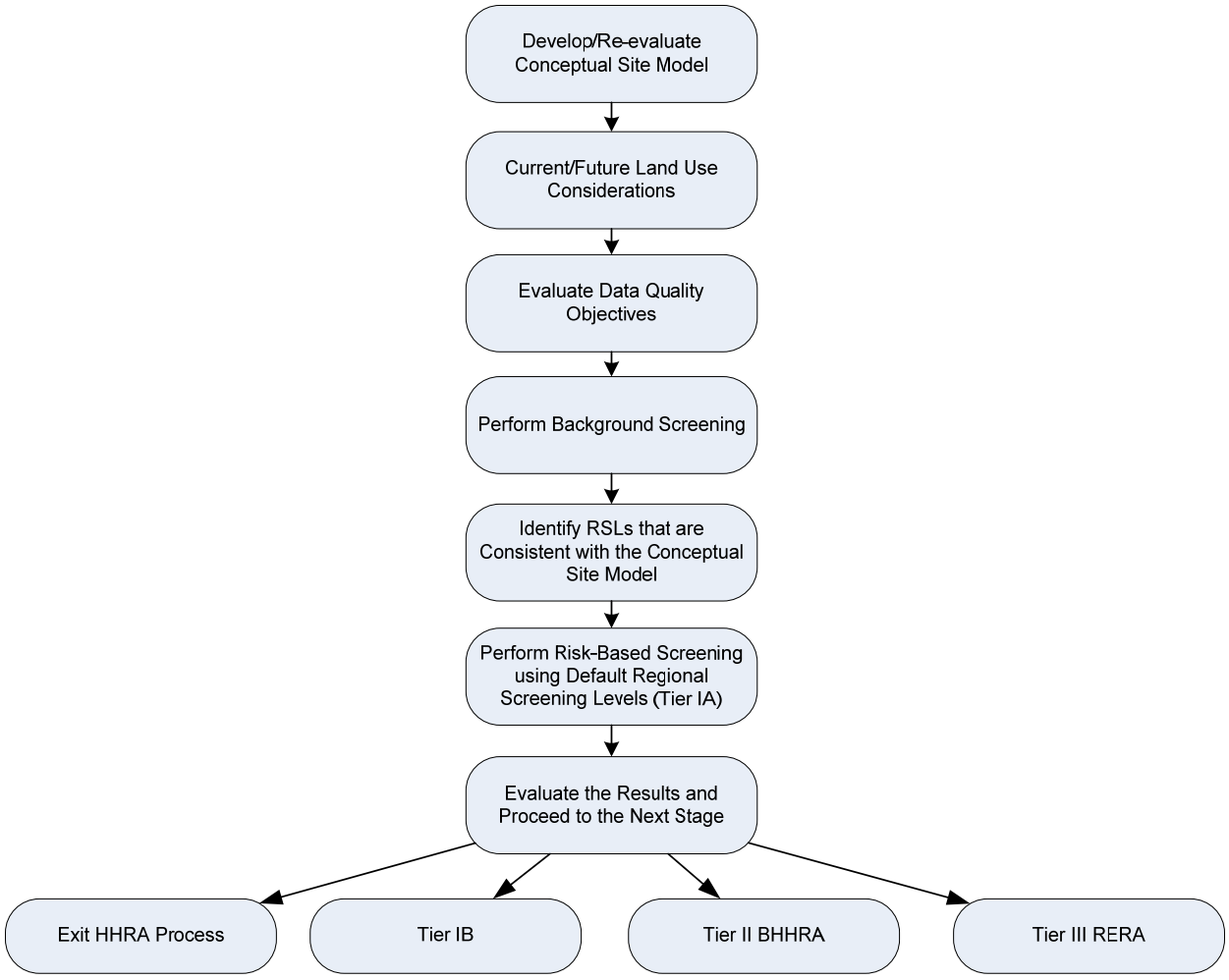
ACRONYMS AND ABBREVIATIONS

BHHRA	Baseline Human Health Risk Assessment
CNO	Chief of Naval Operations
COPC	Chemical of Potential Concern
CR	Cancer Risk
CSF	Cancer Slope Factor
CSM	Conceptual Site Model
DQO	Data Quality Objective
EC	Engineering Control
EPC	Exposure Point Concentration
HHRA	Human Health Risk Assessment
HI	Hazard Index
IC	Institutional Control
IEUBK	Integrated Exposure Uptake Biokinetic
LUC	Land Use Control
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
µg/dL	Micrograms per Deciliter
mg/kg	Milligrams per Kilogram
NFA	No Further Action
NOAEL	No Observed Adverse Effect Level
ORNL	Oak Ridge National Laboratory
RBSC	Risk-Based Screening Concentration
RfD	Reference Dose
ROD	Record of Decision
RPM	Remedial Project Manager
RSL	Regional Screening Level
SSL	Soil Screening Level
TRW	Technical Review Workgroup
UCL	Upper Confidence Limit
USEPA	United States Environmental Protection Agency

7.0 Introduction

This chapter details the process for risk-based screening. Risk-based screening compares site chemical concentrations to conservative risk-based regional screening levels (RSLs) or site-specific risk-based screening concentrations (RBSCs) in order to determine if the site may exit the human health risk assessment (HHRA) process. Figure 7.1 presents an overview of the risk-based screening process. The following sections present the purpose, objectives, methodology, and key assumptions that should be considered when performing risk-based screening.

Figure 7.1 – Overview of the Risk-Based Screening Process



7.1 Purpose and Objectives

The purpose of risk-based screening is to cost-effectively determine, early in the process, whether or not a site poses acceptable risks using conservative default exposure assumptions. Risk-based screening is an efficient way to evaluate sites for several reasons.

- Risk-based screening is a standard part of the risk assessment process. The United States Environmental Protection Agency (USEPA) has increasingly emphasized this approach, because it saves time and money while protecting human health: "Human health risk assessment includes effort-intensive steps which require many detailed calculations by experts. A few chemicals and a few routes of exposure dominate most baseline risk assessments. Effort expended on minor contaminants and exposure routes, i.e., those which do not influence overall risk, is essentially wasted. This guidance is intended to identify and focus on dominant contaminants of concern and exposure routes at the earliest feasible point in the baseline risk assessment. Use of these methods will decrease effort and time spent assessing risk, without loss of protectiveness" (USEPA, 1993). In addition, the outcomes of risk-based screening are consistent with what would occur if a complete HHRA was performed (USEPA, 1993).

- The process is relatively quick and easy to perform.

- Regulatory agencies recognize the utility of risk-based screening and accept decisions that are made based on the results.

Risk-based screening is a useful step in the site evaluation process because a site will either be eliminated from further consideration, or a subset of chemicals at the site will be identified as being of concern and will become the focus of subsequent site investigation and evaluation.

7.2 Tier IA and IB Exit Criteria

7.2.1 Exit Criteria

Exit criteria are used to evaluate the risk-based screening results to determine if a site can exit the HHRA process. Exit criteria are quantitative expressions of acceptable risks that may be used in conjunction with institutional controls (ICs) and land use to determine if a site can exit the HHRA process or if it warrants further evaluation. The three ways to exit the HHRA process from the risk-based screening step are as follows.

1.) **Incomplete Exposure Pathways** – If chemicals present on site are not accessible to humans (e.g., non-volatile chemicals under a building foundation, no human populations present, etc.) then there is no possibility for human exposure, no risk, and the site may exit the HHRA process.

2.) **Background** – If there are no chemical concentrations present on site that are greater than background concentrations then the site may exit the HHRA process. *Note: This applies to all chemicals that are present in background samples. If a chemical was not detected in background samples, then it should not be screened out and should be evaluated further, using risk-based approaches*.

3.) **Risk-Based Screening** – If there are no chemicals present on site that are greater than default risk-based RSLs in Tier IA or site-specific RBSCs in Tier IB then the site may exit the HHRA process. *Note: This comparison should also include chemicals detected at concentrations that are not representative of background concentrations. Essential nutrients (i.e., calcium,*

magnesium, potassium, and sodium) should be eliminated from consideration in the risk assessment because they are not associated with toxicity in humans under normal circumstances. Also, chemicals that are detected infrequently and at low concentrations (e.g., less than five percent frequency of detection and at concentrations slightly above the detection limit) should be eliminated from further consideration in the risk assessment process (USEPA, 1989). In addition, if analysis has determined that a chemical is present in a form that is not bioavailable, the chemical may be eliminated from further consideration. See the Framework for Metals Risk Assessment (USEPA, 2007) for guidance on evaluating the potential bioavailability of chemicals.

Note: If an "Interim Removal Action" is performed (i.e., if all, or some, of the contamination is removed) then the site should be re-evaluated using the exit criteria identified above to determine whether or not it may exit the HHRA process.

After completing Tier IA, a site will either go to Tier IB, Tier II, Tier III, or exit the HHRA process (i.e., no further action will be taken or a proposed plan with ICs will be implemented). Sites that are evaluated in Tier IB will either go to Tier II, Tier III, or exit the HHRA process. Figure 7.2 presents exit criteria for risk-based screening in the context of the overall site remediation process. Regardless of the initial exit criteria that are selected, it is important for Remedial Project Managers (RPMs) to continually re-evaluate the site throughout the process with regard to the exit criteria to determine if it may exit the HHRA process.

Note: If a site exits the HHRA process, Maximum Contaminant Levels [MCLs] or non-zero Maximum Contaminant Level Goals [MCLGs] and ecological risks should still be considered. In addition, the exit criteria presented in this section should not be viewed as discrete values. RPMs should evaluate each site on a case-by-case basis to determine if the risks are considered acceptable or unacceptable (USEPA, 1991a). In some situations, risks that are acceptable at one site may not be considered acceptable at another site. This may be due to a variety of site-specific factors, such as the uncertainty associated with characterizing exposure or the uncertainties associated with the toxicity values for chemicals responsible for the majority of the risk.

7.2.2 Basis For Exit Criteria

Exit criteria are developed based on regulatory benchmarks and cancer and noncancer health risks. They may also take into account land use or ICs. The regulatory benchmarks and land use are discussed below. For more information on cancer and noncancer risks see Chapter 8 – Tier II Baseline Human Health Risk Assessment.

Regulatory Benchmarks

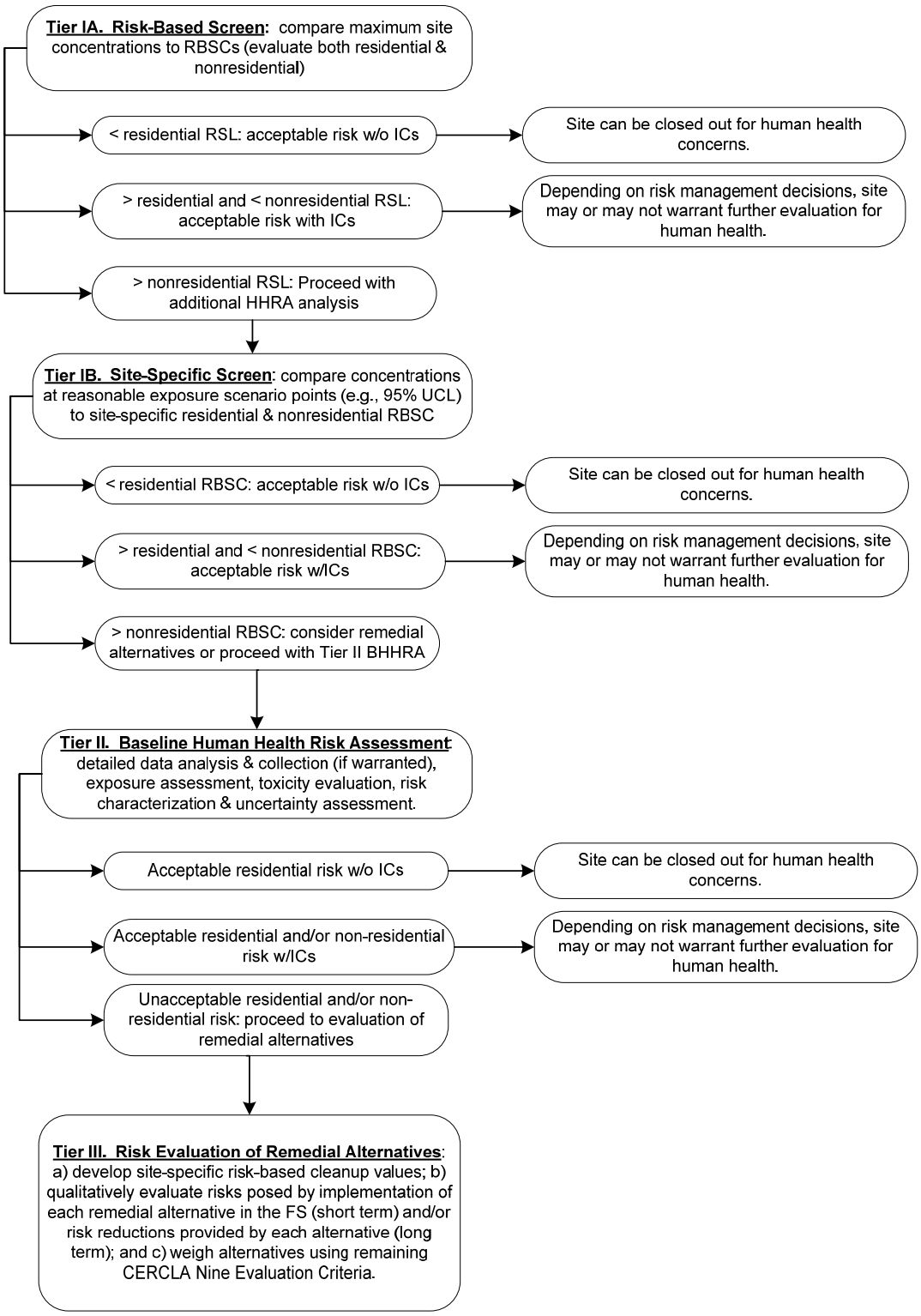
RSLs and RBSCs are calculated based on default exposure scenarios and assumptions using a carcinogenic risk goal of one chance in one million (1×10^{-6}) and noncarcinogenic hazard quotient of 1 (USEPA, 1991a; ORNL, 2008). In other words, RSLs and RBSCs are set at concentrations that are below levels of regulatory concern. In instances where there are both cancer- and noncancer-based effects, the lower of the two values (usually the cancer-based value) is selected as the RSL or RBSC for the chemical.

Note: Some states and USEPA regions use different target risk goals depending on the type of evaluation being performed and the number of chemicals being evaluated. For example, USEPA Region III recommends that a target risk goal of 1/10th of the RSL be used when screening chemical concentrations versus noncancer RSLs (USEPA, 2008). Therefore, it is important to check state and USEPA regional guidance, if available, to determine the target risk goals that should be used in risk-based screening.

Impact of Land Use Controls and Institutional Controls on Exit Criteria

In some cases, the Tier IA or IB screening evaluation results depend on land use controls (LUCs), such as ICs or future land use decisions. It is important to understand the benefits of LUCs, as well as the restrictions that accompany them. Implementing LUCs for a site can be beneficial because they allow the risk assessment to reflect actual future land use, which can lower the cost of the remediation if a land use other than residential is specified. This is due to the fact that exit criteria for land uses other than residential (e.g., industrial) are typically less stringent. Although LUCs may present a viable option as part of a remedy, it is important to consider the long-term, life-cycle, costs of LUCs (e.g., long-term monitoring). The implementation of LUCs is a risk-management decision and long-term costs of LUCs should be weighed against the additional costs of cleanup to unrestricted use. Additional information about monitoring and enforcing LUCs is available from the Department of the Navy (USNAVY, 2003).

Figure 7.2 – Navy Tiered CERCLA HHRA Process



7.3 Tier IA and Tier IB Risk-Based Screening

Risk-based screening compares site chemical concentrations to risk-based concentrations (i.e., either RSLs or RBSCs). RSLs and RBSCs are concentrations of chemicals in soil, air, and water that are considered protective of human health. They are determined by performing a reverse risk assessment: standard risk assessment equations are rearranged to solve for media concentrations rather than risk. For Tier IA RSLs are used, which incorporate default residential and industrial exposure scenarios combined with USEPA toxicity values and target risk goals (e.g., a cancer risk of 1×10^{-6} and a hazard quotient of 1) to determine acceptable concentrations of chemicals in each medium. The Oak Ridge National Laboratory (ORNL), working under contract with the USEPA, has prepared default RSLs, which are available at http://epa-prgs.ornl.gov/chemicals/.

For Tier IB RBSCs are used, which incorporate site-specific exposure scenarios combined with USEPA toxicity values and target risk goals to determine acceptable concentrations of chemicals in each medium.

The Tier I Risk-Based Screening process consists of the following steps:

1.) develop a conceptual site model (CSM);

2.) evaluate data quality objectives (DQOs);

3.) compare site concentrations to background and eliminate chemicals that are not elevated above background;

4.) identify RSLs or RBSCs appropriate for Tier IA or Tier IB;

5.) identify appropriate Tier IA or Tier IB site chemical concentrations for each medium;

6.) perform risk-based screening by comparing chemical concentrations to RSLs or RBSCs for each medium; and

7.) evaluate the results of the screening using the exit criteria to determine if the site can exit the cleanup process or if it warrants further study.

Each of these topics is discussed in detail in the following sections.

7.3.1 Develop the Conceptual Site Model

A key step in the risk-based screening process is the development of a CSM that identifies the likely contaminant source areas, exposure pathways, and potential receptors. The exposed populations and exposure pathways identified in the CSM can then be compared to the assumptions (e.g., exposed population) used to calculate the RSLs. If there are significant complete exposure pathways that are not included in the RSLs, then it may be necessary to perform a Tier IB using RBSCs or a Tier II evaluation in order to evaluate the additional pathways. Also, it is important to evaluate each potential exposure pathway to determine if a complete exposure pathway exists. In some instances the exposure pathways may not be complete (e.g., ingestion of groundwater from a non-potable aquifer is not a complete exposure pathway) and should not be included in the CSM. Depending on the site conditions, it may also be appropriate to screen for indirect exposure pathways, such as screening soil for impacts to groundwater and screening soil and groundwater based on vapor intrusion.

Table 7.1 presents the exposure scenarios and exposure pathways that were used by the ORNL to develop RSLs. The current and future potentially-exposed populations primarily depend on land use. Therefore, it is important that the CSM take into account likely future land use. This topic is presented in the following section.

Table 7.1 – Exposure Scenarios Used to Develop Regional Screening Levels (ORNL, 2008)

Medium Exposure Route	Residential Land Use	Industrial Land Use[1]
Target Cancer Risk Level	1×10^{-6}	1×10^{-6}
Target Hazard Quotient	1	1
Groundwater		
Ingestion	X	
Inhalation of volatiles	X	
Soil		
Ingestion	X	X
Inhalation of particulates	X	X
Inhalation of volatiles	X	X
Exposure to groundwater contaminated by soil leachate	X	
Dermal absorption	X	X
Ambient Air		
Inhalation	X	X

Note:
[1]Industrial values in table assume outdoor exposure

The Importance of Land Use Considerations

Land use is a critical component of the risk assessment process because it dictates which exposure scenarios and receptors (e.g., residential, industrial, or other) are appropriate for use in the risk-based screening process. Land use concerns are addressed in both the risk assessment and the risk management efforts. Risk assessment addresses land use in terms of actual and assumed exposure scenarios, which determine exposed populations and affect exposure mechanisms, durations, and frequencies. The role of risk management in land use involves making decisions based on the use of the property, both current and plausible future use, and how any potential risk might be mitigated. Under these circumstances, land use information is shared between the risk assessment and risk management processes. In the event a site is proposed for use or re-use with restrictions, the issue of LUCs must be addressed.

Land Use Controls

The Chief of Naval Operations (CNO) issued interim final guidance on LUCs (USNAVY, 1999). LUCs are divided into two types: engineering controls (ECs) and ICs. ECs refer to engineered remedies that contain or reduce contamination and/or limit access to the contaminated property (including both land and water). ECs may include fences, signs, landfill caps, provision of potable water supplies, and guards (to prevent access). ICs are legal devices that ensure ECs are properly managed and ensure land use restrictions are enforced. ICs include easements, restrictive covenants, zoning, permits, and educational programs (informing those potentially exposed of the risk and appropriate actions to mitigate that risk).

Note that specific state and regional regulatory agencies may have established separate requirements for LUC implementation. Although LUCs may present a viable option as part of a remedy, it is important to consider the long-term, life-cycle, costs of LUCs (e.g., long-term monitoring). The long-term costs of LUCs should be weighed against the additional costs of cleanup to unrestricted use. Additional information about monitoring and enforcing LUCs is available from the Department of the Navy (USNAVY, 2003).

Determining Future Land Use

Land use assumptions for conducting HHRAs should be based on a factual understanding of site-specific conditions and reasonably anticipated use. The land use evaluated in the risk assessment should not be

based on a residential exposure scenario (i.e., the default worst-case) unless residential land use is plausible for the site. The USEPA has made the following recommendations in regard to land use considerations:

- future land use assumptions allow the baseline risk assessment and the feasibility study to focus on the development of practical and cost-effective remedial alternatives, leading to site activities that are consistent with the reasonably anticipated future land use;
- a range of land uses, and therefore exposure assumptions, may be considered, depending on the amount and certainty of information supporting a land use evaluation;
- discussions with local land-use planning authorities, appropriate officials, and the public, as appropriate, should be conducted as early as possible in the planning/scoping phase of the project; and
- sites that are located on federal facilities may have different land use considerations than those located on private property because the future land use assumptions (e.g., industrial, recreational, etc.) at sites that are undergoing base closure may be different than at sites where a federal agency will be maintaining control of the facility (USEPA, 1995).

Various sources of information, including activity master plans and local zoning plans, can be utilized in making educated decisions about potential land use for a given site. Land use assumptions should take into consideration the interests of all affected stakeholders, including the local residents and municipal government. Land use issues should be carefully documented and resolved by maintaining regular communication between the risk manager and the risk assessor.

7.3.2 Evaluate Data Quality Objectives

The analytical data for a site should be evaluated prior to risk-based screening to ensure that the site-specific DQOs have been achieved. DQOs ensure that the information needed to perform a credible risk-based screening evaluation is collected. The key DQOs for risk-based screening are as follows.

- **Data Quality** – The analytical data should be of suitable quality for HHRA purposes. That is, data should be collected in a manner that provides a basis for making remedial decisions at a site.
- **Site Characterization** – There should be enough samples to adequately characterize the site. In addition to sample density and sample coverage considerations, it is important that all media of concern are sampled at likely exposure points in order to provide a consistent basis for comparing site data and the RSLs or RBSCs.
- **Analytical Detection Limits** – It is important that the analytical methods selected for a site are sensitive enough to support the needs of the risk assessment (i.e., the detection limits for chemicals of potential concern (COPCs) should be less than their RSLs and RBSCs). The value of risk-based screening is diminished if the detection limits are greater than the RLs and RBSCs.

7.3.3 Background Screening

Purpose of Background Screening

On 30 January 2004 the CNO issued the Navy Policy on the Use of Background Chemical Levels (USNAVY, 2004). The purpose of this policy is to provide clarification of the Navy's policy on the consideration of background chemical levels in the list of COPCs in the Environmental Restoration Program. The Policy describes how to consider background chemical levels in the program by:

1.) identifying those chemicals that are in the environment due to releases from the site;

2.) eliminating from consideration in the risk assessment process both naturally occurring and anthropogenic chemicals that are present at levels below background;

3.) ensuring documentation and discussion of potential risk from chemicals that have been eliminated during the background evaluation process; and

4.) developing remediation action levels that are not below background.

Screening out chemicals based on site-specific background or reference-area concentrations is an important step in the identification of COPCs. The purpose of background screening is to focus the risk assessment on COPCs that are related to site activities and to eliminate chemicals that are present at background concentrations. Background is defined in the Navy Policy on the Use of Background Chemical Levels as either naturally occurring (non-anthropogenic) or anthropogenic (ambient), which are unrelated to Navy activities or operations (USNAVY, 2004). The purpose of a site risk assessment is to estimate the incremental risks associated with contamination present at the site due to Navy activities, not background contamination.

Determining Background Concentrations

Background concentrations of chemicals can be determined from existing site or base-wide information, published regional or national background concentrations, or by developing a sampling program to establish background concentrations. The following Navy guidance documents present approaches for identifying background concentrations of chemicals and determining whether or not site concentrations are significantly different.

- NAVFAC. 2002. Naval Facilities Engineering Command. NAVFAC Guidance for Environmental Background Analysis, Volume I: Soil. User's Guide UG-2049-ENV. April 2002. https://portal.navfac.navy.mil/portal/page/portal/navfac/navfac_ww_pp/navfac_nfesc_pp/environmental/erb/gpr/bg_soil_guide.pdf

- NAVFAC. 2003. Naval Facilities Engineering Command. NAVFAC Guidance for Environmental Background Analysis, Volume II: Sediment. User's Guide UG-2054-ENV. April 2003. https://portal.navfac.navy.mil/portal/page/portal/navfac/navfac_ww_pp/navfac_nfesc_pp/environmental/erb/gpr/ug-2054-sed-guide.pdf

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7.3.4 IDENTIFYING APPROPRIATE RISK-BASED SCREENING CONCENTRATIONS

Tier IA Regional Screening Levels

It is important to select the most appropriate default risk-based RSLs for use in evaluating sites based on probable future land use. For example, if the site is currently used for industrial purposes (and expected future use is industrial), or if master plans indicate that future land use at a site is industrial, then industrial RSLs should be selected for comparison to site concentrations. The ORNL, working under contract with the USEPA, has prepared default RSLs, which are available at http://epa-prgs.ornl.gov/chemicals/.

Note: Some states and USEPA regions use different target risk goals depending on the type of evaluation being performed and the number of chemicals being evaluated. For example, USEPA Region III recommends that a target risk goal of 1/10th of the RSL be used when screening chemical concentrations versus noncancer RSLs (USEPA 2008). Therefore, it is important to check state and USEPA regional guidance, if available, to determine the target risk goals that should be used in risk-based screening.

Tier IB Risk-Based Screening Concentrations

Tier IB RBSCs should be developed based on plausible site-specific exposure scenarios. Land use will determine the site-specific RBSC exposure scenarios, including what populations are being exposed and how often they are being exposed. In some cases, site-specific RBSCs may be calculated based on current land use involving very specific exposure scenarios such as property that is used for commercial purposes. In other cases site-specific RBSCs may be developed based on future land use considerations. Additionally site-specific or scenario-specific RBSCs may be developed for a certain geographical region (e.g., Alaska) where the activity patterns of the exposed population are likely to be significantly different from the generic default RBSC exposure scenarios. These examples highlight the importance of considering land use and developing realistic and defensible CSMs when calculating site-specific RBSCs. ORNL has also provided a spreadsheet that can be used to calculate site-specific RBSCs. This spreadsheet is available at http://epa-prgs.ornl.gov/cgi-bin/chemicals/csl_search.

Identifying Tier IA and Tier IB Risk-Based Screening Concentrations For Lead

The traditional risk assessment approach for evaluating effects from exposure to chemicals involves a comparison of chemical intakes to a reference dose (RfD) or a cancer slope factor (CSF). This approach is inappropriate for lead because a no observed adverse effect level (NOAEL) for lead has not been identified (i.e., there is no RfD for lead) by the USEPA. Similarly, the USEPA has not established a CSF for lead to evaluate carcinogenic risks. Blood-lead concentrations are accepted as the preferred measure of cumulative lead exposures. The Centers for Disease Control and Prevention has stated that children with blood-lead levels greater than 10 micrograms per deciliter (µg/dL) are a level of concern for adverse health impacts (CDC, 2005). The USEPA recommends that exposure to lead in soil should not result in a blood lead level greater than10 µg/dL for more than 5 percent of the population (USEPA, 1994; 1998). In other words, a typical child (or group of similarly exposed children) would have less than a five percent chance of exceeding the 10 µg/dl blood lead level of concern based on exposure to lead in soil.

Tier IA RSLs and Tier IB RBSCs for lead should be based on the latest information available from the USEPA's Technical Review Workgroup (TRW) for lead. For residential exposures to lead in soil, the USEPA recommends a screening level of 400 mg/kg (USEPA, 1998). For other exposure scenarios, site-specific RBSCs should be developed based on the Integrated Exposure Uptake Biokinetic (IEUBK) Model and the Adult Lead Model, as appropriate. See the Issue Paper *Final Standard Operating Procedures: Investigating and Managing Lead Risks at Navy Installations* (DeGrandchamp, 2005) for more information on evaluating lead exposures.

7.3.5 PERFORMING RISK-BASED SCREENING

Risk-Based Screening Process

Risk-based screening incorporates all of the information that is known about a site at an early juncture in the decision-making process. Default RSLs and site-specific RBSCs are identified based on information about current and future land use. Site chemical concentrations are then compared to RSLs or RBSCs to determine if the site warrants further evaluation. Figure 7.3 illustrates the risk-based screening process.

Note: Chemicals that are not detected in any samples, or are detected at a low frequency (e.g., less than five percent frequency of detection and at low concentrations) for a medium are typically eliminated from further consideration in the risk assessment process. Also, essential nutrients (i.e., calcium, magnesium, potassium, and sodium) should be eliminated from consideration in the risk assessment because they are not associated with toxicity in humans under normal circumstances (USEPA, 1991b).

Tier IA Screening Process

The maximum detected chemical concentration for each medium is compared to the appropriate residential or industrial default RSL.

Figure 7.3 – Example of Tier 1A Risk-Based Screening

Step 1 – Identify Default RSLs

Chemical	Example Industrial Soil RSL (Outdoor Worker) (mg/kg)
Inorganics	
Arsenic (inorganic)	1.6 (c)
Zinc and Compounds	31,000 (n)
Pesticides/PCBs	
Aroclor 1254	0.74 (c)
Endosulfan I	370 (n)
Semi-Volatile Organic Compounds	
Benzo(a)pyrene	0.21 (c)
Hexachlorobutadiene	22 (c)

c – Based on cancer endpoint and target cancer risk = 1×10^{-6}
n – Based on noncancer endpoint and target hazard index = 0.1

Step 2 – Determine Site Chemical Concentrations

Chemical	Number of Samples Analyzed	Frequency of Detection (%)	Maximum Detected Concentration (mg/kg)
Inorganics			
Arsenic (inorganic)	10	90%	72
Zinc and Compounds	5	100%	1470
Pesticides/PCBs			
Aroclor 1254	50	22%	145
Endosulfan I	50	50%	900
Semi-Volatile Organic Compounds			
Benzo(a)pyrene	11	64%	101
Hexachlorobutadiene	12	58%	5

Step 3 – Compare Site Chemical Concentrations to Default RSLs

Chemical	Maximum Detected Concentration (mg/kg)	Example Industrial Soil RSL (mg/kg)	Exceed RSL?
Inorganics			
Arsenic (inorganic)	72	1.6	Yes
Zinc and Compounds	1470	31,000	No
Pesticides/PCBs			
Aroclor 1254	145	0.74	Yes
Endosulfan I	900	370	Yes
Semi-Volatile Organic Compounds			
Benzo(a)pyrene	101	0.21	Yes
Hexachlorobutadiene	5	22	No

Note: The RSL shown is for outdoor workers.

Tier IB Screening Process

In contrast to Tier IA, the representative upper bound exposure point concentration (EPC) for each chemical is compared to the appropriate site-specific RBSC in Tier IB. See the Data Evaluation and Reduction Section in Chapter 8 – Tier II Baseline Human Health Risk Assessment for more information on calculating upper bound EPCs.

The following sources provide detailed information on developing RBSCs.

- ORNL (ORNL, 2008). Spreadsheet for calculation of site-specific screening concentrations. http://epa-prgs.ornl.gov/cgi-bin/chemicals/csl_search

- USEPA Risk Assessment Guidance for Superfund. Human Health Evaluation Manual, Part B: Development of Risk-Based Preliminary Remediation Goals (USEPA, 1991c). http://www.epa.gov/oswer/riskassessment/ragsb/index.htm

7.3.6 Evaluate the Results

The results of the risk-based screening process should be evaluated in the context of the exit criteria presented in section 7.2 – Tier IA and IB Exit Criteria, to determine if a site can exit the HHRA process or if it warrants further evaluation (e.g., Tier II). If the site chemical concentrations meet the exit criteria, then the site may exit the HHRA process as a no further action (NFA) site. Further evaluation may include additional sampling, consideration of background levels in the environment, reassessment of the assumptions contained in the RSL and RBSC estimates, and/or performance of a baseline risk assessment.

Note: It is important that RPMs critically evaluate factors such as the limitations of RSLs, RBSCs, DQOs, and potential ICs, to determine the appropriate next step for each site on a case-by-case basis.

Ecological Risks

The RSLs and RBSCs discussed in this chapter are protective of human health and do not take into account potential risks to ecological receptors. Ecological impacts should also be evaluated using the Navy Guidance for Conducting Ecological Risk Assessments (online at http://web.ead.anl.gov/ecorisk/).

Indirect Exposure Pathways

Depending on the site conditions, it may also be appropriate to screen for indirect exposure pathways, such as screening soil for impacts to groundwater and screening soil and groundwater based on vapor intrusion. If impacts to groundwater from soil are a concern, then RBSCs for soil may need to be adjusted by evaluating USEPA Soil Screening Levels (1996) in order to account for potential groundwater impacts. If vapor intrusion is a potential pathway of concern, the *Tri-Services Handbook for the Assessment of the Vapor Intrusion Pathway (*USAF et al., 2008) may be consulted.

7.4 Documentation

As with all risk assessment activities, it is important that the risk-based screening process is transparent and defensible. Transparency results when all of the data and assumptions that were utilized in the evaluation are well documented so that others can easily understand and review the process. However, the level of documentation will vary based on the regulatory framework and the results of the evaluation. At a minimum, the documentation for a risk-based screening evaluation should include:

- presentation and discussion of site characterization information;

- a CSM that documents the current and future land use and exposure scenarios;

- a table that summarizes site media concentrations that are compared to RSLs or RBSCs (e.g., frequency of detection, minimum detected concentration, detection limits, and the maximum detected concentration [Tier IA] or the representative upper bound concentration [Tier IB]);
- a table that presents the RSLs or RBSCs used in the evaluation. For Tier IB, the exposure assumptions used to calculate site-specific RBSCs should be identified and the sources and assumptions clearly documented;
- an appendix that presents all of the analytical data for the site; and
- an appendix that presents more detailed statistical summaries, (e.g., number of samples analyzed, number of detected results, range of nondetects, range of detects, 95% upper confidence limit [UCL], etc.)

Note: The Tier I evaluation may be presented as a stand-alone document or as part of a Tier II Baseline Human Health Risk Assessment (BHHRA). For example, if the results of the Tier IA risk-based screening indicate that a Tier II BHHRA is warranted, then the Tier IA RSL screening may be presented in the BHHRA.

7.5 References

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USEPA. 1991b. EPA Region X Supplemental Risk Assessment Guidance for Superfund. Seattle, WA.

USEPA. 1991c. Risk Assessment Guidance for Superfund: Volume 1 – Human Health Evaluation Manual (Part B, Development of Risk-Based Preliminary Remediation Goals). Interim. Office of Emergency Response, Washington, D.C. Publication 9285.7-01C. http://www.epa.gov/oswer/riskassessment/ragsb/index.htm.

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U.S. Navy Human Health Risk Assessment Guidance

Chapter 8 – Tier II Baseline Human Health Risk Assessment

Table of Contents

List of Tables

List of Figures

ACRONYMS AND ABBREVIATIONS

ADI	Average Daily Intake
AT	Averaging Time
ATSDR	Agency for Toxic Substances and Disease Registry
BHHRA	Baseline Human Health Risk Assessment
BW	Body Weight
CalEPA	California Environmental Protection Agency
CF	Conversion Factor
CNO	Chief of Naval Operations
COC	Chemical of Concern
COPC	Chemical of Potential Concern
CRAVE	Carcinogen Risk Assessment Verification Endeavor
CSM	Conceptual Site Model
CTE	Central Tendency Exposure
DI	Daily Intake
DQO	Data Quality Objective
EC	Engineering Control
ED	Exposure Duration
EF	Exposure Frequency
EPC	Exposure Point Concentration
GI	Gastrointestinal
HEAST	Health Effects Assessment Summary Tables
HHRA	Human Health Risk Assessment
HI	Hazard Index
HIF	Human Intake Factor
HQ	Hazard Quotient
IC	Institutional Control
IEUBK	Integrated Exposure Uptake Biokinetic
IRIS	Integrated Risk Information System
LADI	Lifetime Average Daily Intake
LOAEL	Lowest Observed Adverse Effect Level
LUC	Land Use Control
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MRL	Minimal Risk Level
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NOAEL	No Observed Adverse Effect Level
PAH	Polycyclic Aromatic Hydrocarbon
PPRTV	Provisional Peer Reviewed Toxicity Value
RBSC	Risk-Based Screening Concentration

RfC	Reference Concentration
RfD	Reference Dose
RME	Reasonable Maximum Exposure
RPM	Remedial Project Manager
RSL	Regional Screening Level
SF	Slope Factor
SQL	Sample Quantitation Limit
STSC	Superfund Health Risk Technical Support Center
TRW	Technical Review Workgroup
UCL	Upper Confidence Limit
USEPA	United States Environmental Protection Agency

8.0 Introduction

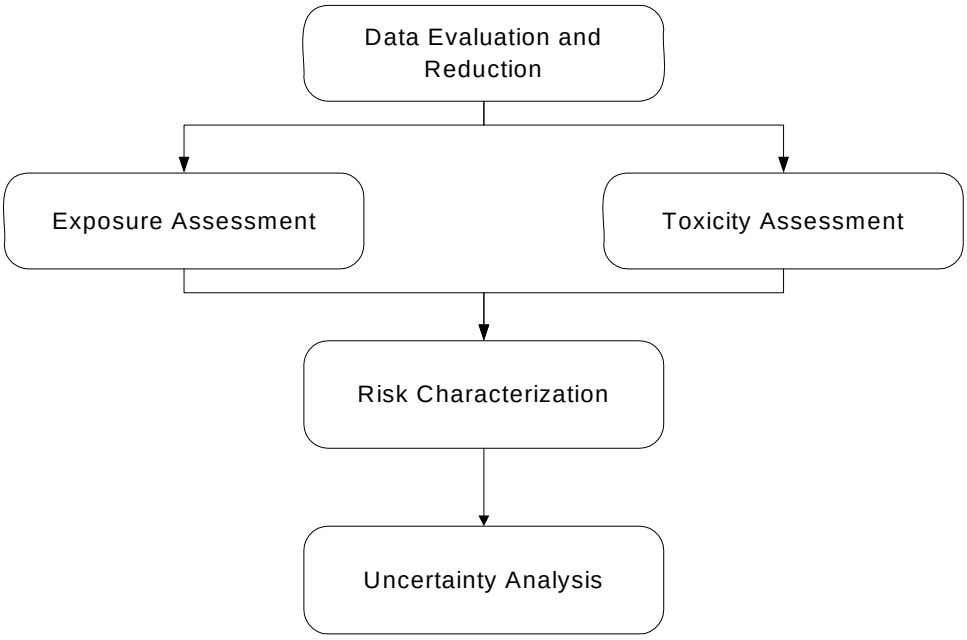
This chapter presents the steps that comprise a baseline human health risk assessment (BHHRA). The BHHRA is the second tier of the risk assessment evaluation process. BHHRAs are appropriate for sites that are too complex to be evaluated or eliminated from further consideration based on Tier I approaches. A Tier II BHHRA is performed when:

1.) site chemical concentrations are greater than Tier IA default risk-based regional screening levels (RSLs); and/or

2.) site chemical concentrations are greater than Tier IB site-specific risk-based screening concentration RSBCs (optional step).

BHHRAs are also appropriate for sites where the conceptual site model (CSM) is different from the CSM that serves as the basis for the standard RSLs. Figure 8.1 presents an overview of the BHHRA process. The following sections discuss the components of the BHHRA.

Figure 8.1 – Overview of the Baseline Human Health Risk Assessment Process



8.1 Purpose and Objectives

The purpose of a BHHRA is to determine if a site poses acceptable risk levels based on current or future land use and current (i.e., baseline) site conditions if no remediation or institutional controls (ICs) are applied at the site (United States Environmental Protection Agency [USEPA], 1989). BHHRAs also provide a basis for determining levels of chemicals that can remain on site and still be adequately protective of public health.

BHHRAs are site-specific and therefore, may vary both in detail and the extent to which qualitative and quantitative analyses are used, depending on the complexity and particular circumstances of the site (USEPA, 1989). The risk assessment report can range from a small chapter in the site characterization report, to a large, complex, independent document with many appendices (USEPA, 1989). The BHHRA is

a vital component of risk management as it can identify what sites or chemicals pose the greatest risk and therefore indicate where resources can be most effectively applied.

Note: As with all risk assessment activities, it is important that the BHHRA process is transparent and that the assumptions incorporated into the evaluation are appropriate to the site. Transparency results when all of the data and assumptions used in the evaluation are well documented so that others can easily understand and review the process.

8.2 Tier II Exit Criteria

8.2.1 Exit Criteria

Exit criteria are quantitative expressions of acceptable risks that may be used in conjunction with ICs and land use to determine if a site can exit the human health risk assessment (HHRA) process or if it warrants further evaluation. In general, if a BHHRA is performed it means that there are chemical concentrations present at a site that are greater than background concentrations and also greater than default RSLs (Tier IA) and/or site-specific RBSCs (Tier IB). The BHHRA provides risk estimates for different exposure scenarios and land uses. This information is used by Remedial Project Managers (RPMs) to make one of the following risk management decisions.

1.) **Exit the Human Health Risk Assessment Process** due to:

   a. **Incomplete Exposure Pathways** – The chemicals present on site are not currently accessible to humans or will not be accessible based on future land use (e.g., non-volatile chemicals under a building foundation, no human populations present, etc.), then there is no possibility for human exposure and, therefore, no risk.

   b. **Background** – There are no chemical concentrations present on the site that are greater than background concentrations. *Note: This applies to all chemicals that are present in background samples. If a chemical was not detected in background samples, then it should not be screened out and should be evaluated further using risk-based approaches.*

   c. **Risk-Based Screening** – There are no chemicals present at the site that are greater than RSLs or RBSCs. *Note: This comparison should also include chemicals detected at concentrations that are not representative of background concentrations. Essential nutrients (i.e., calcium, magnesium, potassium, and sodium) should be eliminated from consideration in the risk assessment because they are not associated with toxicity in humans under normal circumstances. Also, chemicals that are detected infrequently and at low concentrations (e.g., less than five percent frequency of detection and at concentrations slightly above the detection limit) may be eliminated from further consideration in the risk assessment process (USEPA, 1989). In addition, if analysis has determined that a chemical is present in a form that is not bioavailable, the chemical may be eliminated from further consideration. See the Framework for Metals Risk Assessment (USEPA, 2007a) for guidance on evaluating the potential bioavailability of chemicals.*

2.) **Determine that the Risks are Acceptable** (i.e., a hazard index [HI] less than 1 or a cancer risk less than $1x10^{-4}$). Risk managers may determine that risks are acceptable based on the BHHRA and decide that no further action is necessary. The site would then exit the risk assessment process, although Maximum Contaminant Levels (MCLs) or non-zero Maximum Contaminant Level Goals (MCLGs), which are used to evaluate drinking water and ecological risks should still be evaluated.

3.) **Determine that the Risks are Unacceptable** (i.e., an HI greater than 1 or a cancer risk greater than $1x10^{-4}$). Risk managers may determine that risks are unacceptable based on the BHHRA and decide that further action is necessary. The options available at that point include:

   a. **Modifying Future Land Use Assumptions** - Modify the BHHRA based on ICs that will result in a different land use (only with stakeholder input).

   b. **Gathering Additional Site-Specific Information** - The results of the BHHRA may, for example, suggest that a single pathway of exposure is determining the overall outcome of the risk assessment. An RPM could address the issue by collecting more site-specific exposure information, to reduce the uncertainty associated with evaluating this pathway in the BHHRA.

   c. **A Feasibility Study** - Evaluate different remedial alternatives to determine if there are feasible ways for minimizing the risk.

4.) **Perform an Interim Removal Action** - Remove some or all of the contamination and then re-evaluate the site using the exit criteria presented above.

Note: If a site exits the human health risk assessment process, MCLs or non-zero MCLGs and ecological risks should still be considered. In addition, the exit criteria and risks presented in this section should not be viewed as discrete values. RPMs should evaluate each site on a case-by-case basis to determine if the risks are considered acceptable or unacceptable (USEPA, 1991a). In some situations, risks that are acceptable at one site may not be considered acceptable at another site. This may be due to a variety of site-specific factors, such as the uncertainty associated with characterizing exposure or the uncertainties associated with the toxicity values of chemicals responsible for the majority of the risk.

After completing Tier II, a site will either go to Tier III or exit the HHRA process. Figure 8.2 presents exit criteria for the BHHRA in the context of the overall site remediation process. Regardless of the initial exit criteria that are pursued, it is important for RPMs to continually re-evaluate their sites throughout the process with regard to the exit criteria, to determine if they may exit the HHRA process. In addition, sites that exit the HHRA portion of the process are not necessarily no further action sites. For example, an industrial site that meets the exit criteria through the implementation of ICs would require a proposed plan, action Record of Decision (ROD), and five-year review.

8.2.2 Basis for Exit Criteria

Exit criteria are developed based on regulatory benchmarks and health risks (both cancer and noncancer). They may also take into account land use and/or institutional controls. The regulatory benchmarks and land use are discussed below. For more information on cancer and noncancer risks see sections 8.6 – Toxicity Assessment and 8.7 – Risk Characterization in this chapter.

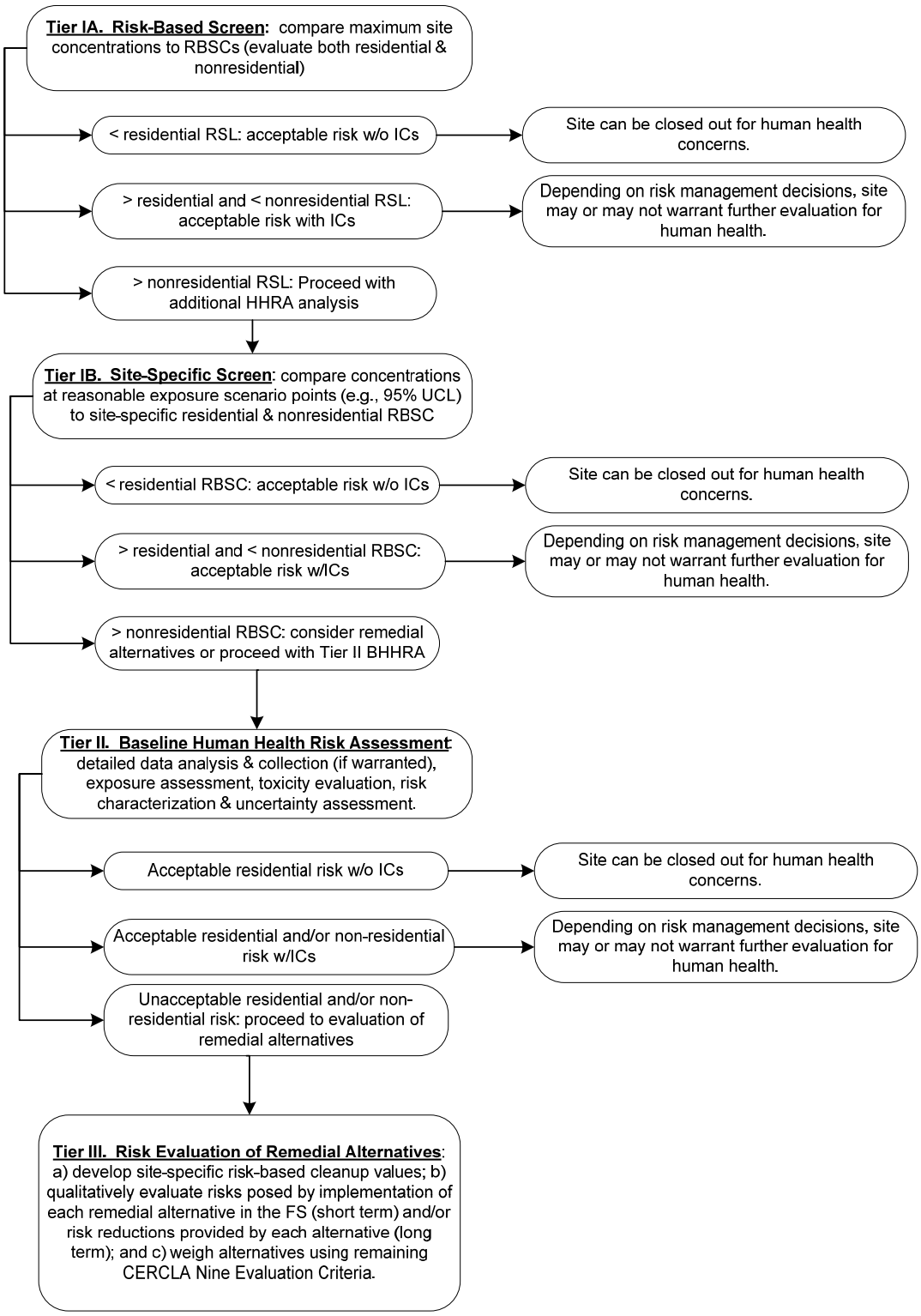
Regulatory Benchmarks

The USEPA has typically used an HI (i.e., the cumulative noncancer risks for all chemicals) of 1 or greater or an HI for a target organ/critical effect of 1 or greater as a benchmark for evaluating noncarcinogenic HIs. For carcinogenic risk, the USEPA's approach emphasizes the use of one chance in one million [i.e., $1x10^{-6}$] as the point of departure while allowing site or remedy-specific factors, including potential future uses, to enter into the evaluation of what is appropriate at a given site. As risks increase above one chance in one million, they become less desirable, and the risk to individuals generally should not exceed one in ten thousand (i.e., $1x10^{-4}$) (USEPA, 1991a). The USEPA recommends, "Where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than $1x10^{-4}$ and the non-carcinogenic hazard index is less than 1, action generally is not warranted unless there are adverse environmental impacts. However, if MCLs or non-zero MCLGs are exceeded, action generally is warranted." (USEPA, 1991a).

Impact of Land Use and Institutional Controls on Exit Criteria

In some cases the Tier II BHHRA results depend on land use controls (LUCs), such as ICs or future land use decisions. It is important to understand the benefits of LUCs, as well as the restrictions that accompany them. Implementing LUCs for a site can be beneficial because it allows the risk assessment to reflect actual future land use, which can lower the cost of the remediation if a land use other than residential is specified. This is due to the fact that exit criteria for land uses other than residential (e.g., industrial) are typically less stringent. Although LUCs may present a viable option as part of a remedy, it is important to consider the long-term, life-cycle, costs of LUCs (e.g., long-term monitoring). The implementation of LUCs is a risk management decision and the long-term costs of LUCs should be weighed against the additional costs of cleanup to unrestricted use.

Figure 8.2 – Navy Tiered CERCLA Process



8.3 Elements of Tier II

The BHHRA process is iterative because many of the steps depend on other steps which, in turn, depend on information that is generated as part of the site evaluation process. For example, when additional site sampling data are gathered, new chemicals are often added to the risk assessment, which will result in changes to the toxicity assessment. In other cases, site characterization activities may indicate that an additional media is contaminated, which will result in modifications to both the CSM and the exposure assessment.

The BHHRA can be divided into five different steps that are organized as follows.

1.) Data Evaluation and Reduction

- collate the data
- assess the quality of the data based on the site-specific Data Quality Objectives (DQOs)
- evaluate the data to identify chemicals of potential concern (COPCs)
  - compare site concentrations to background concentrations
  - compare site concentrations to default RSLs (Tier IA) and/or site-specific RBSCs (Tier IB)
  - eliminate essential nutrients and chemicals detected infrequently from further consideration in the BHHRA

2.) Exposure Assessment

- develop or update the CSM. This includes identifying exposure scenarios and complete exposure pathways (for an example CSM see Figure 8-6)
- calculate exposure point concentrations (EPCs)
- identify exposure factors for receptors of concern
- calculate exposures for each COPC/medium/pathway combination

3.) Toxicity Assessment

- identify toxicity values for the COPCs
- identify alternative approaches for evaluating toxicity for COPCs that do not have toxicity values
- identify target organ(s)/critical effect(s) for non-cancer effects
- identify carcinogenic weight-of-evidence and mode of action for potential carcinogens

4.) Risk Characterization

- calculate the cancer risks and noncancer HIs

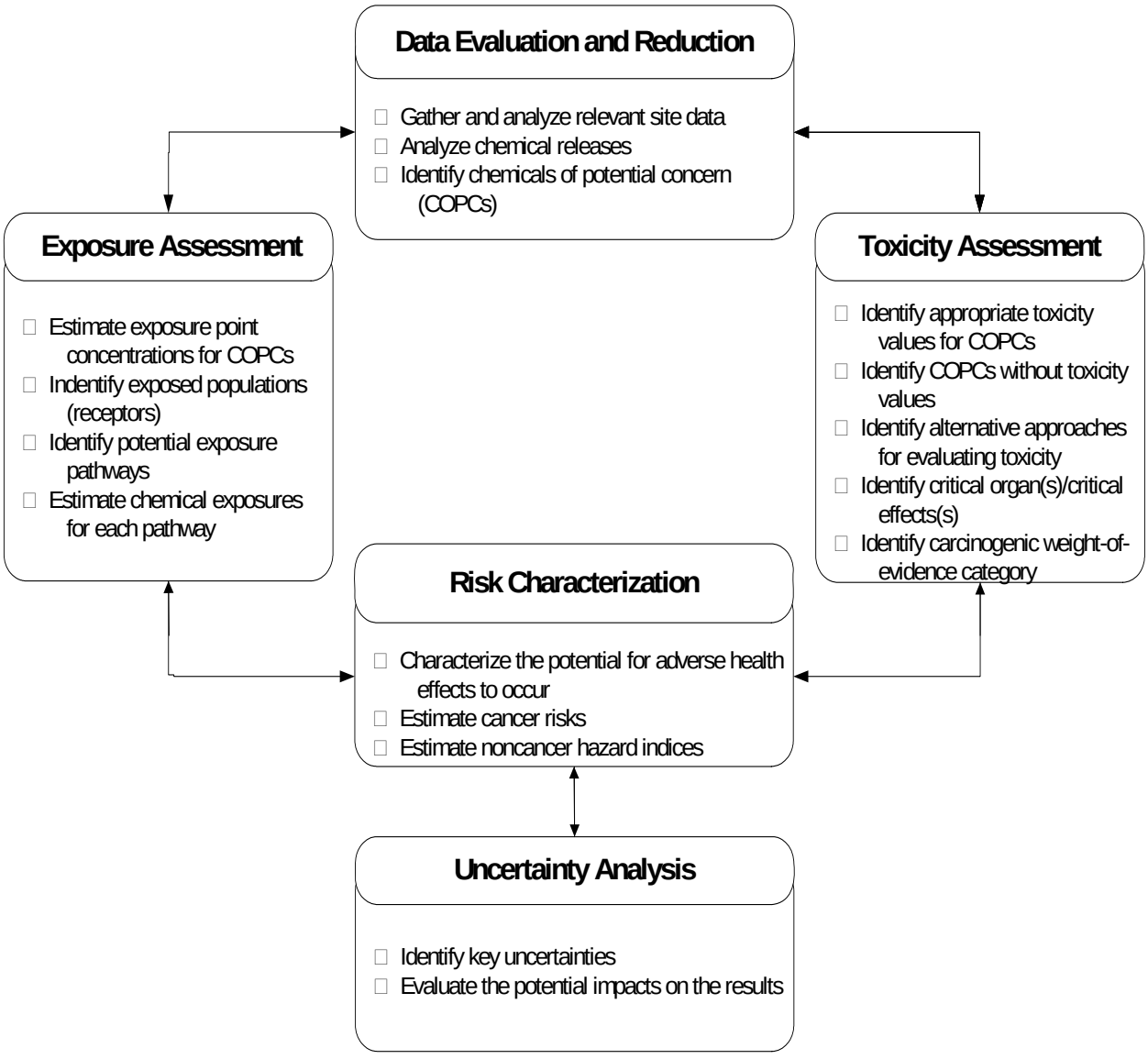
- summarize the site risks by chemical and medium for the receptors, exposure scenarios, and exposure pathways identified in the CSM

5.) Uncertainty Analysis

- Identify key uncertainties and evaluate their potential impacts on the results.

The BHHRA process is presented in Figure 8.3.

Figure 8.3 – Baseline Risk Assessment Process



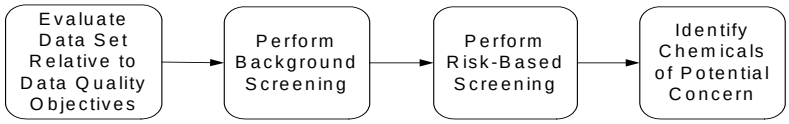
Data Evaluation and Reduction is the process of identifying COPCs for evaluation in the BHHRA. The Exposure Assessment begins with the refinement of the CSM and is completed when all of the plausible exposure pathways have been identified and exposures to the COPCs have been calculated. The

Toxicity Assessment identifies toxicity values and effects in order to evaluate cancer risks and noncancer hazards. Risk Characterization integrates the information from previous steps to produce numerical estimates of cancer risks and noncancer hazards. The Uncertainty Analysis identifies key uncertainties and evaluates their potential impacts on the risks. Each of these steps in the BHHRA process is discussed in detail in the following sections.

8.4 Data Evaluation and Reduction

The purpose of the data evaluation and reduction process is to ensure the data are appropriate for use in a BHHRA and to identify COPCs. This process entails a variety of different analytical steps that result in a useable data set for evaluating exposures at a site. The level of effort and need for each step depends on the quantity of the data, the complexity of the site, and analytical results. Figure 8.4 identifies the steps in the process, which are discussed below.

Figure 8.4 – Data Evaluation and Reduction Process



8.4.1 Evaluate Data Quality Objectives

Analytical data are the foundation of a BHHRA and should be evaluated to ensure that the site-specific DQOs have been achieved. DQOs ensure that the information needed to perform a credible BHHRA is collected. The key DQOs for a BHHRA include the following.

- **Data Quality** – The analytical data should be of suitable quality for HHRA purposes. That is, data should be collected in a manner that provides a basis for making remedial decisions at a site.

  Note: Some of the data collected for the site investigation (e.g., Hnu organic vapor detector measurements) may not be suitable for the purposes of the BHHRA, because they do not meet the DQOs.

- **Site Characterization** – Enough samples should be collected to adequately characterize the site. In addition to sampling density and coverage considerations, it is important that all media of concern are sampled at likely exposure points.

  Note: In many cases a BHHRA is performed after several different rounds or phases of data collection. It is important to incorporate all of the available data into the data evaluation and reduction process. If data are excluded from consideration in the risk assessment, then the rationale should be clearly documented.

- **Analytical Detection Limits** – The analytical methods used at a site are critical to the BHHRA because they can significantly influence the EPCs and, ultimately, the results of the evaluation. Therefore, it is important that the analytical methods selected for a site are sensitive enough to support the needs of the risk assessment (i.e., the detection limits for COPCs should be less than the applicable exit criteria).

8.4.2 BACKGROUND SCREENING

Purpose of Background Screening

On 30 January 2004 the Office of the Chief of Naval Operations (CNO) issued the Navy Policy on the Use of Background Chemical Levels in Risk Assessment (USNAVY, 2004). The purpose of this policy is to provide clarification of the Navy's policy on the consideration of background chemical levels in the list of COPCs in the Environmental Restoration Program. The Policy describes how to consider background chemicals levels in the program by:

1.) identifying those chemicals that are in the environment due to releases from the site;

2.) eliminating from consideration in the risk assessment process both naturally occurring and anthropogenic chemicals that are present at levels below background;

3.) ensuring documentation and discussion of potential risk from chemicals that have been eliminated during the background evaluation process; and

4.) developing remediation action levels that are not below background.

Screening out chemicals based on site-specific background or reference-area concentrations is an important step in the identification of COPCs. The purpose of background screening is to focus the risk assessment on COPCs that are related to site activities and to eliminate chemicals that are present at background concentrations. Background is defined in the Navy Policy on Background Chemical Levels as either naturally occurring (non-anthropogenic) or anthropogenic (non-naturally occurring), which are unrelated to Navy activities or operations (USNAVY, 2004). The purpose of a site risk assessment is to estimate the incremental risks associated with contamination present at the site due to Navy activities, not background contamination.

Determining Background Concentrations

Background concentrations of chemicals can be determined from existing site or base-wide information, published regional or national background concentrations, or by developing a sampling program to establish background concentrations. The following Navy Guidance documents present approaches for identifying background concentrations of chemicals and determining if site concentrations are significantly different.

- NAVFAC. 2002. Naval Facilities Engineering Command. NAVFAC Guidance for Environmental Background Analysis, Volume I: Soil. User's Guide UG-2049-ENV. April 2002. https://portal.navfac.navy.mil/portal/page/portal/navfac/navfac_ww_pp/navfac_nfesc_pp/environmental/erb/gpr/bg_soil_guide.pdf

- NAVFAC. 2003. Naval Facilities Engineering Command. NAVFAC Guidance for Environmental Background Analysis, Volume II: Sediment. User's Guide UG-2054-ENV. April 2003. https://portal.navfac.navy.mil/portal/page/portal/navfac/navfac_ww_pp/navfac_nfesc_pp/environmental/erb/gpr/ug-2054-sed-guide.pdf

- NAVFAC. 2004. Naval Facilities Engineering Command. NAVFAC Guidance for Environmental Background Analysis, Volume III: Groundwater. User's Guide UG-2059-ENV. April 2004. https://portal.navfac.navy.mil/portal/page/portal/navfac/navfac_ww_pp/navfac_nfesc_pp/environmental/erb/gpr/ug-2059-bkgrnd-analysis.pdf.

8.4.3 RISK-BASED SCREENING

Tier IA or Tier IB risk-based screening should be performed on the data set to help focus the BHHRA on COPCs that will contribute significantly to the risk. Chemicals that are present at concentrations lower

than their RSL or RBSC should be excluded from the BHHRA. Chemicals that are present at concentrations higher than their RSL or RBSC should be retained for further evaluation in the BHHRA. See Chapter 7 – Tier IA and Tier IB Risk-Based Screening for more information. Sites should be evaluated on a case-by-case basis because there are exceptions to these general rules. For example, if there are a number of chemicals present at concentrations just below their respective RSLs or RBSCs, they may be retained for further evaluation in the BHHRA because, collectively, they may impact the total risk.

Note: Some states and USEPA regions use different target risk goals depending on the type of evaluation being performed and the number of chemicals being evaluated. For example, USEPA Region III recommends that a target risk goal of 1/10th the default RSL be used when screening chemical concentration versus noncancer RSLs (USEPA 2008). Therefore, it is important to check state and USEPA regional guidance, if available, to determine the target risk goals that should be used in risk-based screening.

8.4.4 Develop a List of Chemicals of Potential Concern

The purpose of this step is to identify a list of chemicals at a site that are present due to Navy activities. A list of COPCs is determined once analytical methods, quantification limits, qualifiers, and blanks have been evaluated and background screening and risk-based screening have been completed. These COPCs will then be the focus of the BHHRA. Eliminating chemicals from further consideration reduces the level of effort and focuses the BHHRA on chemicals that pose the majority of the risks. Criteria for identifying COPCs for a site are as follows.

1.) Chemicals that were not detected in any samples for a particular medium should be eliminated from further consideration in the BHHRA (USEPA, 1989).

2.) Essential nutrients (i.e., calcium, magnesium, potassium, and sodium) should be eliminated from consideration in the BHHRA because they are not associated with toxicity in humans under normal circumstances (USEPA, 1991b).

3.) Chemicals that are detected infrequently and at low concentrations (e.g., less than five percent frequency of detection and at concentrations slightly above the detection limit) may be eliminated from further consideration in the BHHRA (USEPA, 1989).

4.) Chemicals detected at concentrations that are not representative of background concentrations should be retained for further evaluation in the BHHRA.

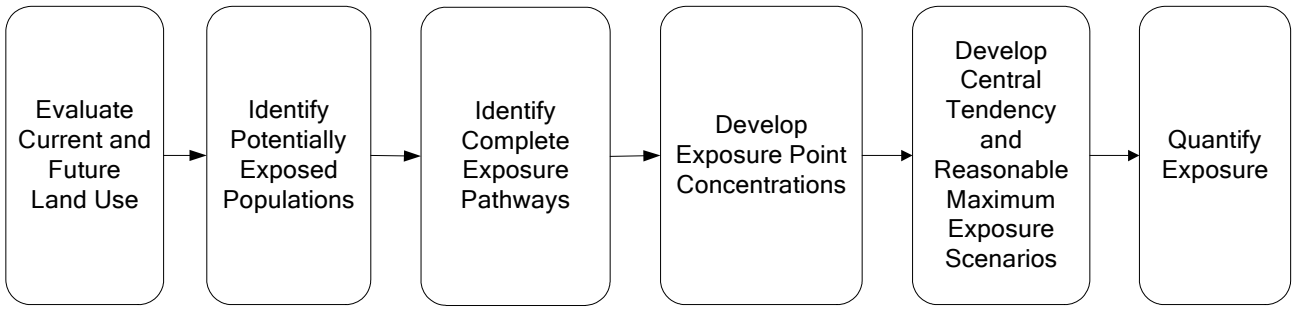
5.) Chemicals detected at concentrations that exceed RSLs or RBSCs should be retained for further evaluation in the BHHRA.

The use of these criteria is contingent on the availability of sufficient data to characterize the site. It is also important to work with regulators and stakeholders to ensure that they agree with the decision rules that are employed to eliminate chemicals from further consideration in the BHHRA.

8.5 Exposure Assessment

The purpose of the exposure assessment is to quantify human exposure to COPCs for complete exposure pathways. The results of the exposure assessment are combined with toxicity information to characterize potential risks. Figure 8.5 identifies the major steps in the exposure assessment and how these steps are related.

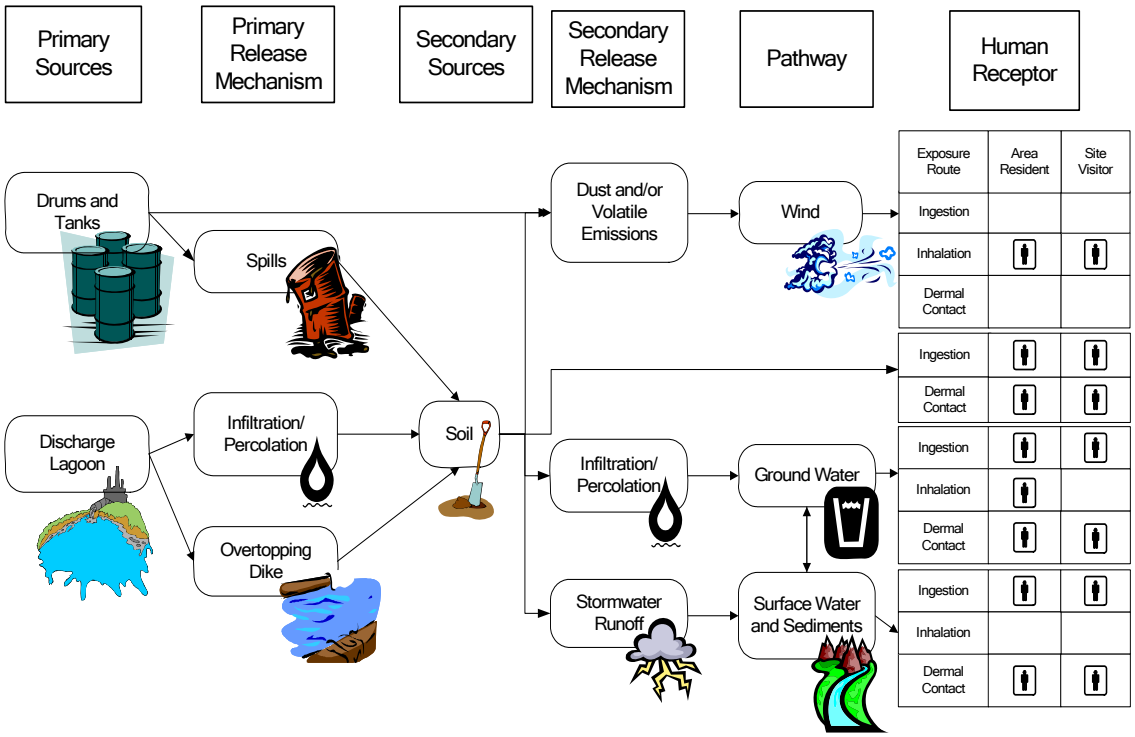
Figure 8.5 – Exposure Assessment Process



8.5.1 DEVELOP/RE-EVALUATE THE CONCEPTUAL SITE MODEL

The purpose of a CSM is to provide an understanding of the potential for exposure (under current and future land use) to chemicals at a site based on the source(s) of contamination, the release mechanism(s), the exposure pathway(s), and the receptor(s). One of the first steps in the exposure assessment is to review the CSM and to revise it, if appropriate – based on new site-specific information. This may result in changes in the exposure scenarios, receptors, and exposure pathways that are evaluated in the BHHRA. Figure 8.6 presents an example of a CSM.

Figure 8.6 – Example of a Conceptual Site Model



8.5.2 CURRENT/FUTURE LAND USE CONSIDERATIONS

The Importance of Land Use Considerations

Land use is a critical component of the risk assessment process because it dictates which exposed populations (e.g., residential, industrial, or other) should be evaluated in the BHHRA. Land use concerns are addressed in both the risk assessment and the risk management efforts. Risk assessment addresses land use in terms of actual and assumed exposure scenarios, which determine exposed populations and affect exposure mechanisms, durations, and frequencies. The role of risk management in land use involves making decisions based on the use of the property, both current and plausible future use, and how any potential risk might be mitigated. Under these circumstances, land use information is shared between the risk assessment and risk management processes. In the event that a site is proposed for use or re-use with restrictions, the issue of LUCs must be addressed.

Land Use Controls

The CNO issued interim final guidance on LUCs (USNAVY, 1999). LUCs are divided into two types: engineering controls (ECs) and ICs. ECs refer to engineered remedies that contain or reduce contamination and/or limit access to the contaminated property (including both land and water). ECs may include fences, signs, landfill caps, provision of potable water supplies, and guards (to prevent access). ICs are legal devices that ensure that ECs are properly managed and land use restrictions are enforced. ICs include easements, restrictive covenants, zoning, permits, and educational programs. Note that specific state and regional regulatory agencies may have established separate requirements for LUC implementation. Additional information about monitoring and enforcing LUCs is available from the Department of the Navy (USNAVY, 2003).

Determining Future Land Use

Land use assumptions for conducting HHRAs should be based on a factual understanding of site-specific conditions and reasonably-anticipated use. The land use evaluated in the risk assessment should not be based on a residential exposure scenario (i.e., the default worst-case), unless residential land use is plausible for the site. The USEPA has made the following recommendations in regard to land use considerations:

- future land use assumptions allow the baseline human health risk assessment and the feasibility study to focus on the development of practicable and cost-effective remedial alternatives, leading to site activities that are consistent with the reasonably-anticipated future land use;
- a range of land uses, and therefore exposure assumptions, may be considered dependent upon the amount and certainty of information supporting a land use evaluation;
- discussions with local land use planning authorities, appropriate officials, and the public, as appropriate, should be conducted as early as possible in the planning/scoping phase of the project; and
- sites that are on federal facilities (e.g., military bases) may have different land use considerations than those located on private property, because land use assumptions at sites that are undergoing base closure may be different than at sites where a federal agency will be maintaining control of the facility (USEPA, 1995a).

Various sources of information, including activity master plans and local zoning plans, can be utilized in making educated decisions about potential land use for a given site. Land use assumptions should take into consideration the interests of all affected stakeholders, including the local residents and municipal government. Land use issues should be carefully resolved, maintaining regular communication between the risk manager and the risk assessor.

8.5.3 DESCRIBE EXPOSURE SETTING

The exposure setting consists of a description of the physical environment as well as the potentially-exposed populations. Basic characteristics such as climate, vegetation, groundwater hydrology, and the presence and location of surface water should be identified. In addition, population characteristics that influence exposure, such as location of people relative to the site, activity patterns, and presence of sensitive subpopulations, should be identified. A short summary of the site's history is often useful to readers because they may not be familiar with the site. An effective presentation of the exposure setting is important because it provides the reader with an understanding of key factors at a site that influence exposure to chemicals.

8.5.4 IDENTIFY COMPLETE EXPOSURE PATHWAYS

Exposure pathways are identified based on consideration of the sources, releases, types, and locations of chemicals at the site. In order for a COPC to pose a risk to human health, a complete exposure pathway must be present. A complete exposure pathway consists of the following elements:

1.) a source and mechanism of chemical release to the environment (e.g., contaminated soil);

2.) an environmental transport medium for the released chemical (e.g., air);

3.) an exposure point (i.e., a point of potential human contact with the contaminated medium) that includes a location where humans are present and where there is activity that results in exposure, referred to as an "exposure scenario;" and

4.) an exposure route at the point of exposure (e.g., inhalation).

The identification of complete exposure pathways is a key step in the development of the CSM. If there are no complete exposure pathways under current and plausible future land use conditions, then there is no reason to perform a BHHRA because there is no risk to human health.

Exposure pathways should be plausible and consistent with site-specific information. For example, the incorporation of indirect exposure pathways, such as ingestion of homegrown beef/dairy/fruits/vegetables, in the BHHRA should be critically evaluated and should only be considered when warranted by site-specific information (e.g., a subsistence farmer living in the area). In addition, temporal trends should be considered when identifying complete exposure pathways. In some cases, receptors may not be currently exposed to COPCs but may be in the future (e.g., COPCs in groundwater that migrate laterally and, in the future, impact a well used for drinking water). In this case exposures to contaminated groundwater should be evaluated based on exposures that are expected to occur in the future. If vapor intrusion is a potential pathway of concern, the *Tri-Services Handbook for the Assessment of the Vapor Intrusion Pathway (*USAF et al., 2008) may be consulted.

8.5.5 DEVELOP EXPOSURE POINT CONCENTRATIONS FOR CHEMICALS OF POTENTIAL CONCERN

The next step in the process is to determine representative concentrations of each chemical to which populations will be exposed. The issues associated with developing representative EPCs are discussed in the following sections.

Field Duplicate Samples

Field duplicates are often collected as part of the quality assurance process to evaluate a laboratory's ability to provide reproducible results. Field duplicate results can either be combined into one sample or they can be included in the risk assessment as discrete results. In some cases, including both field results as independent samples may bias the overall EPCs by over representing a sample location. If this is a concern, then the field duplicate data can be grouped together using decision rules, such as:

- if a chemical is detected in both of the field duplicate samples, then use either the maximum of the two values or the average of the two values;
- if a chemical is detected in only one of the field duplicate samples, then use the detected value; or
- if a chemical is not detected in either of the field duplicate samples, then use the higher of the two sample-specific detection limits.

These decision rules should be modified in order to incorporate site-specific considerations.

Approaches for Incorporating Non-Detected Data into the Calculation of EPCs

Most chemicals at a site are not detected in every sample, and therefore, the sample quantitation limit (SQL) is usually reported. SQLs are the sample-specific detection limits and take into account sample characteristics, sample preparation, and analytical adjustments. They are the most relevant quantitation limits for evaluating non-detected chemicals. From a risk assessment perspective, these results provide valuable information that should be incorporated into the evaluation. A chemical that was not detected above the SQL in a sample could actually be present in the sample at a concentration that is less than the SQL.

Incorporating non-detected results into the BHHRA requires professional judgment and site-specific information. The guiding principle when evaluating non-detected data is that the EPCs should be representative of site conditions. The USEPA recommends that if there is reason to believe that the chemical is present in a sample at a concentration below the SQL, then a proxy level should be used to represent the sample concentration in the sample(s) that the chemical was not detected in. Historically, the USEPA recommended that one-half of the SQL could be used as a proxy concentration (USEPA, 1989). Additional guidance on incorporating non-detected data into EPCs calculations is available from the USEPA (USEPA, 2001, 2002a; 2007b). Recently, the USEPA has changed their position on the appropriateness of using one-half the SQL as a proxy concentration when calculating EPCs (USEPA, 2007b). The current USEPA guidance (2007b) should be referred to for additional information on how to handle non-detected results.

RME and CTE Exposure Point Concentrations

The USEPA recommends that both a high-end descriptor of risk (i.e., Reasonable Maximum Exposure [RME]) and a central tendency exposure (CTE) (e.g., average or median estimate) descriptor of risk should be included in the BHHRA (USEPA, 1995b). Evaluating RME and CTE scenarios provides risk managers with a range of risks, which is useful in the decision-making process. In general, CTE estimates are created by replacing the exposure factors and, in some cases, the EPCs, used in the RME scenario, with average or median values. The USEPA recommends that the RME be based on a plausible upper-bound estimate of exposure rather than the worst-case exposure scenario. The CTE exposure estimate should be either the arithmetic mean exposure (average estimate) or the median exposure (median estimate) (USEPA, 1995b).

For the RME scenario, the EPC should be based on the 95 percent upper confidence limit (95% UCL) on the arithmetic mean. For the CTE scenario, the EPC may be based on the average, logarithmic average, median concentration, or the 95% UCL. The underlying distribution of the analytical data should be evaluated to determine if the arithmetic, logarithmic, gamma, or non-parametric statistics should be used. See the USEPA's *Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazard Waste Sites* document (USEPA, 2002a) for additional information.

Note: The RME and CTE EPCs should not exceed the maximum detected concentration which may occur due to elevated SQLs. This may also be indicative of data gaps due to insufficient sampling to perform the site characterization. In instances where this occurs, the maximum detected concentration

may be used as the EPC. The additional uncertainties associated with using the maximum detected concentration as the EPC should be discussed in the uncertainty section of the BHHRA.

Developing Representative Exposure Point Concentrations

The key step in determining representative EPCs is understanding the nature and extent of contamination at the site. For example, data at a site with a hot spot (i.e., significantly elevated chemical concentrations in a discrete area) may be grouped together differently than at a site that doesn't have a hot spot. At other sites there may be distinctly different patterns of contamination between surface soil and subsurface soil. In every case, the foundation of a good risk assessment is a clear understanding of the chemical data.

There are a variety of different ways to evaluate sites in order to develop representative EPCs, such as:

- subdivide the site based on future land use if portions of the site are going to be used for different purposes;
- subdivide the site based on historical information (e.g., production or disposal areas). For example, it is a good idea to evaluate hot spots separately from the rest of the site. Identifying hot spots eliminates the possibility that a small area of contamination will bias the overall evaluation; and/or
- subdivide data based on temporal trends. If the concentrations are significantly different over time it may make sense to use only the most current data.

Data Presentation Strategies

An important part of a BHHRA is the presentation of the chemical data that are used to develop EPCs. In general, brief statistical summaries of the site's chemicals should be presented in the body of the BHHRA, and the underlying data and summary statistics should be presented in an appendix. The key to effectively presenting data in the BHHRA is to help focus the reader on the chemicals that are responsible for the majority of the risks. This requires coordination between the Risk Characterization and Data Evaluation and Reduction steps. The following list presents recommendations for effectively presenting data:

- present all of the steps that were used to identify COPCs for evaluation in the BHHRA;
- discuss significant site-specific considerations associated with the data (e.g., quality control issues);
- present all the steps that were taken to identify naturally-occuring and anthropogenic background concentrations, and which statistical tests were used to compare site concentrations to background;
- identify the source of the RSLs or RBSCs and the appropriateness of their use for screening out chemicals; and
- use maps, graphs, and other visual summaries to present chemical concentrations.

Some sites have a lot of data that, if presented in detail in the body of the BHHRA, might overwhelm the reader with unnecessary information. The data evaluation section should summarize the data in a manner that enables the reader to easily understand how the data were reduced to the final data set that is evaluated in the BHHRA.

8.5.6 EXAMPLE EXPOSURE ALGORITHMS AND PARAMETERS TO CALCULATE EXPOSURE

The USEPA has identified standard default exposure parameters that are appropriate to use as a starting point when evaluating exposures at sites (USEPA, 1991c). Tables 8.1 through 8.4 present example algorithms and exposure parameters for incidental soil ingestion, dermal exposure to soil, inhalation of soil, and ingestion of groundwater for residential and industrial scenarios. However, each parameter in these equations has a range of possible values associated with it. The exposure parameters for a given pathway should be selected so that the combination of all exposure parameters results in a realistic estimate of the CTE and RME for that pathway. The source for each exposure parameter should be fully documented in the BHHRA so the goal of transparency can be met.

8.5.7 QUANTIFYING EXPOSURE

The last step in the exposure assessment is quantifying the daily intake of chemicals for the receptors identified in the CSM. The general equation used to calculate daily intake of a chemical is:

$$DI = C \times HIF$$

where,

Parameter	Definition
DI	Daily intake (mg of COPC per kg of body weight per day [mg/kg-day])
C	Concentration of the COPC (mg/kg, mg/m^3, mg/L, etc.)
HIF	Human intake factor (day)$^{-1}$. Calculated by solving the exposure parameters portion of the intake equation.

Quantitative characterization of carcinogenic and noncarcinogenic risks requires estimating the potential human intake levels for each COPC. Daily intakes for carcinogens are averaged over the lifetime of the exposed individual (i.e., 70 years) and are referred to as the Lifetime Average Daily Intake (LADI). Daily intakes for noncarcinogens are averaged over the duration of exposure and are referred to as the Average Daily Intake (ADI).

Table 8.1 – Example Exposure Parameters for Evaluating Incidental Soil Ingestion[a,b]

$$\text{Daily Intake}\left(\frac{mg}{kg-day}\right) = \frac{C_s \times FC \times IR \times ED \times EF \times CF}{BW \times AT}$$

Exposure Parameter	Definition	Units	Residential				Industrial	
			Child (0-6) CTE	Child (0-6) RME	Adult CTE	Adult RME	Adult CTE	Adult RME
C_S	Chemical concentration in soil[c]	mg/kg	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific
FC	Fraction from contaminated source	%	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific
IR	Ingestion rate	mg/day	100	200	100	100	50	50
ED	Exposure duration	years	3[d]	6	9[e]	30	9[f]	25
EF	Exposure frequency	days/year	275[e]	350	275[e]	350	250	250
CF	Conversion factor	kg/mg	1E-06	1E-06	1E-06	1E-06	1E-06	1E-06
BW	Body weight	kg	15	15	70	70	70	70
AT_{nc}	Averaging time - noncarcinogenic	days	1,095	2,190	3,285	10,950	3,285	9,125
AT_{carc}	Averaging time - carcinogenic (lifetime)	days	25,550	25,550	25,550	25,550	25,550	25,550

[a]RME exposure parameters without footnotes are USEPA Standard Defaults (USEPA, 1991c). CTE exposure parameters were based on RME exposure parameters except where noted.
[b]Some USEPA Regions require integrating the child and adult exposures into a single estimate of exposure and risk. Check the appropriate regional guidance to verify the approach for calculating intake.
[c]The CTE and RME concentrations should be calculated as described in Section 8.5.5 Develop Exposure Point Concentrations for Chemicals of Potential Concern.
[d]Assumes half the RME.
[e]Source is the USEPA Region X Supplemental Guidance for Superfund (USEPA, 1991b).
[f]Assumes that the duration of employment is equivalent to the average amount of time a resident lives at a location.

Table 8.2 – Example Exposure Parameters for Evaluating Dermal Contact With Soil[a,b, c]

$$\text{Daily Intake Absorbed}\left(\frac{mg}{kg-day}\right) = \frac{C_s \times FC \times AF \times AB \times SA \times ED \times EF \times CF}{BW \times AT}$$

Exposure Parameter	Definition	Units	Residential				Industrial	
			Child (0-6) CTE	Child (0-6) RME	Adult CTE	Adult RME	Adult CTE	Adult RME
C_S	Chemical concentration in soil[d]	mg/kg	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific
FC	Fraction from contaminated source	%	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific
AF	Soil to Skin Adherence Factor	mg/cm^2	0.4[e]	0.4[e]	0.06[e]	0.06[e]	0.1[e]	0.1[e]
ABS	Absorption fraction	%	Chemical Specific	Chemical Specific	Chemical Specific	Chemical Specific	Chemical Specific	Chemical Specific
SA	Skin surface area	cm^2	2,800[f]	2,800[f]	5,700[f]	5,700 [f]	3,300[f]	3,300[f]
ED	Exposure duration	years	3[g]	6	9[h]	30	9[i]	25
EF	Exposure frequency	days/year	275[h]	350	275[h]	350	250	250
CF	Conversion factor	kg/mg	1E-06	1E-06	1E-06	1E-06	1E-06	1E-06
BW	Body weight	kg	15	15	70	70	70	70
AT_{nc}	Averaging time - noncarcinogenic	days	1095	2,190	3,285	10,950	3,285	9,125
AT_{carc}	Averaging time - carcinogenic (lifetime)	days	25,550	25,550	25,550	25,550	25,550	25,550

[a] RME exposure parameters without footnotes are USEPA Standard Defaults (USEPA, 1991c). CTE exposure parameters were based on RME exposure parameters except where noted.

[b] Some USEPA Regions require integrating the child and adult exposures into a single estimate of exposure and risk. Check the appropriate regional guidance to verify the approach for calculating intake.

[c] Additional guidance for evaluating the dermal pathway can be found in the USEPA's Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) (USEPA, 2004).

[d] The CTE and RME concentrations should be calculated as described in section 8.5.5 Develop Exposure Point Concentrations for Chemicals of Potential Concern.

[e] Source is the USEPA's Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) (USEPA, 2004). AF value for children is the 95th percentile value for a child playing in dry soil; AF value for adult resident is the 95th percentile value for a resident; AF value for an adult industrial worker is the 95th percentile value for a commercial/industrial worker.

[f] Source is the USEPA's Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) (USEPA, 2004).

[g] Assumes half the RME.

[h] Source is the USEPA Region X Supplemental Guidance for Superfund (USEPA, 1991b).

[i] Assumes that the duration of employment is equivalent to the average amount of time a resident lives at a location.

Table 8.3 – Example Exposure Parameters for Evaluating Inhalation of Particulates and Vapors[a]

$$\text{Daily Intake}\left(\frac{mg}{kg-day}\right) = \frac{C_a \times FC \times IR \times ED \times EF}{BW \times AT}$$

Exposure Parameter	Definition	Units	Residential				Industrial	
			Child (0-6) CTE	Child (0-6) RME	Adult CTE	Adult RME	Adult CTE	Adult RME
C_a	Chemical concentration in air[b]	mg/m^3	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific
FC	Fraction from contaminated source[c]	%	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific
IR	Inhalation rate	m^3/day	7.5	7.5	20	20	20	20
ED	Exposure duration	years	3[e]	6	9[d]	30	9[f]	25
EF	Exposure frequency	days/year	275[d]	350	275[d]	350	250	250
BW	Body weight	kg	15	15	70	70	70	70
AT_{nc}	Averaging time – noncarcinogenic	days	1,095	2,190	3,285	10,950	3,285	9,125
AT_{carc}	Averaging time - carcinogenic (lifetime)	days	25,550	25,550	25,550	25,550	25,550	25,550

[a] RME exposure parameters without footnotes are USEPA Standard Defaults (USEPA, 1991c). CTE exposure parameters were based on RME exposure parameters except where noted.
[b] The CTE and RME concentrations should be calculated as described in section 8.5.5 Develop Exposure Point Concentrations for Chemicals of Potential Concern.
[c] Outdoor and indoor inhalation exposures may be partitioned based on the amount of time an individual is outdoors. Adult and child residents are assumed to spend 30% of their time outdoors. This value is based on information presented in the Standard Default Exposure Factors which indicates that residents spend 5 out of 16 waking hours outdoors (USEPA, 1991c).
[d] Source is the USEPA Region X Supplemental Guidance for Superfund (USEPA, 1991b).
[e] Assumes half the RME.
[f] Assumes that the duration of employment is equivalent to the average amount of time a resident lives at a location.

Table 8.4 – Example Exposure Parameters for Evaluating Ingestion of Water[a]

$$Daily\ Intake\ \left({}^{mg}/_{kg-day}\right) = \frac{C_w \times FC \times IR \times ED \times EF}{BW \times AT}$$

Exposure Parameter	Definition	Units	Residential				Industrial	
			Child (0-6) CTE	Child (0-6) RME	Adult CTE	Adult RME	Adult CTE	Adult RME
C_w	Chemical concentration in water[b]	mg/l	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific
FC	Fraction from contaminated source	%	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific	Site Specific
IR	Ingestion rate	l/day	1	1	1.4[c]	2	1	1
ED	Exposure duration	years	3[d]	6	9[c]	30	9[e]	25
EF	Exposure frequency	days/year	275[c]	350	275[c]	350	250	250
BW	Body weight	kg	15	15	70	70	70	70
AT_{nc}	Averaging time - noncarcinogenic	days	1,095	2,190	3,285	10,950	3,285	9,125
AT_{carc}	Averaging time - carcinogenic (lifetime)	days	25,550	25,550	25,550	25,550	25,550	25,550

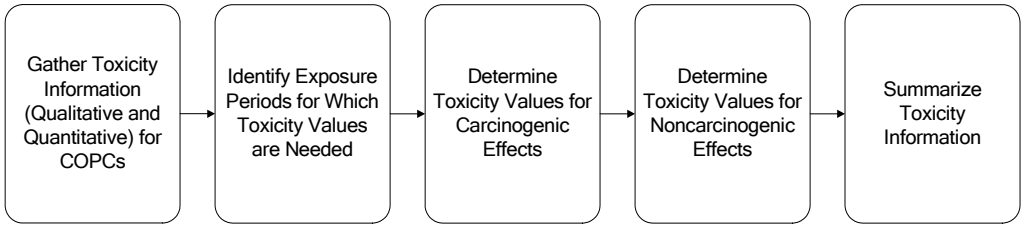
[a] RME exposure parameters without footnotes are USEPA Standard Defaults (USEPA, 1991c). CTE exposure parameters were based on RME exposure parameters except where noted.
[b] The CTE and RME concentrations should be calculated as described in section 8.5.5 Develop Exposure Point Concentrations for Chemicals of Potential Concern.
[c] Source is the USEPA Region X Supplemental Guidance for Superfund (USEPA, 1991b).
[d] Assumes half the RME.
[e] Assumes that the duration of employment is equivalent to the average amount of time a resident lives at a location.

8.6 Toxicity Assessment

8.6.1 Introduction

The USEPA states that the purpose of the toxicity assessment is to "weigh available evidence regarding the potential for particular contaminants to cause adverse effects in exposed individuals and to provide, where possible, an estimate of the relationship between the extent of exposure to a contaminant and the increased likelihood and/or severity of adverse effects (USEPA, 1989)." The USEPA has completed the toxicity assessment for most chemicals found at sites and the resulting toxicity values have been peer reviewed. At some sites though, there will be issues that require toxicological evaluations. In general, the toxicity assessment step of the BHHRA consists of locating and collating toxicity information that can be combined with the Exposure Assessment information to calculate risks. The steps in the Toxicity Assessment are presented in Figure 8.7. Each of these steps is discussed below.

Figure 8.7 – Toxicity Assessment Process



8.6.2 Carcinogenic Toxicity Values

USEPA describes the mechanism for carcinogenesis as a "non-threshold" process, meaning any level of exposure to such a chemical poses a probability of generating cancer. Risk at low exposure levels cannot be measured directly either by animal experiments or by epidemiological studies; therefore, a number of mathematical models and procedures have been developed for use in extrapolating risks from high to low doses. Different extrapolation models or procedures, while they may reasonably fit the observed data, may lead to large differences in the projected risk at low doses. It is assumed by the USEPA in developing carcinogenic slope factors (SFs) that the risk of cancer is linearly related to dose. This means that relatively high doses, which are often used in animal studies, can be extrapolated downward to extremely small doses, with some incremental risk of cancer always possible. This assumes that even a small number of molecules (possibly a single molecule) of a carcinogen may cause changes in a single cell that could result in the cell dividing in an uncontrolled manner, eventually leading to cancer.

Note: There is some dispute as to whether or not extrapolation from high to low doses is a realistic approach. It has been argued that at low doses, cells may have the ability to detoxify carcinogens or repair cellular damage. Therefore, it is important to recognize the possibility that some carcinogens may have a threshold for toxicity.

A SF is a numerical estimate of the potency of a chemical, which, when multiplied by the LADI, gives the probability of an individual developing cancer over a lifetime. SFs are usually derived by the USEPA by means of a linear, multistage model and reflect the upper-bound limit of cancer potency of any chemical. As a result, the calculated carcinogenic risk is likely to represent a plausible upper limit to the risk. The actual risk is unknown but is likely lower than the predicted risk, and may be as low as zero (USEPA, 1989).

The USEPA uses a weight-of-evidence approach to classify the likelihood that a chemical is a carcinogen. This qualitative information is important to consider when using the SFs to estimate potential risk. Each chemical is assigned a weight-of-evidence for carcinogenicity (USEPA, 2005). The USEPA has recently changed their weight-of-evidence classifications. Table 8.5 presents the updated classifications that USEPA assigns to the chemicals that have been evaluated for carcinogenicity.

Table 8.5 – USEPA Weight-of-Evidence Classifications for Carcinogenicity

Weight of Evidence Classification	Description of Evidence
Carcinogenic to Humans	There is strong evidence of human carcinogenicity
Likely to be Carcinogenic to Humans	The weight-of-evidence is adequate to demonstrate carcinogenic potential to humans, but does not reach the weight of evidence for the classification of "Carcinogenic to Humans"
Suggestive Evidence of Carcinogenic Potential	The weight of evidence is suggestive of carcinogenicity; a concern for potential carcinogenic effects in humans is raised, but the data are judged not sufficient for a stronger conclusion
Inadequate Information to Assess Carcinogenic Potential	Available data are judged inadequate for applying one of the other classifications
Not Likely to be Carcinogenic to Humans	The available data are considered robust enough for deciding that there is no basis for human health hazard

In many instances, the USEPA may not have updated the weight-of-evidence for chemicals. In these instances, it is appropriate to still list the old weight-of-evidence classifications (USEPA, 1986). These weight-of-evidence categories were as follows:

- Group A – Human Carcinogen (Sufficient evidence from epidemiological studies to support a causal associations between exposure and cancer),
- Group B1 – Probable Human Carcinogen (Limited evidence of carcinogenicity in humans from epidemiological studies; sufficient evidence in animals),
- Group B2 – Probable Human Carcinogen (Sufficient evidence of carcinogenicity in animals and no or inadequate evidence in humans),
- Group C – Possible Human Carcinogen (Limited evidence of carcinogenicity in animals),
- Group D – Not Classified (Inadequate evidence of carcinogenicity in animals),
- Group E – No Evidence of Carcinogenicity (No evidence of carcinogenicity in at least two adequate animal tests or in both epidemiological and animal studies).

Both the SF and the weight-of-evidence category should be reported in the BHHRA.

8.6.3 NONCARCINOGENIC TOXICITY VALUES

A reference dose (RfD) is defined as "An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious [e.g., organ damage, biochemical alterations, birth defects] effects during a lifetime (USEPA, 2007c)." RfDs have been developed by the USEPA for subchronic (short-term exposures), chronic (long-term exposures), and developmental exposures (e.g., birth defects).

Similarly, to assess noncarcinogenic effects from inhalation exposures, the USEPA derives reference concentrations (RfCs). RfCs are defined as, "An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime" (USEPA, 2007c). For ease of use in risk assessment calculations, the RfC can be converted to an inhalation RfD by using the adult body weight of 70 kg and adult daily inhalation rate of 20 m^3/day as follows:

$$\mathrm{RfD}_{\mathrm{inhalation}}\left(\frac{\mathrm{mg}}{\mathrm{kg\text{-}day}}\right)=\frac{\mathrm{RfC}\left(\frac{\mathrm{mg}}{\mathrm{m}^3}\right)\times 20\left(\frac{\mathrm{m}^3}{\mathrm{day}}\right)}{70\ \mathrm{kg}}$$

Noncarcinogenic chemicals are thought to exhibit threshold characteristics. That is, exposures less than a specific threshold dose will not result in adverse health effects, whereas exposures exceeding the threshold dose may produce adverse health effects. The assumption of a threshold for toxicity is based on the concept that the body has certain protective mechanisms that must be overcome before adverse effects are manifest. For example, there could be a large number of cells performing the same or similar function whose population must be significantly depleted before a toxic effect is observed.

The threshold concept is important in the regulatory context. The threshold hypothesis holds that a range of exposures from zero to some finite value can be tolerated by an individual with essentially no chance of expression of the toxic effect. Further, it is often prudent to focus on the most sensitive members of the population; therefore, regulatory efforts are generally made to keep intakes below the population threshold, which is defined as the lowest of the thresholds of the individuals within a population (USEPA, 2007c).

In general, an RfD is derived from a no observed adverse effect level (NOAEL) or a lowest observed adverse effect level (LOAEL) obtained from animal studies, or, occasionally, from human studies, by the application of standard order-of-magnitude uncertainty factors. In certain cases, an additional modifying factor is employed to account for professional assessment of scientific uncertainties in the available data (USEPA, 1989).

A NOAEL is an experimentally determined dose at which there was no statistically or biologically significant indication of the toxic effect of concern. The study chosen to establish the NOAEL is based on the criterion that the measured endpoint represents the most sensitive target organ or tissue (i.e., critical organ) for that chemical. In an experiment with several NOAELs, generally the lowest one is chosen as the critical NOAEL. Since many chemicals can produce toxic effects on several organ systems, with each toxic effect possibly having a separate threshold dose, the distinction of the critical toxic effect provides added confidence that the NOAEL is protective of human health. The USEPA's Integrated Risk Information System (IRIS) profiles identify the target organ or critical effect that was identified in the study(ies) used to derive the RfD or RfC.

Once the critical NOAEL is identified, the next step is to derive the RfD by dividing the NOAEL by safety factors as follows:

$$RfD\ (average\ daily\ human\ dose)=\frac{NOAEL_{Experimental\ Dose}}{Safety\ Factors+Modifying\ Factor}$$

Generally, each safety factor represents a specific area of uncertainty inherent in the available data and accounts for uncertainties, such as:

- differences in responsiveness between humans and animals in prolonged exposure studies (factor of 10);

- variation in susceptibility among individuals in the human population (factor of 10); and
- incomplete databases (e.g., those for which only the results of subchronic studies are available) (factor of 10) (USEPA, 2007c).

In addition to the safety factors, a modifying factor is applied in some instances. Modifying factors range from zero to 10 and are included to reflect a qualitative professional assessment of additional uncertainties in the critical study and in the entire database for the chemical not explicitly addressed by the uncertainty factors. The default value for the modifying factor is one (USEPA, 2007c).

The BHHRA should document the RfD or RfC, the target organ or critical effect identified by USEPA, and the safety and modifying factors used to derive the RfD/RfC.

8.6.4 IDENTIFY THE SOURCES OF TOXICITY VALUES

The USEPA has evaluated numerous chemicals and has published the corresponding toxicity values, which have undergone peer review. USEPA recommends that the following hierarchy of human health toxicity values should be consulted to obtain toxicity values for use in a BHHRA (USEPA, 2003):

Tier 1: USEPA's IRIS (USEPA, 2007c);

Tier 2: USEPA's Provisional Peer Reviewed Toxicity Values (PPRTVs). The Office of Research and Development/National Center for Environmental Assessment/Superfund Health Risk Technical Support Center (STSC) develops PPRTVs on a chemical-specific basis. These values need to be requested from the STSC,

Tier 3: Other toxicity values, including USEPA and non-USEPA sources. These sources include, but are not limited to, the Health Effects Assessment Summary Tables–Annual Update (HEAST) (USEPA, 1997b), California Environmental Protection Agency (CalEPA) toxicity values, and Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Levels (MRLs). Priority in Tier 3 values should be given to sources that provide information on toxicity that is based on similar methods and procedures (including peer review) used to determine Tier 1 and Tier 2 values.

Many of the toxicological summaries on IRIS were developed prior to 1996 and the information and values presented were verified by either the USEPA Reference Dose/Reference Concentration (RfD/RfC) Work Group or the USEPA Carcinogen Risk Assessment Verification Endeavor (CRAVE). IRIS entries from 1997 to the present represent USEPA consensus information. IRIS toxicity values are used to evaluate chronic exposure, which is generally considered as exposure lasting more than seven years. PPRTV values have been derived to replace the toxicity values in HEAST, and include both chronic and subchronic toxicity values. Subchronic toxicity values are generally used for evaluating exposures lasting between two weeks to seven years.

Additional guidance about identifying appropriate toxicity values from Tier 3 sources is available in Attachment 1 to the Memorandum from the Department of Defense RE: Actions in Response to Perchlorate Releases (DoD, 2007).

8.6.5 ROUTE-TO-ROUTE EXTRAPOLATION TO DETERMINE INHALATION AND DERMAL TOXICITY VALUES

Toxicity values are used in conjunction with exposure information to evaluate the potential for noncarcinogenic health effects and cancer risks. Most available chemical-specific toxicity values have been derived for the oral route of exposure, while criteria for the inhalation route of exposure are available for only a limited number of chemicals. For dermal exposure, the USEPA has not developed toxicity values specifically for evaluating potential human health concerns. Due to the lack of inhalation and dermal toxicity values, an interim decision was made by the Superfund program to estimate toxicity

criteria based on existing oral criteria (i.e., route-to-route extrapolation). Route-to-route extrapolation of oral toxicity values to derive inhalation and dermal toxicity values are discussed below.

Route-to-Route Extrapolation for Inhalation Toxicity Values

Extrapolation of inhalation toxicity values from oral toxicity values is sometimes done when toxicity values are not available for the inhalation exposure route. Using this approach, the oral toxicity value is assumed to be the same as the inhalation toxicity value. This approach assumes that the route of exposure has no effect on the systemic toxicity seen once the chemical is absorbed into the body. This extrapolation method relies on the following assumptions:

- that the health effects following exposure are not route specific; and
- that portal-of-entry effects (e.g., respiratory effects associated with inhalation exposure) are not the principal effects of concern. For example, the USEPA recommends that the use of oral toxicity values is not appropriate for chemicals that are associated with respiratory tract irritation or sensitization, such as isocyanates (USEPA, 1994a).

If extrapolation from an oral toxicity value to an inhalation toxicity value is needed, careful review of the study used to derive the oral toxicity value should be performed to verify that these assumptions are valid. If these assumptions are not valid for a specific chemical, then route-to-route extrapolation should not be performed.

Route-to-Route Extrapolation for Dermal Toxicity Values

Most exposure pathways, such as incidental soil ingestion, quantify exposure based on the amount of a chemical that an individual comes in contact with on a daily basis (i.e., intake). The toxicity values used to evaluate the risks associated with these exposure pathways are typically consistent with this approach in that they are also developed based on intake (often referred to by toxicologists as administered dose). In contrast, dermal exposure is determined based on the amount of chemical that penetrates the skin and is absorbed into the blood stream. Consequently, toxicity values based on administered dose should be adjusted to reflect the absorbed dose when evaluating the risks associated with dermal exposure.

The approach developed by USEPA to derive dermal toxicity values from oral toxicity values adjusts the administered dose based on how much of the chemical was absorbed in the gastrointestinal (GI) tract. Ideally the amount of GI absorption would be measured in the original oral toxicity study. However, this is rarely done. The current method recommended by the USEPA for converting toxicity values from administered to absorbed dose relies on the following assumptions:

- that the health effects following exposure are not route specific; and
- that portal-of-entry effects (e.g., dermatitis associated with dermal exposure) are not the principal effects of concern. For example, the USEPA recommends that the current default for evaluating dermal exposure is inappropriate for carcinogenic polycyclic aromatic hydrocarbons (PAHs), because this group of chemicals cause skin cancer through direct action at the point of application (e.g., portal-of-entry effects) (USEPA, 1989, 2004). The USEPA further recommends that risks from dermal exposure to these chemicals be qualitatively evaluated.

The USEPA recommends that oral toxicity values should only be adjusted from administered to absorbed dose when there is convincing empirical data that suggests that GI absorption is less than 50%. While this is less conservative than assuming some default value, it does avoid the problem of incorporating overly-conservative values in the absence of good data. Due to the lack of empirical data on GI absorption for most chemicals, the USEPA's Supplemental Guidance for Dermal Risk Assessment (USEPA, 2004) recommends that toxicity values only be adjusted for select inorganic chemicals (i.e., antimony, barium, beryllium, cadmium, chromium III, chromium IV, manganese, mercuric chloride, nickel,

silver, and vanadium). The percent of GI absorption to assume for each of these chemicals, and the approach for converting oral toxicity values into dermal toxicity values, is presented in USEPA's dermal guidance (USEPA, 2004).

8.6.6 CHEMICAL BIOAVAILABILITY

At some sites, information on the speciation (i.e., the valence state of metals) of some site-specific chemicals is available. The species of chemicals present can play a large role in the relative toxicity of the chemical, as some toxicity values have been derived on a species-specific basis. Speciation of chemicals can be expensive, and therefore it is not commonly performed (or needed). However, where species-specific information is present, toxicity values associated with the species present should be identified. See the Framework for Metals Risk Assessment (USEPA, 2007a) for guidance on evaluating the potential bioavailability of chemicals.

8.7 Risk Characterization

Risk characterization integrates the results of the data evaluation and reduction, exposure assessment, and toxicity assessment into quantitative expressions of risk. The key components of the risk characterization process include the following:

- quantify risks from individual chemicals;
- quantify risks from multiple chemicals;
- combine risks across exposure pathways; and
- consider site-specific human studies (USEPA, 1989).

Risk characterization is the starting point for risk management considerations and the foundation for regulatory decision making, but it is only one of the important components in such decisions.

8.7.1 Regulatory Risk Benchmarks and Cancer and Noncancer Risks

The USEPA has typically used an HI (i.e., the cumulative noncancer risks for all chemicals) of 1 or greater, or an HI for a target organ/critical effect of 1 or greater as a benchmark for evaluating noncarcinogenic HIs. For carcinogenic risk, the USEPA's approach "emphasizes the use of one chance in one million (i.e., 1×10^{-6}) as the point of departure while allowing site or remedy-specific factors, including potential future uses, to enter into the evaluation of what is appropriate at a given site." As risks increase above one chance in one million, they become less desirable, and the risk to individuals generally should not exceed one in ten thousand (i.e., 1×10^{-4}) (USEPA, 1991a). The USEPA recommends that "where the cumulative carcinogenic site risk to an individual based on RME for both current and future land use is less than 1×10^{-4} and the non-carcinogenic hazard index is less than 1, action generally is not warranted unless there are adverse environmental impacts. However, if MCLs or non-zero MCLGs are exceeded, action generally is warranted" (USEPA, 1991a).

Quantifying Cancer Risks

The risk of cancer from chemical exposure is described in terms of the probability that an exposed individual will develop cancer during his/her lifetime from that exposure. The risk estimate is calculated by multiplying the daily intake of a particular chemical over a lifetime by the SF.

When the cancer risk is less than one in 100 (i.e., 1×10^{-2}), the following equation is used (USEPA, 1989):

$$RISK = LADI \times SF$$

When the cancer risk is greater than one in 100 (i.e., 1×10^{-2}), the following one-hit equation should be used (USEPA, 1989):

$$RISK = 1 - \exp\left(-LADI \times CSF\right)$$

where,

Parameter	Definition
RISK	Lifetime probability of developing cancer due to exposure to a chemical in the environment
LADI	Lifetime average daily intake of a chemical (mg/kg-day)
SF	Carcinogenic slope factor for a chemical (mg/kg-day)$^{-1}$
exp	The exponential

All carcinogenic risks for chemicals for each scenario and receptor are then summed to yield the total carcinogenic risk. A one in one million cancer risk (i.e., 1×10^{-6}) means that, in a population of 1,000,000 people exposed under an identical exposure scenario (i.e., had exactly the same daily intake of a carcinogen over the same time period), there could be one additional case of cancer in the population.

Evaluating Noncancer Health Effects

Adverse noncarcinogenic health effects from exposure to a COPC are quantitatively expressed as a hazard quotient (HQ). The HQ is the ratio of a human's estimated intake of a particular chemical to the RfD.

$$HQ = \frac{ADI}{RfD}$$

where,

Parameter	Definition
HQ	Hazard quotient – The ratio of the estimated dose of a chemical to the RfD
ADI	Average daily intake of a chemical (mg/kg-day)
RfD	Reference dose for a chemical (mg/kg-day)

The RfD is the threshold intake level for a particular chemical below which it is unlikely that even sensitive subpopulations would experience adverse health effects. Usually, only chronic HQs are evaluated, as the subchronic effects within a given exposure scenario are typically less than or equal to the chronic effects for the same scenario.

For noncancer health effects, HQs are added across chemicals when they target the same organ, or produce the same critical effect to calculate a segregated HI. Segregation of HIs requires the identification of the adverse effects of each chemical, which could include those seen at higher doses than the critical effect (e.g., the chemical may cause liver damage at a dose of 5 mg/kg-day and neurotoxicity at a dose of 25 mg/kg-day). Major effect categories include:

- neurotoxicity;

- developmental toxicity;
- reproductive toxicity;
- immunotoxicity; and
- adverse effects by target organ (i.e., hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, dermal, and ocular effects).

Although higher exposure levels may be required to produce adverse health effects other than the critical effect, the RfD can be used as the toxicity value for each effect category as a conservative and simplifying step (USEPA, 1989).

If the total segregated HI is less than 1, it indicates that adverse noncarcinogenic health effects are unlikely. If the total segregated HI is greater than 1, it indicates that adverse health effects are possible. Often times all HQs are added together to determine the total HI. If the total HI is greater than 1, then the HQs should be segregated by target organ or critical effect and then compared to the target risk goal.

8.7.2 Evaluating the Health Effects Associated with Lead Exposures

The traditional risk assessment approach for evaluating noncancer effects from exposure to chemicals involves comparison of chemical intakes to an RfD. This approach is inappropriate for lead because a NOAEL for lead has not been identified (i.e., there is no RfD for lead) by the USEPA. Blood-lead concentrations are accepted as the preferred measure of cumulative lead exposures. A blood lead level of 10 µg/dL has been identified by the Centers for Disease Control and Prevention as a level of concern in children (CDC, 2005). The USEPA recommends limiting a child's exposure to lead in soil such that there is no more than a five percent probability of a child exceeding the 10 µg/dL blood lead level of concern (USEPA, 1994b; 1998).

The risks associated with lead exposures should be evaluated based on the latest information available from the USEPA's Technical Review Workgroup (TRW) for lead. The TRW has developed approaches, such as the Integrated Exposure Uptake Biokinetic (IEUBK) Model and the Adult Lead Model, for evaluating exposures to lead that are protective of human health. See the Issue Paper Final Standard Operating Procedures: Investigating and Managing Lead Risks at Navy Installations (DeGrandchamp, 2005) for more information on evaluating lead exposures.

8.7.3 Total Risk and Incremental Risk

The goal of the BHHRA is to provide regulators, stakeholders, and risk managers with an understanding of the potential incremental risks to human health posed by a specific site and to document the uncertainties that are necessary to put the risks into proper context (USEPA, 1991a). This goal is consistent with the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which states that the BHHRA should "characterize the current and potential threats to human health and the environment that may be posed by contaminants migrating to groundwater or surface water, releasing to air, leaching through soil, remaining in soil, and bioaccumulating in the food chain" (Federal Register, 1990). Incremental risks are the risks associated with exposure to chemicals related to a specific site and do not include other chemical exposures such as exposure to automobile exhaust. Total risks include the risks associated with exposures in the environment regardless of whether or not they are associated with the site under evaluation. The key point is that incremental risks differ from total risks and that only incremental risks should be evaluated at sites.

8.7.4 SUMMARIZING THE RISKS

The Risk Characterization section is the most important section of the BHHRA report because it summarizes the results of the assessment. The risk characterization discussion should include the following components, as appropriate.

- **Risk Information**
  - present the magnitude of the cancer risks and noncancer HIs relative to the regulatory benchmarks (e.g., the cancer risk range of 1×10^{-4} to 1×10^{-6} and a noncancer HI of 1) for each location and receptor.
  - identify chemicals of concern (COCs), exposure pathways, and media responsible for the majority of the risks.
  - segregate noncarcinogenic hazard indices by endpoint or critical effect if the total HI is greater than 1.
- **Exposure and Toxicity Information**
  - identify unique characteristics of the exposed populations that may be useful to decision makers (e.g., sensitive subpopulations in the area).
  - summarize the results of site-specific health studies, when available.
  - present the number of chemicals for which toxicity information was not available (USEPA, 1989).

In many cases, some of the information identified above may not be included in the BHHRA because it is not pertinent to the site being evaluated. The principle that should be adhered to is that the risk characterization section of the report should effectively identify and highlight noteworthy risk conclusions (USEPA, 1995b).

8.8 Uncertainty Analysis

8.8.1 PURPOSE OF THE UNCERTAINTY ANALYSIS

The purpose of the uncertainty analysis is to present an evaluation of the uncertainties that enter the risk assessment at each step of the process in order for regulators, stakeholders, and risk managers to put the risks in proper context. The risks presented in BHHRAs are conditional estimates, based on a number of assumptions about exposure and toxicity given a particular land use scenario. Uncertainties are introduced to a risk assessment because a range of values could be used for each assumption, but only a few actually are. Consistent with USEPA policy, more conservative (i.e., upper bound) values are generally chosen for each parameter, while other values (i.e., values closer to the central tendency) may be more representative of site-specific conditions (USEPA, 1989). Choosing upper bound values for each parameter typically results in overly conservative risks that do not reflect site-specific conditions. Uncertainties are used to "bracket" the range of risks that could result from choosing alternate values for the parameters used in calculating risks. USEPA guidance for Risk Characterization states that, "Particularly critical to full characterization of risk is a frank and open discussion of the uncertainty in the overall assessment and in each of its components" (USEPA, 1995b). There are several key reasons why uncertainty should be discussed in the BHHRA:

- risk characterization involves the integration of a variety of different types of information. It is important to communicate the uncertainties associated with the different types of information in order to provide a context for evaluating the overall results;

- in order for a risk manager or stakeholder to evaluate a BHHRA, the magnitude of the uncertainties in the evaluation must be understood; and

- discussions of the uncertainties in a BHHRA will help risk managers evaluate the need for collecting additional information (USEPA, 1995b).

8.8.2 General Approaches for Performing An Uncertainty Analysis

An uncertainty analysis for a BHHRA can take on many forms depending on the complexities of the site. The types of uncertainty analyses that are typically performed as part of a BHHRA are as follows.

- **Qualitative** – A qualitative uncertainty analysis for a BHHRA is the most common type of uncertainty analysis. The relative direction and magnitude of the uncertainty associated with the key assumptions/parameters used to calculate the risks are identified, usually in table form, based on the professional judgment of the risk assessor. This approach highlights the key uncertainties and attempts to provide some measure of the potential uncertainty and related impact on the site risk estimates.

- **Semi-Quantitative** – A semi-quantitative uncertainty analysis for a BHHRA is less common than the qualitative uncertainty analysis. This approach is used to evaluate the sensitivity of the risks to key model parameters (e.g., exposure factors) by recalculating the model with alternative assumptions. This provides information on the plausible upper and lower bounds of the risk estimates.

- **Quantitative** – A quantitative uncertainty analysis for a BHHRA is relatively uncommon. This approach is similar to the Semi-Quantitative approach, however more sophisticated statistical techniques (e.g., Monte Carlo Simulation) are used to evaluate/quantify uncertainty. The advantage of this approach is that a continuous distribution of risk, rather than an upper and lower bound distribution of risk, is developed. In addition, key issues, such as correlations between model parameters can be accounted for in the statistical evaluation. See Chapter 9 – Other Tools: Using Probabilistic Risk Assessment to Further Characterize Risks for more detailed information.

Each approach for evaluating uncertainty should include a discussion of site-specific uncertainties and uncertainties inherent to the risk assessment process. Examples of each are presented below. Table 8.6 presents a sample format for presenting uncertainties.

- **Examples of Site-Specific Uncertainties**:
  - sampling methods;
  - analytical methods;
  - representativeness of the EPCs;
  - representativeness of the exposure scenarios, pathways, and parameters;
  - land use assumptions;
  - fate and transport models; and

- the availability of toxicity values by route of exposure (i.e., how many COPCs had toxicity values from Tier 1 sources).

- **Examples of Uncertainties Inherent to the Risk Assessment Process**:

  - extrapolating from animal studies to human toxicity;

  - using dose response information from homogeneous animal populations or healthy human populations to predict effects that may occur in the general population, including sensitive subpopulations;

  - high-to-low-dose extrapolation methods used to develop toxicity values;

  - lack of chemical-specific dermal toxicity values; and

  - synergistic or antagonistic effects associated with multiple chemical exposure.

Table 8.6 – Example of a Summary of Uncertainties in the Baseline Human Health Evaluation

Source of Uncertainty	Direction[a]	Magnitude[b]	Action or Result
Data Evaluation and Reduction			
Identification of COPCs present in soil	+/-	0	Used site-specific information to develop sampling work plan and to focus sampling efforts.
Quality of analytical data	+/-	0	Used quality-assured data in evaluation.
Exposure Assessment			
Attenuation or enrichment of chemical concentrations in soil	+/-	2	Assumed that no attenuation or enrichment of soil concentrations occurs over time. This may result in an underestimation or overestimation of the risks.
Exposure assumptions	+/-	2	Used site-specific and USEPA Standard Default Exposure Factors in the evaluation.
Experimental dermal absorption rates	+/-	2	Used experimentally-derived dermal absorption rates to evaluate dermal contact with soil.
Toxicity Assessment			
Failure to include all chemicals because of lack of USEPA approved toxicity values	-	3	Results in an underestimation of the risks. Oral RfDs were available for 10 of the 25 COPCs, and Inhalation RfDs were available for seven of the 25 COPCs. Oral slope factors were available for eight of the 25 COPCs and inhalation slope factors were available for seven of the 25 COPCs.
Extrapolation from animal studies to human toxicity	+	3	Used the USEPA's conservative approach of incorporating safety factors and upper-bound estimates.
Lack of chemical-specific dermal toxicity values	-	1	Used oral toxicity values as surrogates for dermal toxicity values, in order to evaluate risks associated with dermal exposure. This may result in an underestimation of the risks.
Using dose-response information from homogeneous animal populations or healthy human populations, to predict effects that may occur in the general population, including sensitive subpopulations.	-	1	This may underestimate the risks.
Risk Characterization			
Assumed that health effects of chemicals are additive	+/-	3	Assumed that health effects of chemicals are additive in risk calculations. Antagonistic and synergistic effects of chemical mixtures were not evaluated.

[a]Direction of Effect + = May result risks that are overly conservative
- = May result in risks that are not conservative

[b]Magnitude of Effect 0 = Negligible impact on risk calculations
1 = Small effect on risks calculations
2 = Medium effect on risk calculations

3 = Large effect on risk calculations

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U.S. Navy Human Health Risk Assessment Guidance

Chapter 9 – Other Tools: Using Probabilistic Risk Assessment to Further Characterize Risks

Table of Contents

List of Tables

List of Figures

ACRONYMS AND ABBREVIATIONS

BHHRA	Baseline Human Health Risk Assessment
HHRA	Human Health Risk Assessment
MCA	Monte Carlo Analysis
PDF	Probability Density Function
PRA	Probabilistic Risk Assessment
RME	Reasonable Maximum Exposure
RPM	Remedial Project Manager
USEPA	United States Environmental Protection Agency

9.0 Introduction

This chapter presents a technique for more thoroughly evaluating risk, and evaluating and characterizing the uncertainty and variability associated with risks presented in a baseline human health risk assessment (BHHRA). While a BHHRA uses a single value or point estimate (also called a deterministic approach) to calculate risks, a probabilistic risk assessment (PRA) uses a range of estimates to calculate the risks. This results in a more detailed evaluation that determines a range of risks and highlights the predominant contributing factors (United States Environmental Protection Agency [USEPA], 2001).

Performing a PRA is one way to accomplish the USEPA's goal of using several descriptors of risk. Most BHHRAs use only a single descriptor of risk (usually the reasonable maximum exposure [RME] scenario) (USEPA, 1995). A variety of PRA modeling techniques can be used to characterize the variability and uncertainty in risk. Monte Carlo Analysis (MCA), is one of the most common probabilistic methods used for human health risk assessment (HHRA) purposes. While a PRA can be a useful tool to characterize and quantify variability and uncertainty in risk assessments, it is not appropriate for every site (USEPA, 2001). Remedial Project Managers (RPMs) should consider the option of developing PRAs on a case-by-case basis.

9.1 Purpose and Objectives

A risk assessment performed using probabilistic methods is very similar in concept and approach to the traditional deterministic method used in the BHHRA, with the main difference being the methods used to incorporate uncertainty and variability into the risk estimate (USEPA, 2001). In the point estimate approach (i.e., BHHRA), a single numerical value (i.e., point estimate) is chosen for each variable. For example, point estimates may include a drinking water ingestion rate of two L/day and a body weight of 70 kg for an adult. Based on the choices that are made for each individual variable, a single estimate of risk is calculated. This differs from the PRA approach where a range of values is used as an input to the risk equation. Consequently, a range of risks is calculated based on various combinations of the input values.

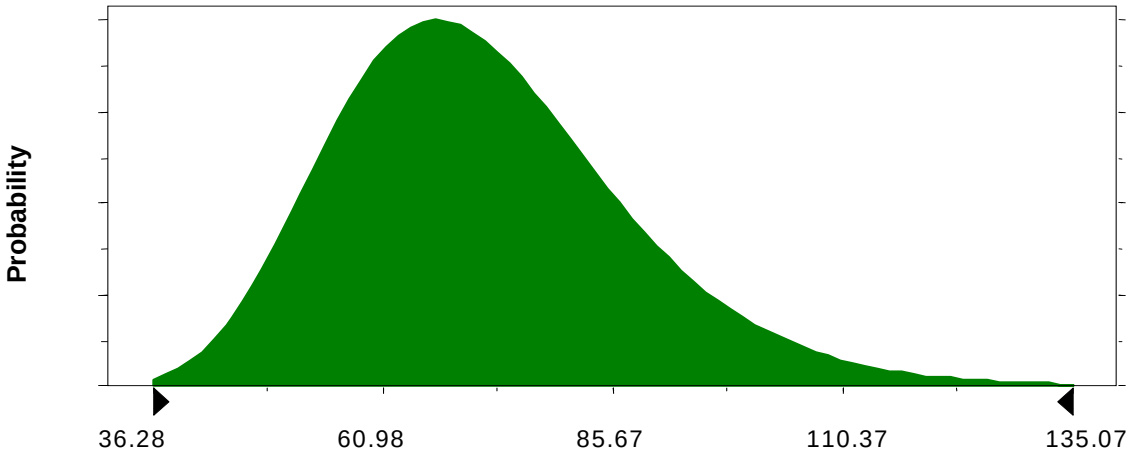
9.1.1 Goal of Probabilistic Risk Assessment

The primary goal of a PRA analysis is to characterize the uncertainty and variability in the estimates of exposure or risk. A secondary goal is to identify key sources of this uncertainty and variability, and to quantify their relative contribution to the overall variance of the BHHRA results (USEPA, 1997). A PRA can also be used to determine risk.

9.1.2 Probability Density Functions

PRA is a way to evaluate thousands of "what if" scenarios. The same calculation is performed over and over, with various combinations of input parameters. The input parameters are randomly selected from a range of values, also called a probability density function (PDF). PDFs are functions representing the distribution of a variable. The density (i.e., the height of the graph curve) at a point refers to the probability that the variable will have a specific value. Figure 9.1 presents an example of a PDF.

Figure 9.1 – Example Probability Density Function



Explanatory Text for Figure 9-1*. In an exposure calculation that includes exposure parameter X, a single value is randomly selected from the distribution. This process occurs for each parameter for which there is a distribution (each calculation is called an iteration). Each iteration of a PRA analysis represents a combination of exposure and toxicity variables. A convenient aid to understanding the PRA approach for quantifying variability is to visualize each iteration as representing a single individual and the collection of all iterations as representing a population. In general, each iteration should represent a plausible combination of input values, which may require using bounded or truncated probability distributions (USEPA, 2001).*

9.1.3 Uncertainty and Variability

An essential concept in a PRA is the distinction between "uncertainty" and "variability." Efforts to clearly distinguish between uncertainty and variability are important for both risk assessment and risk communication (USEPA, 2001). Uncertainty occurs because of a lack of knowledge. In other words, uncertainty is an expression of the confidence we have that a parameter accurately reflects the population. For example, the uncertainty associated with a study of body weights that included 100 individuals is much higher than that from a study that included 10,000 individuals. Consequently, a risk assessment conducted using a body weight value based on the 10,000-individual study would have less uncertainty than using a body weight value from the 100-person study. Generally, more individuals included in a study results in more confidence in the findings. Theoretically, it is possible to eliminate uncertainty by expanding the study to include all members of a population.

Variability, on the other hand, is an expression of the range of differences between individuals observed for a given population. For example, the mean body weight of a study of 10,000 individuals might be 71.7 kg but the range (i.e., variability) might be from 37 – 135 kg with a standard deviation of 15.9 kg. It is not possible to eliminate variability in heterogeneous populations even if there is no uncertainty.

9.2 Differences Between Deterministic Baseline Human Health Risk Assessments and Probabilistic Risk Assessments

The risks from a single chemical in a BHHRA are determined by combining a number of different values to result in a single estimate of exposure or risk. PRA differs from the point estimate approach by

allowing a value to be chosen from a distribution of plausible values for each exposure variable. Thus, the output of a PRA is a range or distribution of risks experienced by the various members of the population of concern (USEPA, 2001). The advantages and disadvantages of deterministic risk assessments and PRAs are presented in Table 9.1.

Table 9.1 – Advantages and Disadvantages of Deterministic and Probabilistic Risk Assessments

Type of Risk Assessment	Advantages	Disadvantages
Deterministic Risk Assessment	♦ Central tendency and RME estimates of risk provide a semi-quantitative measure of variability ♦ Employs a consistent approach and standard reporting methods. ♦ Requires less time to complete (than a PRA). ♦ Can be easily understood and communicated. ♦ Is based on standard equations and exposure assumptions. ♦ Is consistent with historical risk assessment practice. ♦ Can be used as a screening tool. ♦ Calculations do not require advanced software.	♦ Results in a single-point estimate of risk, which may be viewed as "the answer." ♦ Provides little insight into the range of risks. ♦ Lacks information about variability in the potentially-exposed population. ♦ Addresses uncertainty in a qualitative manner. ♦ Does not provide a measure of the probability that risk exceeds a regulatory level of concern. ♦ Does not provide a level of confidence in the risk estimates.
Probabilistic Risk Assessment	♦ Provides a range of risk estimates. ♦ Provides quantitative information on variability and uncertainty. ♦ Identifies the drivers of risk and exposure by quantitative sensitivity analysis. ♦ Provides more information to decision makers than deterministic method. ♦ Can help to identify data gaps. ♦ Provides confidence limits on the risk estimates. ♦ Uses a wide variety of site-specific information. ♦ Can make more complete use of available data.	♦ Requires investment of time and resources for additional data collection and review. ♦ Requires good information on PDFs. ♦ Possesses less transparency and clarity than a deterministic risk assessment. ♦ May convey false sense of accuracy unless distributions accurately reflect site. ♦ Makes risk management decision more challenging. ♦ Requires extensive use of statistics, possibly limited by available software. ♦ Concepts and approaches may be unfamiliar, causing potential for inadvertent error. ♦ More difficult to communicate the results to regulators, stakeholders, and risk managers.

A key step when performing a PRA is the involvement of regulators and stakeholders early in the process. People who should be involved in the PRA process include USEPA risk assessors and managers, members of the public, representatives from state or county environmental or health agencies, other federal agencies (e.g., health agencies, Natural Resource Damage Assessment trustees, etc.), tribal government representatives, and representatives from federal facilities (Department of Defense, Department of Energy, etc.). PRAs are not routinely performed at sites. Therefore, it is important to

determine why a PRA would be beneficial and how the information that is generated from the PRA will be used to help make risk management decisions.

9.3 When Should Probabilistic Risk Assessments be Performed?

There is no discrete set of criteria for determining when a PRA should be performed at a site. PRAs generally require more time, resources, and expertise on the part of the risk assessor, reviewer, and risk manager than traditional deterministic risk assessments (i.e., BHHRAs). In general, PRAs should only be considered at sites where the remediation costs are high and the savings offered by performing a PRA are significant. Factors that should be considered to determine if a PRA is warranted or feasible at a site are explained below.

- **Cost of Remediation** – If the remediation costs are high, then the level of effort required to perform a PRA might be appropriate.

- **Results of the BHHRA** – The results of the BHHRA should be evaluated to determine if a PRA will provide regulators, stakeholders, and risk managers with more information about the uncertainty and variability associated with the risks presented in the BHHRA. For example, if a few chemicals and exposure pathways drive the risks presented in the BHHRA, then it might be appropriate to develop a PRA to specifically evaluate the uncertainty and variability associated with these risks.

- **Availability of Site-Specific Exposure Data** – If site-specific exposure data (e.g., frequency of exposure, ingestion rates, etc.) are available, then PDFs could be incorporated into the evaluation which would increase the likelihood of acceptance by regulators and stakeholders.

- **Regulators and Stakeholders** – The views of regulators and stakeholders on PRAs should be considered when determining whether or not a PRA should be performed. If regulators or stakeholders are firmly against the use of a PRA, then its value in the risk assessment process may be diminished.

9.4 USEPA Policy on Probabilistic Risk Assessment

The USEPA guidance for performing PRAs states that:

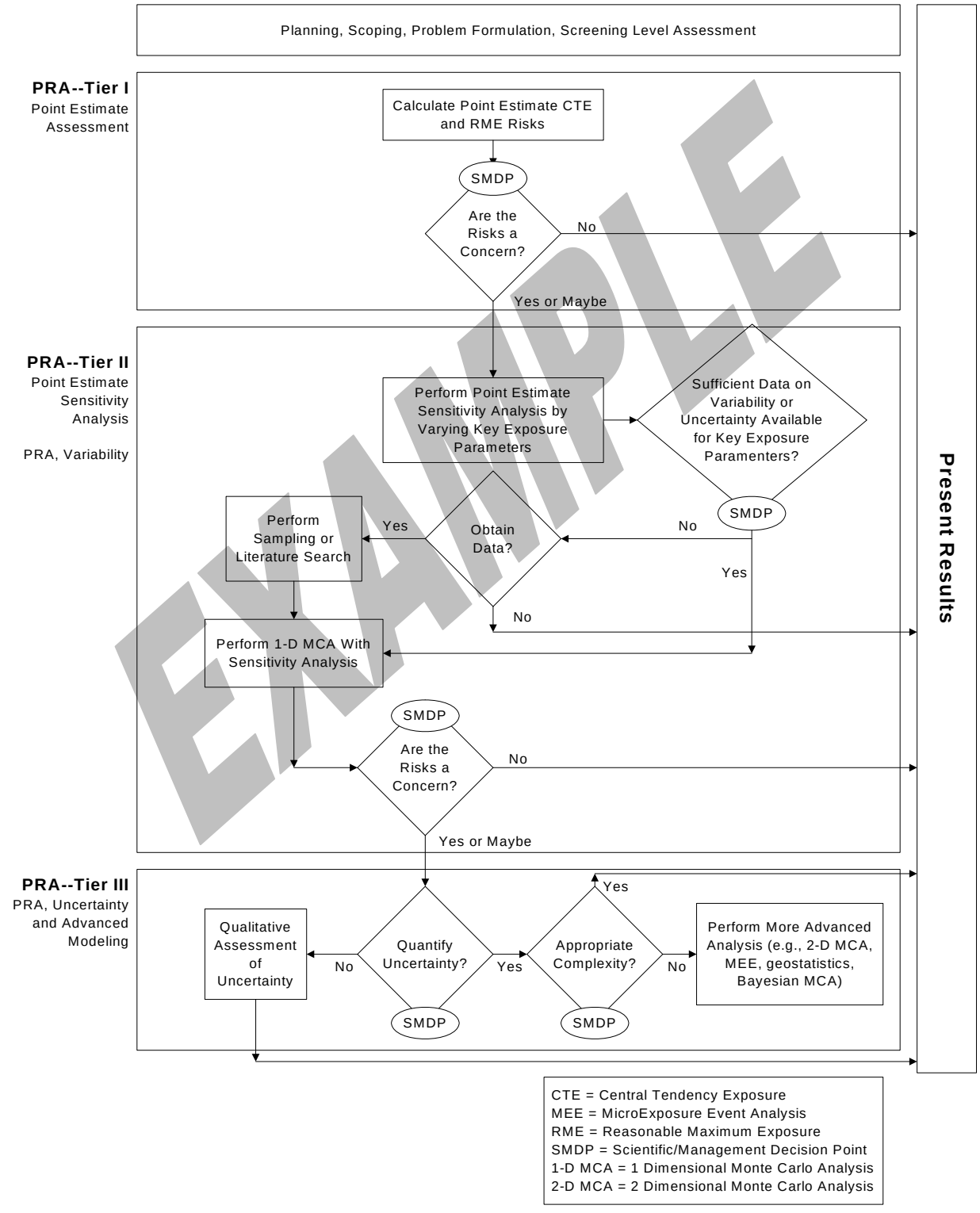
- the USEPA will not evaluate probabilistic analysis without review and approval of a work plan;

- a tiered approach should be used to determine the level of complexity appropriate for the risk assessment and whether or not a PRA should be performed (see Figure 9.2 for an example of a tiered PRA approach);

- PRAs should include single-point (deterministic) RME estimates, and central tendency estimates; and

- PDFs should not be used to represent toxicity values in the Monte Carlo simulation (USEPA, 2001).

Figure 9.2 – Example Tiered Approach for Conducting Probabilistic Risk Assessments



In the *Guiding Principles for Monte Carlo Analysis* (USEPA, 1997) the USEPA has also established the following conditions for Agency review and evaluation of PRAs.

- The purpose and scope of the assessment should be clearly articulated in a "problem formulation" section that includes a full discussion of any highly exposed or highly susceptible subpopulations evaluated (e.g., children, the elderly). The questions the assessment attempts to answer should be discussed and the assessment endpoints should be well defined.

- The methods used for the analysis (including all models used, all data upon which the assessment is based, and all assumptions that have a significant impact upon the results) should be documented and easily located in the report. This documentation should include a discussion of the degree to which the data used are representative of the population under study. Also, this documentation should include the names of the models and software used to generate the analysis. Sufficient information should be provided to allow the results of the analysis to be independently reproduced.

- The results of sensitivity analyses should be presented and discussed in the report. Probabilistic techniques should be applied to the chemicals, pathways, and factors of importance to the assessment, as determined by sensitivity analyses or other basic requirements of the assessment.

- The presence or absence of moderate to strong correlations or dependencies between the input variables should be discussed and accounted for in the analysis, along with the effects these have on the output distribution.

- Information for each input and output distribution should be provided in the report. This includes tabular and graphical representations of the distributions (e.g., PDF and cumulative distribution function plots) that indicate the location of any point estimates of interest (e.g., mean, median, 95th percentile). The selection of distributions should be explained and justified. For both the input and output distributions, variability and uncertainty should be differentiated where possible.

- The numerical stability of the central tendency and the higher end (i.e., tail) of the output distributions should be presented and discussed.

- Calculations of exposures and risks using deterministic (i.e., point estimate) methods should be reported. Providing these values will allow comparisons between the probabilistic analysis and previous risk assessments. Further, deterministic estimates may be used to answer scenario specific questions and to facilitate risk communication. When comparisons are made, it is important to explain the similarities and differences in the underlying data, assumptions, and models.

- Since fixed exposure assumptions (e.g., exposure duration, body weight) are sometimes embedded in the toxicity values (e.g., reference doses and cancer slope factors), the exposure estimates from the probabilistic output distribution should be aligned with the toxicity values.

These conditions reflect the good scientific practices of clarity, consistency, transparency, reproducibility, and the use of sound methods in risk assessment.

9.5 References

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U.S. Navy Human Health Risk Assessment Guidance

Chapter 10 – Tier III Risk Evaluation of Remedial Alternatives

Table of Contents

List of Tables

List of Figures

ACRONYMS AND ABBREVIATIONS

ARAR	Applicable or Relevant and Appropriate Requirements
BHHRA	Baseline Human Health Risk Assessment
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COC	Chemical of Concern
CSM	Conceptual Site Model
CTE	Central Tendency Exposure
EC	Engineering Controls
FRL	Final Remediation Level
FS	Feasibility Study
IC	Institutional Controls
LTM	Long-Term Monitoring
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
PRA	Probabilistic Risk Assessment
PRG	Preliminary Remediation Goal
RA	Remedial Action
RBSC	Risk-Based Screening Concentration
RD	Remedial Design
RERA	Risk Evaluation of Remedial Alternatives
RI/FS	Remedial Investigation/Feasibility Study
ROD	Record of Decision
RME	Reasonable Maximum Exposure
RPM	Remedial Project Manager
RSL	Regional Screening Level
SARA	Superfund Amendments and Reauthorization Act
USEPA	United States Environmental Protection Agency

10.0 Introduction

A Tier III Risk Evaluation of Remedial Alternatives (RERA) is initiated when the results of the Tier I or Tier II assessment indicate that:

1.) site-related chemicals of concern (COC) pose unacceptable risks; or

2.) site-related COCs pose acceptable risks with implementation of institutional controls (ICs) or engineering controls (ECs).

The ultimate goal of the remedy selection process is to choose a remedy that reduces, controls, or eliminates the risks to human health and the environment. RERAs are one component of this process. Information from RERAs is used in conjunction with other information, such as assessments of technical feasibility, identification of Applicable or Relevant and Appropriate Requirements (ARARs), determination of costs, and implementability, to select a remedy for a site. The process of evaluating remedial alternatives begins in the development and screening stage of the Feasibility Study (FS), and may extend to Site Closeout and Long-Term Monitoring (LTM).

10.1 Purpose and Objectives

The purpose of RERAs is to provide Remedial Project Managers (RPMs) with a qualitative and/or quantitative assessment of the potential short-term and long-term health risks associated with remedial alternatives. These alternatives are evaluated, using the nine-remedy selection criteria identified in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), to select the remedy for a site.

10.2 Elements of Tier III

The approach for performing RERAs is consistent with the approach for evaluating risks via a Tier I Risk-Based Screen and a Tier II Baseline Human Health Risk Assessment (BHHRA): exposure and toxicity information are combined to provide estimates of risk. However, RERAs differ from Tier I and Tier II evaluations in that:

- Typically, both short-term and long-term risk evaluations are performed. Short-term risks are those that occur during implementation of a remedial alternative (e.g., risk associated with inhalation of fugitive dust during excavation of impacted soil at a site). Long-term risks include those that remain after the remedial action has been completed. They also consider the alternative's ability to provide protection over time. These risks are often called "residual" risks.

- The exposed populations, exposure pathways, and exposure durations may be different than those that were evaluated in the Tier I and Tier II assessment. For example, remediation workers and the surrounding community will typically be evaluated in a RERA.

- Short-term exposures (i.e., days, weeks, months, or a few years) are typically evaluated and may require short-term (i.e., sub-chronic and acute) toxicity values.

- Additional media and chemicals may be evaluated in the RERA that were not evaluated in the original Tier I or Tier II assessments. For example, there may be new chemicals emitted to air from an air stripper that is used to remediate groundwater contamination.

- RERAs are often qualitative and the level of effort will vary with each remedial alternative and with each site being evaluated. For example, in some instances only a qualitative evaluation

of the risks may be necessary. In other instances a quantitative evaluation of risks using preliminary remediation goals (PRGs) or a deterministic risk assessment may be necessary.

10.3 When RERAs are Performed

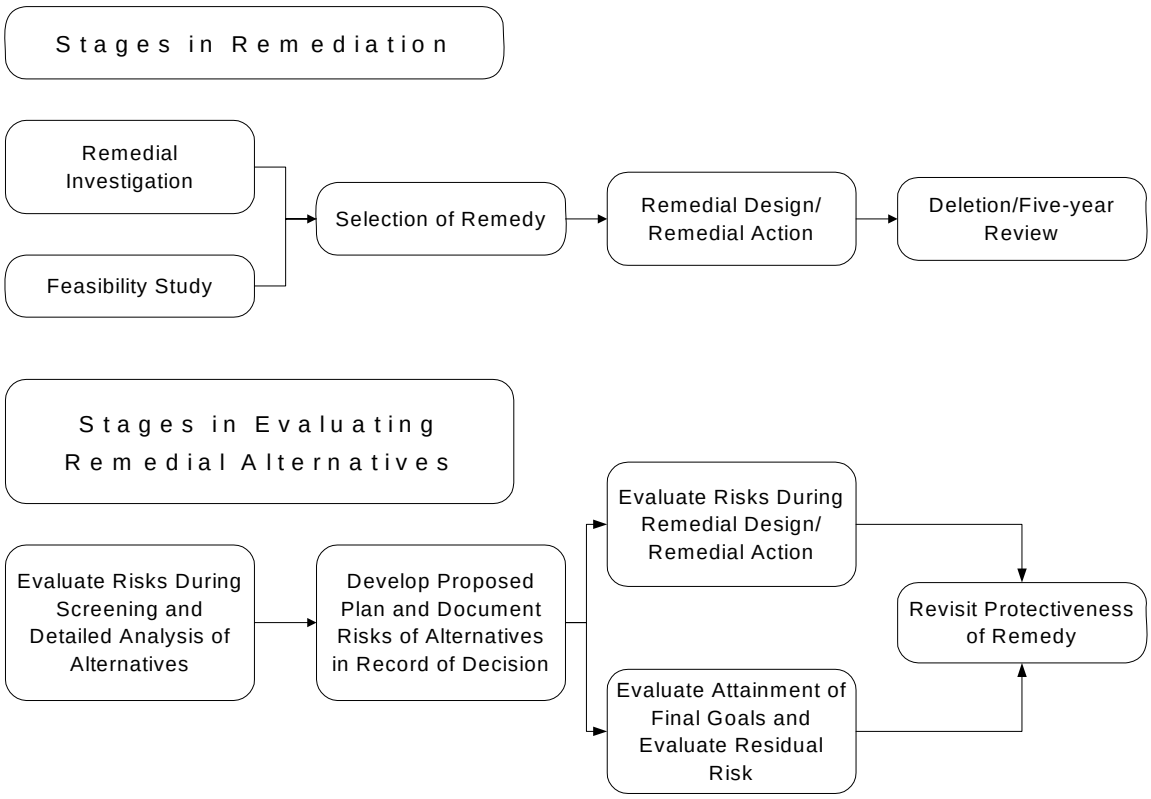
10.3.1 Evaluating Remedial Alternatives

Remedial alternatives are evaluated throughout the remedy selection process. Consequently, RERAs may be conducted at various stages including:

- Identification and Screening of Technologies and Alternatives (part of the FS);
- Detailed Analysis of Alternatives (part of the FS);
- Development of the Proposed Plan;
- Development of the Record of Decision (ROD);
- Remedial Design (RD);
- Remedial Action (RA); and
- Five-year Review.

Figure 10.1 presents an overview of the relationship between the remedy selection process and RERAs.

Figure 10.1 – Relationship Between the Remedy Selection Process and Risk Evaluation of Remedial Alternatives



10.3.2 COMPLEXITY OF RERAS

In contrast to Tier I and Tier II risk evaluations that are performed during the site investigation phases of a project (and are almost always quantitative), RERAs are "In most cases, a qualitative rather than a quantitative evaluation of both long-term and short-term risks..." (United States Environmental Protection Agency [USEPA], 1991a). Some RERAs may be short, qualitative evaluations of risk, others may be detailed, quantitative evaluations of risk, or they may be a combination of both. Therefore, the complexity of RERAs should be commensurate with the complexity of the remedial alternatives, and the concentrations and relative toxicity of the chemicals being remediated (USEPA, 1991a). For example, in the case where excavation of contaminated soil was identified as a potential remedial alternative the short-term risk evaluation may involve:

- An assessment of the potential for excavation activities that may result in transport of site-related contaminants to off-site areas via wind-blown particulates; and
- An assessment of the potential risks to remediation workers.

In this instance the short-term risk evaluation may include either modeling of potential particulate concentrations based on wind direction, wind speed and other site-specific information or may involve measurement of particulate concentrations during excavation activities and comparison of these concentrations to PRGs. The long-term risk evaluation may include a comparison of residual (i.e., post-remediation) soil concentrations to PRGs.

The following two factors are used to determine whether or not a qualitative or quantitative analysis should be performed for each stage of the RERA process:

1.) whether or not the relative short-term or long-term effectiveness of alternatives is an important consideration; and

2.) the perceived risk associated with the alternative. The perceived risk includes both the professional judgment of the site engineers and risk assessors and the concerns of the neighboring communities. The USEPA has identified the following factors that generally lead to a higher perceived risk:

- close proximity of populations;
- presence of highly- or acutely-toxic chemicals;
- technologies with high release potential, either planned or accidental;
- technologies where the amount and identity of releases are uncertain, (e.g., releases that might exist with use of certain innovative technologies);
- multiple chemicals and/or exposure pathways affecting the same individuals;
- multiple releases occurring simultaneously, such as the case when there are several different remedial technologies that operate in close proximity; and
- releases occurring over long periods of time (USEPA, 1991a).

The USEPA recommends that if these or other factors lead to a higher perceived risk, then a more quantitative evaluation of short-term or long-term risks may be helpful in the decision-making process. Tables 10.1 and 10.2 present the USEPA's recommendations on whether or not a RERA should be qualitative or quantitative for each step in the remedy selection process, for short-term and long-term risks, respectively.

Table 10.1 – Summary of Short-Term Risk Evaluations of Remedial Alternatives (USEPA, 1991a)

Stage in the Remedial Process	Type of Evaluation	Primary Purpose
Screening of Alternatives	Qualitative	To identify (and eliminate from consideration) alternatives with clearly unacceptable short-term risks.
Detailed Analysis of Alternatives	Qualitative or Quantitative	To evaluate the short-term risks, of each alternative, to the community and on-site remediation workers during implementation so that these risks can be compared among alternatives.
Proposed Plan	Qualitative or Quantitative	To refine previous analyses, as needed, based on newly-developed information.
Record of Decision	Qualitative or Quantitative	To document short-term risks that may occur during remedy implementation.
Remedial Design	Qualitative or Quantitative	To refine previous analyses, as needed, and identify the need for ECs or other measures to mitigate risks.
Remedial Action	Quantitative	To ensure protection of workers and community by monitoring emissions or exposure concentrations, as needed.
Five-year Review	Generally not applicable	(Generally not applicable because all of the potential risks would be long-term in nature.)

Note: Short-term risks are those that occur during implementation of the remedial action. In some cases short-term risks may occur over a number of years.

Table 10.2 – Summary of Long-Term Risk Evaluations of Remedial Alternatives (USEPA, 1991a)

Stage in the Remedial Process	Type of Evaluation	Primary Purpose
Screening of Alternatives	Qualitative	To identify (and eliminate from consideration) alternatives with clearly unacceptable long-term risks.
Detailed Analysis of Alternatives	Qualitative or Quantitative	To evaluate each alternative's long-term residual risk and its ability to provide continued protection, over time, so that these risks can be compared to other remedial alternatives.
Proposed Plan	Qualitative or Quantitative	To refine previous analyses, as needed, based on newly-developed information.
Record of Decision	Qualitative or Quantitative	To document risks that may remain after completion of remedy and determine need for five-year reviews.
Remedial Design	Qualitative or Quantitative	To refine previous analyses, as needed, and identify need for ECs or other measures to mitigate risks.
Remedial Action	Quantitative	To evaluate whether or not remediation levels specified in the ROD have been attained, and to evaluate residual risk after completion of remedy to ensure protectiveness.
Five-year Review	Qualitative or Quantitative	To confirm that a remedy (including any ECs or ICs) remains operational and functional and to evaluate whether or not cleanup standards are still protective.

Note: Long-term risks include those that remain after implementation of the remedy has been completed and also consider the alternative's ability to provide protection over time.

At sites where sediments are being evaluated, the Navy Policy on Sediment Site Investigation and Response Action (USNAVY, 2002) is a good resource and should be consulted for the general approach used to develop a RERA.

10.4 Decision Criteria

There are nine decision criteria used to evaluate each remedial alternative and ultimately decide on which one(s) will be used at a site. The information provided by RERAs is a component of these nine criteria, and is present in the criteria that address protection of human health and the environment, short-term effectiveness, and long-term effectiveness. The nine decision criteria are discussed below.

10.4.1 Nine Decision Criteria

The results of RERAs are used by RPMs, in conjunction with other information, to evaluate each remedial alternative with respect to nine evaluation criteria identified in the NCP [40 CFR 300.430(e)(9)(iii)]. These criteria are presented in Table 10.3.

Table 10.3 – Nine Decision Criteria Used to Evaluate Remedial Alternatives		
Category	**Regulatory Importance**	**Specific Criteria**
Threshold Criteria	Must be met for a remedial action to be acceptable	1) overall protection of human health and the environment 2) compliance with ARARs (unless a waiver is obtained)
Balancing Criteria	Used to help rank the remedial alternatives that meet the Threshold Criteria	3) long-term effectiveness and permanence 4) reduction of toxicity, mobility, or volume 5) short-term effectiveness 6) implementability 7) cost
Modifying Criteria	Criteria that may result in the selection of a less desirable (i.e., less desirable in terms of the Threshold and Balancing Criteria) remedial alternative as the remedy for a site	8) state acceptance 9) community acceptance

The alternatives are analyzed individually against each criterion; and then compared against one another, to determine their respective strengths and weaknesses and to identify the key trade-offs that must be balanced for the site. The results of the detailed analysis are summarized so that an appropriate remedy may be selected.

10.4.2 Background Information on Remedy Selection Criteria

Threshold Criteria

The goal of the remedy selection process is to choose alternative(s) that are protective of human health and the environment, that maintain protection over time, and that minimize untreated waste. Section 121 of the Superfund statute (i.e., Comprehensive Environmental Response, Compensation, and Liability Act [CERCLA]) established two principal requirements for the selection of remedies. Remedies must:

1.) protect human health and the environment; and

2.) comply with ARARs unless a waiver is justified (USEPA, 1997).

The remedy selection process links the analysis of site-cleanup alternatives with the documentation of the selected remedy.

Balancing Criteria

Once a limited number of viable alternatives have been developed and ARARs have been identified, the alternatives are then evaluated using the five primary Balancing Criteria. The five criteria and their associated components are presented in Table 10.4.

Table 10.4 – Balancing Criteria for Evaluating Remedial Alternatives (USNAVY, 2006)

Criteria	Explanation
Long-term effectiveness and permanence	♦ Residual risk from untreated waste or treatment residuals remaining after remediation. ♦ Adequacy and reliability of protective measures – including reliance on land disposal, potential need to replace, and risk posed should components need replacement.
Reduction of toxicity, mobility, or volume through treatment	♦ Processes used. ♦ Amount of hazardous substances, pollutants, or chemicals that are destroyed, treated, or recycled. ♦ Degrees of reduction in toxicity, mobility, and volume. ♦ Irreversibility of treatment. ♦ Type, quantity, persistence, toxicity, and mobility of the remaining chemicals and their propensity for bioaccumulation. ♦ Reduction in principal threats at the site.
Short-term effectiveness	♦ Community impacts during implementation. ♦ Impact on workers and the effectiveness and reliability of protective measures. ♦ Environmental impacts during implementation and the effectiveness and reliability of mitigating measures.
Implementability	♦ Technical feasibility including technical difficulties and unknowns in construction and operation, reliability, ease of replacement or augmentation, and ability to monitor effectiveness. ♦ Administrative feasibility, including the need to coordinate with other agencies and ability and time required for permits and approvals. ♦ Availability of services, materials, equipment, and specialists.
Cost	♦ Indirect and direct capital costs. ♦ Annual operation and maintenance. ♦ Net present value.

Modifying Criteria

The two other criteria that are used to evaluate potential alternatives are state and community acceptance. State and local community acceptance may not be evaluated fully until the proposed plan is published and public review is completed during the remedy selection step. State and community acceptance are important factors that may result in the selection of a less desirable (i.e., less desirable in terms of the Threshold and Balancing Criteria) remedial alternative for a site.

10.5 Development of Preliminary Remediation Goals and Final Remediation Levels

10.5.1 Preliminary Remediation Goals and Final Remediation Levels

PRGs are developed to quantify the standards (i.e., chemical-specific media concentrations) that selected remedial alternatives must meet, to achieve the Threshold Criteria stipulated in the NCP (i.e., overall protection of human health and the environment and compliance with ARARs). The NCP [300.430(e)(2)] states that:

> Remediation goals shall establish acceptable exposure levels that are protective of human health and the environment and shall be developed by considering the following:
>
> (A) Applicable or relevant and appropriate requirements ..., and the following factors:
>
> (1) For systemic toxicants, acceptable exposure levels shall represent concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, incorporating an adequate margin of safety;
> (2) For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper-bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using the information on the relationship between dose and response. The 10^{-6} risk level shall be used as the point of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of multiple contaminants at a site or multiple pathways of exposure.

PRGs are developed early in the site evaluation process for each chemical and media of concern. These values are typically calculated based on a hazard quotient of 1 and a cancer risk of 1×10^{-6}. Tier IA default risk-based regional screening levels (RSLs) and Tier IB site-specific risk-based screening concentrations (RBSCs) may be used to develop PRGs (see Chapter 7 – Tier IA and Tier IB Risk-Based Screening for more information). However, when Tier IA default RSLs are used to develop PRGs, the conceptual site model (CSM) should be compared with the assumptions used to develop the RSLs, to ensure that they are consistent. If they are not, then site-specific PRGs should be developed (this approach is similar to developing site-specific RBSCs in Tier IB).

PRGs may be modified as additional information becomes available during the site evaluation process. For example, the results of the Tier II BHHRA are typically used to refine the PRGs based on site-specific factors (e.g., land use, exposure, and uncertainty). Cumulative risks (i.e., the risks associated with exposure to multiple chemicals and multiple media) are also considered and used to modify the PRGs to ensure that the cumulative risks at a site are consistent with the target risks identified in the NCP. Consequently, the PRGs developed early in the process may be adjusted downward (i.e., made more protective), to account for exposures to multiple chemicals and/or media. PRGs should be developed considering indirect exposure pathways such as transfer of contaminants from soil to groundwater and vapor intrusion, where the CSM indicates that these exposure pathways are complete.

Note: PRGs and RSLs/RBSCs are developed using similar approaches and assumptions, and yet their purposes are different. PRGs are chemical- and media-specific concentration goals for a site that are used during analysis and selection of remedial alternatives. PRGs are similar to RSLs and RBSCs in that they are developed based on conservative exposure assumptions and target risk goals. However, PRGs differ from RSLs and RBSCs in that they may be adjusted downward or upward based on site-specific information (e.g., cumulative risks associated with multiple chemical exposures, ARARs, etc.). RSLs and RBSCs are chemical- and media-specific concentrations used to determine whether or not a site poses a risk to human health. If it is determined that a site poses a risk to human health, then PRGs are developed, often initially based on the RSLs or RBSCs, to provide the remedial design staff with long-term target cleanup goals to assist in the selection of remedial alternatives.

Final remediation levels (FRLs) are chemical- and media-specific remediation levels that are to be attained at the site after implementation of the remedy is complete. FRLs are documented in the ROD for a site and are developed using the PRGs identified during the Remedial Investigation/Feasibility Study (RI/FS) process. However, it is important to note that regardless of the approach used to develop and refine the PRGs, the FRLs may differ substantially from the PRGs because of modifications resulting from consideration of uncertainties, technical limitations, exposure factors, as well as from all nine evaluation criteria outlined in the NCP. FRLs should be developed considering indirect exposure pathways such as

transfer of contaminants from soil to groundwater and vapor intrusion. FRLs also involve an element of risk management, in that the risk managers must agree what level of risk they feel is appropriate for the site. As such, when FRLs are based on site- and media-specific risk-based levels, the risk managers must interact with the risk assessors that are helping calculate these levels (see Chapter 12 – Risk Management for more information).

10.5.2 Key Considerations for Developing Preliminary Remediation Goals and Final Remediation Levels

Key factors that should be considered by RPMs when evaluating PRGs and potential FRLs are presented below.

- **Current and Future Land Use** – Land use plays an important part in developing PRGs and FRLs for a site. For example, risk-based PRGs for residential land use sites will typically be more protective (i.e., the chemical and media-specific concentrations will be lower) than risk-based PRGs for industrial land use sites. USEPA guidance states, "…the most appropriate future land use for a site should be selected so that the appropriate exposure pathways, parameters, and equations can be used to develop risk-based PRGs" (USEPA, 1991b). Consequently, residential land use should not be assumed for every site. Other land uses, such as industrial, recreational, and agricultural, should be used to develop PRGs and FRLs, if appropriate. For active installations, future land use assumptions should generally be based on current land use conditions. In instances where it is difficult to use current land use to predict future land use (e.g., a vacant lot), the RPM should consult base master-development plans and other land-use planning documents to assist in determining the most plausible future land use for a site. It is important to note that if the appropriate future land use for a site is not residential, then typically it may be necessary to implement ICs (e.g., a deed restriction) and perform LTM at the site.

- **Institutional Controls** – PRGs and FRLs should reflect ICs or ECs that are part of the remedy. For example, if a deed restriction is in place that limits land use to commercial purposes, then PRGs and FRLs should be based on a CSM that reflects this land use. Another example is an EC, such as a cap, that would eliminate or severely reduce potential exposure to COCs. The PRGs and FRLs should be based on a CSM that reflects the implementation and maintenance of the EC. Additional information about monitoring and enforcing LUCs is available from the Department of the Navy (USNAVY, 2003).

- **Site-Specific Background Concentrations** – Site-specific background concentrations of chemicals should be used during the Tier I and Tier II risk evaluations to eliminate chemicals that are present at or below background concentrations from further consideration in the risk assessment. However, in some situations this step may have been omitted. Therefore, it is important that the PRGs and FRLs are compared to background concentrations to ensure that they are not below background.

- **Multi-Media Fate and Transport Issues** – The CSM should be re-evaluated during the remedy selection process to determine if PRGs or FRLs need to be developed for media that may not have been evaluated, or were determined to not be of concern, in the Tier I or Tier II risk evaluations. For example, the results of the BHHRA may have indicated that, for a site with soil and groundwater issues, exposures to soil were of concern while exposures to groundwater were not of concern. In this instance, PRGs and FRLs would be developed for exposures to soil and not to groundwater. However, in some cases, potential migration of contaminants in soil to groundwater may be of concern and should be considered when developing the PRGs and FRLs for soil.

- **Risk Goals** – For chemicals lacking Maximum Contaminant Levels (MCLs) or non-zero Maximum Contaminant Level Goals (MCLGs), PRGs and FRLs should be established at concentrations that achieve 1×10^{-6} excess cancer risk or a hazard quotient of 1 (for noncarcinogens), modified as appropriate based on exposure, uncertainty, and technical feasibility factors. It should be noted, however, that the risk goals identified in the NCP, and further clarified in the USEPA Memo "*Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions"* (USEPA, 1991c), are not discrete values that, if exceeded, automatically indicate that remedial action is warranted at a site. For example, a site with a cumulative cancer risk greater than 1×10^{-4} may be considered protective of human health based on site-specific conditions and, therefore, remedial action would not be warranted. Conversely, in other situations a site with a cumulative cancer risk less than 1×10^{-4} may not be considered protective of human health and, therefore, remedial action would be warranted. The target risk levels that are appropriate for a site should be agreed upon by the risk managers (see Chapter 12 – Risk Management for more information).

- **Multiple Descriptors of Risk** – RPMs and other decision makers should incorporate multiple risk descriptors, such as the Central Tendency Exposure (CTE) and Reasonable Maximum Exposure (RME) risk estimates from a Tier II BHHRA or Probabilistic Risk Assessment (PRA), to assist in developing PRGs and FRLs for a site. This is consistent with USEPA Policy, which states, that information should be presented on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors (e.g., central tendency, high end of individual risk, population risk, important subgroups, if known) consistent with the guidance on Risk Characterization, Agency risk assessment guidelines, and program-specific guidance. In decision-making, risk managers should use information appropriate to their program legislation (USEPA, 1995).

10.6 Impact of Ecological PRGs

The first of the nine evaluation criteria identified in the NCP for analysis of remedial alternatives states that the remedial alternative shall be protective of human health and the environment. Consequently, ecologically-based PRGs should also be considered along with human health-based PRGs and ARARs, when evaluating remedial alternatives at a site. Ecologically-based PRGs may impact the selection of a remedial alternative at some sites because the ecologically-based PRGs may be lower (i.e., more protective) than their corresponding human health-based PRGs (e.g., copper). See the *Navy Guidance on Performing Ecological Risk Assessments* for more information on developing ecological PRGs at http://web.ead.anl.gov/ecorisk/.

10.7 Site Closeout and Long-Term Monitoring

10.7.1 Risk Evaluations After Remedy Selection

After the remedy has been implemented, the Site Closeout phase begins. During this phase additional RERAs may be needed to determine if the remedy has achieved the goals identified in the ROD. This may include an evaluation of media, chemicals, exposed populations, and exposure pathways that were not originally considered in the initial risk assessment or previous risk evaluations. However, the USEPA suggests that risk evaluations may not be needed at every site, and that if an evaluation is necessary, then it may be qualitative or quantitative in nature. The guiding principle is that risk evaluations after the FS should be conducted as necessary to ensure that the remedy is protective (USEPA, 1991a). Additionally, whenever possible, risk information generated early in the process (e.g., BHHRA results) should be utilized in order to minimize the level of effort.

10.7.2 Risk Evaluation During Remedial Design and Remedial Action

The activities that occur during RD and implementation may require consideration of human health risks in order to monitor short-term risks, evaluate attainment of FRLs in the ROD, and/or evaluate residual risks.

Short-Term Risks

If short-term risks are a concern at a site, then it may be necessary to develop a sampling plan and sample potentially-affected media to quantify the short-term risks. The short-term risks should be evaluated using short-term (i.e., subchronic or acute) toxicity criteria based on actual exposure scenarios.

Confirmation Sampling

Depending on the type of remedial alternative selected for a site, confirmation sampling may take place once the remedy has been implemented to ensure that the site complies with the FRLs identified in the ROD. The sampling plan should identify chemicals that will be evaluated and the statistical methodology that will be used to evaluate compliance.

Residual Risk

It also may be necessary to evaluate the residual risk at a site after the remedy has been implemented. For example, the residual risk may be evaluated using the BHHRA but substituting the final confirmation sampling results for the earlier data. The residual risk evaluation should take into account any differences from the BHHRA including:

- new chemicals that were not identified during the BHHRA or that were introduced as part of the remediation process;
- any land use changes; and
- changes in toxicity values (USEPA, 1991a).

If ICs or ECs have been implemented, then it is important to document that either there are incomplete exposure pathways or that the residual risks are acceptable based on the controls in place.

10.7.3 Five-Year Review

Remedies that result in hazardous substances remaining at the site are reviewed at least every five years after the initiation of the remedies. The two types of five-year reviews are statutory and policy. Statutory reviews are completed for sites where hazardous substances are present above levels that allow for unlimited use and unrestricted exposure. These generally include sites with remedies requiring access or land use restriction controls (i.e., remedies that achieve protectiveness through the use of ECs or ICs). Policy reviews are conducted for:

1.) sites with remedies that require five years or longer (i.e., long-term) to achieve levels that would allow for unlimited use and unrestricted exposure; or

2.) sites where the remedies were selected before the Superfund Amendments and Reauthorization Act (SARA), and where hazardous substances are present above levels that allow for unlimited use and unrestricted exposure.

Statutory reviews may be discontinued only if levels of hazardous substances fall permanently to a point that would allow unlimited use and unrestricted exposure. Policy reviews should be discontinued when the remediation goals specified in the ROD are achieved, assuming these levels allow for unlimited use and unrestricted exposure (USEPA, 1991a).

10.8 References

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U.S. Navy Human Health Risk Assessment Guidance

Chapter 11 – Risk Communication Principles and Techniques

Table of Contents

ACRONYMS AND ABBREVIATIONS

BHHRA	Baseline Human Health Risk Assessment
ER	Environmental Restoration
NAVFAC	Naval Facilities Engineering Command
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NMCPHC	Navy and Marine Corps Public Health Center
RPM	Remedial Project Manager

11.0 Introduction

While overall protection of human health and the environment is one of the Threshold Criteria established by the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) for use in evaluating alternatives and selecting a remedy, community acceptance of the remedy is one of the Modifying Criteria.

The success of an environmental restoration (ER) project may depend on the ability to effectively communicate with all interested parties. It is critical that the project team include risk communication from the beginning of the project. Each ER project will likely present its own risk communication challenges due to site-specific conditions. Below is a brief discussion about what risk communication is, how it fits in with ER projects, some information about stakeholders and the three general areas in which risk communication operates. The Navy and Marine Corps Public Health Center (NMCPHC) has prepared a *Risk Communication Primer* to assist remedial project managers (RPMs) with risk communication (http://www-nmcphc.med.navy.mil/HERC/Products/primer.pdf).

Risk communication is communicating with any stakeholder, internal or external, on any issue that could impact your organization's mission. As a result, risk communication requires capabilities in the process of building, maintaining, and repairing relationships with stakeholders that impact your mission. This requires significant communication skills. Risk communication:

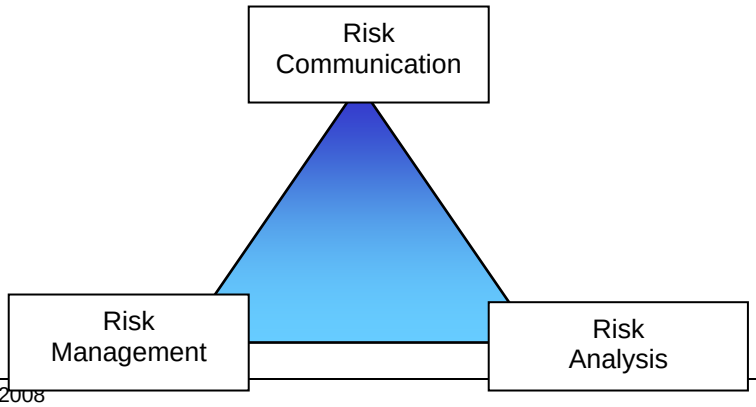
- is not public speaking;
- is not spinning or embellishing messages;
- requires being open, honest, genuine, and sincere;
- requires applying the required communication skills (verbal and nonverbal) in a variety of situations, and
- requires an ongoing commitment to practice and preparation before interacting with stakeholders.

11.1 Risk Analysis, Risk Management, and Risk Communication

The graphic below shows a triangular presentation of three fields:

- Risk Analysis
- Risk Management
- Risk Communication

In this graphic, Risk Analysis represents the science, data and facts. This would be the current knowledge we have about the field such as toxicology, biology, chemistry, engineering, medicine, industrial hygiene, etc. Of course science is always progressing, changing and improving. So, in this instance the Risk Analysis corner is the science as we know it today.



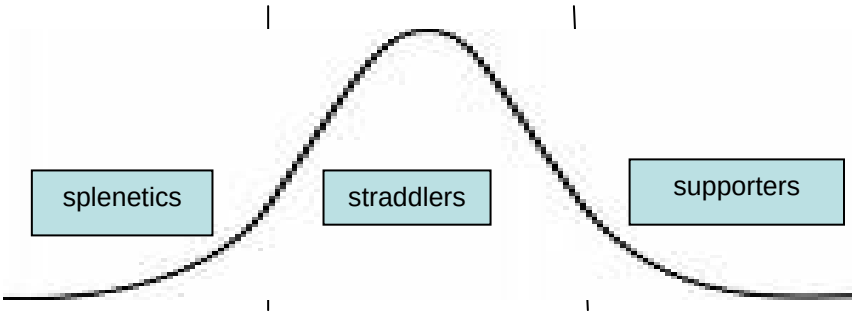
Risk Management is the operative piece. Once we have the risk analysis information, what do we do with it? For example: How do we design? How do we operate? How do we monitor? How do we train? How do we make cost/benefits decisions, et cetera.

Risk Communication is the discussion among stakeholders about the Risk Analysis and the Risk Management. The Risk Communication corner has become more important and more extensive in the past several decades. Waiting until the end of a project to consider risk communication can negatively impact the mission and often results in stakeholder anger and sometimes rejection of the solution. Don't wait until a study is finished to involve the stakeholders. It is much better to have multiple opportunities for stakeholders to provide input throughout the project than to wait until the assessment is completed.

11.2 Principles of Risk Communication

A. **Identify stakeholders that impact your mission, favorably (supporters), neutrally (straddlers) or unfavorably (splenetics.)** (See the curve below).

The splenetics are located at the left end of the curve and are immoveable. They oppose you and do not want to achieve common ground. There are typically not a large number of individuals or groups at that left end of the curve. Many individuals or groups may be toward the left side of that curve, but are open to common ground and/or suggestions. These would be straddlers.



Differentiating stakeholders into these 3 groupings helps you recognize different communication missions.

- For supporters, the primary mission is to maintain the relationship. Keep them informed and keep up the two-way dialogue. Ask them for advice, ideas, other stakeholders to contact, etc.

- For straddlers, the mission is to recognize that this may be your most important stakeholder group and your goal is to move them towards a more supportive position.

- For splenetics, recognize that they will NOT be supportive so your strategy with them is that anything you do with splenetics (provide information, listen to them, and invite them to your meetings) you do so to influence the straddlers not the splenetics. That is, splenetics can not be influenced to support you, so you are wasting your time trying to accomplish that.

- You do want to influence straddlers and this can be done by showing good faith with splenetics. Good faith does not mean you give splenetics what they want; let them disrupt your meetings, etc. Good faith does mean that you are demonstrating to everyone else that you are open to discussion and meetings. By the way, juries and judges are usually in the straddler category and, in a lawsuit, will look at good faith approaches by either side.

B. **Determine where your stakeholders are primarily coming from:**

- Emotions (anger, disgust, irritation, fear);
- Agendas (personal, political, economic, social, historical or cultural), or
- Perception of Risk (think it is riskier than it is or less risky than it is).

This will help you in deciding how to best respond to your stakeholder's concerns. For example, an angry person is not generally open to a lot of facts or figures. It is better to acknowledge the anger, be empathetic and try to engage them in a conversation to learn why they are angry by using open ended questions and then present a fact. Some people will have personal agendas. You need to recognize the situation and address their agenda quickly. The careful listening will help identify agendas and thus the real concern or bottom line. Risk perception issues can be handled in a number of ways including presenting information in ways the stakeholders can understand and using an outside expert.

C. Utilize third party supporters that can informally or formally help you.

A third party supporter is a stakeholder who is trusted and seen as knowledgeable by your straddler stakeholders. Third party supporters can help you in many different ways, from an official stance of support for you, or informal conversations of support with straddler stakeholders, or providing you with intelligence on activities or providing suggestions on approaches, etc.

For internal communication, third party supporters are frequently lower in the hierarchical chain of the organization. Regulators can also be effective third party supporters as can local health officials. In any case, it would be someone who is respected and ideally has extensive experience in the organization and with the community. Another third party supporter is someone who works in your organization, and also lives in a community where you are dealing with risk communication issues.

Third party supporters are frequently missed because often we don't consciously think of that aspect of risk communication when planning. By the way, if you have a third party supporter, they can frequently lead you to other third party supporters. Because we pay our contractors for their work, they are usually not perceived as good third party supporters.

D. Get in front of issues. If it's a crisis issue:

- Tell people what you do know;
- Tell them what you don't know, and
- Update them as you learn new developments.

Getting in front of issues is critical today because there are often many organizations including the media talking/reporting about your issue. The longer your organization takes to get your messages out, the harder it will be to overcome those stories and messages if you disagree with them. So, it's usually advisable to not wait until you get all your facts together before communicating with the public. Instead, say what you do know, what you don't know, and when you'll be back with an update. The longer you delay "getting out" your story/facts, the more the perception of hiding and covering up grows.

E. Ensure your communicators are properly trained.

NMCPHC offers risk communication training and has a risk communication staff ready to assist. Good communication includes what is said verbally and what is said nonverbally.

F. Learn the media communication process and build professional relationships with the media.

Working with the media is generally in the realm of the public affairs office and it is important to include your public affairs officer in your environmental cleanup team. A good public affairs officer will be able to guide and advise you with media relations. Media relations are usually a component of most risk communication training classes.

G. Have a flexible communication planning process.

A communication issues plan has several benefits for you and your organization. It aligns your team/fellow risk communicators. It allows you to measure progress and make necessary adjustments to the plan. It involves stakeholders including third party supporters. It provides a system to adjust to change. The plan needs to be very a flexible and iterative process because risk communication is a social science involving ever changing environments, new stakeholders, new situations, new regulations, elimination of some challenges and creation of new ones. As a result, your plan is dynamic and evolving. The plan is not linear. That is, you don't complete step 1, then start step 2, complete step 2 and start step 3. For example, you may want to change your mission statement after you gather more intelligence from stakeholders. Also, your stakeholders may change from time to time, as new ones "show up" for example. Also, your messages may change as the issue becomes more or less important or as new stakeholders become involved in the issue.

In all these instances noted above, risk communication skills are critical for the ultimate objective of creating good risk management decisions for your organization. Risk communication is therefore critical to the successful operation of your organization.

11.3 Data Presentation Strategies

11.3.1 Effectively Communicating Risk Assessment Information

Risk Assessment Information

There are a variety of effective ways to communicate complicated technical risk assessment information to the public, interest groups, and the news media. One of the key concepts to understand in order to effectively communicate risks to a variety of audiences is that "one-size-does-not-fit-all." At most sites there are a variety of interested parties (e.g., public, regulators, interest groups, media, etc.) that have different backgrounds and interests in the project. It is important to recognize this diversity and to develop a data presentation strategy that will facilitate risk communication with the various groups. The foundation of a successful risk communication strategy is to tailor the risk assessment information provided to the interested parties to their technical background and interests. For example, the executive summary from a Tier II Baseline Human Health Risk Assessment (BHHRA) would be effective risk assessment information for a regulator, and a Fact Sheet, summarizing significant findings presented in the BHHRA in general terms, would be effective risk assessment information for the general public or the media. Several options for communicating risk assessment are presented below.

- **Fact Sheets** - Fact sheets are a good way to present information on a regular basis. Fact sheets should ideally be limited to one page and should be written at a level that is easily understood. This means that there should be no jargon and there should be short, clear, relevant messages.

- **Informational Posters** - Informational posters and graphics are useful ways to present information at open houses or at public facilities that are near the site. Care should be taken though, to avoid developing informational posters that are perceived as propaganda rather than as vehicles to present complex technical information in a useable format.

- **Internet Web Site -** An Internet web site is a good way to provide up-to-date information in an easily accessible format (fact sheets can be linked to more detailed information for those who need it). In addition, a web site provides a mechanism for developing a historical record of issue summaries or fact sheets. However, if this approach is to be utilized, it is important to make sure that the general public does in fact have access to Internet resources (e.g., public libraries have computers connected to the Internet).

- **Public Notices** - Public notices are announcements published in the print media or broadcast on radio or television. They also can be used to publicize opportunities for the community to participate in planning for a risk assessment or to review documents such as a work plan. Major media outlets are not the only or necessarily the best sources to use. Often, ethnic or foreign language publications, niche radio stations, church bulletins, and postings at local gathering places provide more effective coverage. A public notice is a relatively inexpensive way of spreading the word, but is unlikely to generate a large response. As a result, public notices should always be used in conjunction with other techniques.

Selecting the right option, or options, for effective risk communication depends on the level and frequency of interactions with stakeholders and the degree to which stakeholders have been involved in the process.

Risk Assessment Documents

Risk assessment reports are very technical documents that are intended for review by regulators and other interested parties who have a risk assessment background. Therefore, the process of evaluating potential risks should be thoroughly documented (i.e., be transparent), so that the reader can easily understand the underlying assumptions. Transparency means that all of the information that an independent party would need to recreate the final risk numbers is presented in the report in a logical and organized manner. Suggestions for organizing the risk assessment report to maximize transparency are presented below.

- Develop an executive summary that focuses on the key factors in the evaluation that determine the overall risks and summarize those risks. In many cases the executive summary is the only portion of the document that is reviewed by many stakeholders. Therefore, it is very important to develop effective executive summaries that identify the key information and provide “road maps” for more-detailed information in the rest of the document. NMCPHC has a primer on writing executive summaries that provides guidance and examples (http://www-nmcphc.med.navy.mil/HERC/Products/primer.pdf).

11.4 Sources of Assistance for Risk Communication

Each year, the Naval Facilities Engineering Command (NAVFAC) funds NMCPHC, located in Portsmouth, VA, to provide risk communication support for ER Program. Examples of NMCPHC’s support include site/project specific training, preparation for public meetings, developing key messages and risk communication materials and assistance with restoration advisory boards.

11.5 References

NMCPHC (Navy and Marine Corps Public Health Center) Risk Communication Primer.
http://www-nmcphc.med.navy.mil/HERC/Products/primer.pdf

U.S. Navy Human Health Risk Assessment Guidance

Chapter 12 – Risk Management

Table of Contents

ACRONYMS AND ABBREVIATIONS

ARAR	Applicable or Relevant and Appropriate Requirements
BHHRA	Baseline Human Health Risk Assessment
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
COC	Chemical of Concern
CSM	Conceptual Site Model
CTE	Central Tendency Exposure
DQO	Data Quality Objective
EC	Engineering Control
FRL	Final Remediation Level
FS	Feasibility Study
IC	Institutional Control
LUC	Land Use Control
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NERP	Navy Environmental Restoration Program
PRA	Probabilistic Risk Assessment
PRG	Preliminary Remediation Goal
RA	Risk Assessment
RI	Remedial Investigation
RME	Reasonable Maximum Exposure
RPM	Remedial Project Manager
ROD	Record of Decision
SI	Site Investigation
USEPA	United States Environmental Protection Agency

12.0 Introduction

The purpose of this chapter is to present guidelines that risk managers should consider when evaluating risk assessment information in order to make risk management decisions at a site. This chapter is not meant to serve as a guidance document, but is meant to be a primer on risk management and serve as an overview of the risk management process. Guidance documents for risk management are referenced below in this chapter.

The first section of this chapter presents risk management guidelines for evaluating sites, to determine if remedial action is warranted. The second section focuses on incorporating risk assessment information into the evaluation of remedial alternatives. The third section discusses exit criteria.

The Department of the Navy Environmental Restoration Program (NERP) Manual provides risk management guidance for RPMs, and states that "Risk management integrates the results of the risk assessment with other considerations such as economic, technical, or legal concerns to select a remediation approach that is feasible as well as protective of human health and the environment, and in some cases will support a 'no further action' decision," (USNAVY, 2006).

The United States Environmental Protection Agency (USEPA) makes a very clear distinction between risk management and risk assessment. Risk management is the process of evaluating risks and other considerations (e.g., applicable statutes), to make and justify regulatory decisions at a site (USEPA, 1995). Risk management decisions are made at various stages in the Site Investigation/Remedial Investigation/Feasibility Study (SI/RI/FS) process. Risk managers (e.g., Remedial Project Managers, RPMs) are responsible for determining the significance of the risks at a site and whether or not, and how, the risks should be addressed (USEPA, 1989). It is not unusual for risk managers to accept different degrees of risk depending on the stage of the projects (e.g., SI, RI, FS, etc.). Risk assessment is the process of selecting, evaluating, and presenting scientific information without considering issues such as cost, feasibility, or how the scientific analysis might influence the regulatory or site-specific decision. Risk assessors are responsible for:

- generating a credible, objective, realistic, and scientifically-balanced analysis;
- presenting information on hazards, dose-responses, exposures and risks; and
- explaining confidence in each assessment by clearly delineating strengths, uncertainties and assumptions, along with the impacts of these factors (e.g., confidence limits, use of conservative/non-conservative assumptions) on the overall assessment. See Section 8.8 of this guidance document for a discussion regarding the uncertainties associated with the various components of risk assessments.

Risk assessors should not make decisions on the acceptability of any risk level for protecting public health or selecting procedures for reducing risks (USEPA, 1995). In practical terms, this means that risk assessment reports should clearly present the risks in a way that can be used by risk managers, while avoiding making value judgments about what actions should be taken. However, it is recommended that risk managers consult with risk assessors to discuss the risks and their associated uncertainties prior to making risk management decisions.

12.1 Risk Management Guidelines for Determining if a Site Requires Remedial Action

The ultimate goal of the remedial process is to identify and remediate sites that pose a threat to human health and the environment. Risk managers must integrate a variety of information (e.g., risks,

uncertainty, stakeholders' concerns, etc.) in order to determine which sites require remediation and those that do not (i.e., No Further Action sites). The purpose of this section is to provide guidelines on how the results of Tier I and Tier II risk assessments (i.e., risk-based information) should be used to assist in determining whether or not a site warrants remediation.

The USEPA Memo, "Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions" (USEPA, 1991a) identifies key points that should be considered when determining if a site requires remedial action. These points are summarized below.

- **Acceptable Risk Range** – If the cumulative carcinogenic risk to an individual based on reasonable maximum exposure (RME) for both current and future land use is less than 1×10^{-4} and the non-carcinogenic hazard index is less than 1, action generally is not warranted unless there are unacceptable ecological risks. The NERP Manual states that the cancer risk range between 1×10^{-4} and 1×10^{-6} is the risk management range, where remediation may not be warranted. State-specific "acceptable" risk ranges may also be available, and should be considered before determining if remediation is warranted. However, if maximum contaminant levels (MCLs) or non-zero maximum contaminant level goals (MCLGs) are exceeded, action generally is warranted.

  Note: The upper boundary of the risk range is not a discrete line at 1×10^{-4}, although USEPA generally uses 1×10^{-4} in making risk management decisions. A risk estimate that is greater than 1×10^{-4} may be considered acceptable if justified based on site-specific conditions. For example, this situation may occur when several conservative assumptions have been made that don't necessarily reflect the reasonable future use of the site (e.g., risk results may be elevated due to the soil ingestion risk at a site that is intended to be paved in the future). Conversely, a risk manager may also decide that a baseline risk level less than 1×10^{-4} is unacceptable and that remedial action is warranted due to site specific reasons. For example, this situation may occur when future use of the site indicates that sensitive receptors such as children and the elderly may be present.

- **Evaluate Current and Future Exposures** – Both current and reasonable future exposures should be assessed to determine whether or not a site poses an unacceptable risk to human health and the environment.

- **Evaluate Exposure Assumptions** – The exposure assumptions used to calculate risk may either over- or underestimate the true risk. For example, assuming that all chromium at a site is present as chromium^{+6},or assuming that residential soil exposure occurs for 350 days/year in an area where the ground is frozen during winter months can result in a significant overestimate of the true risk. Use of conservative exposure assumptions can provide the rationale for using the higher end of the risk range to determine whether or not remedial action is warranted.

- **Consider the Data Quality** – For sites with a limited amount of data, it may be more cost-effective to collect more data and recalculate the risks before making a final risk management decision. It is also important to ensure that the data collection and analysis methods met the project-specific data quality objectives (DQOs) and therefore provide appropriate inputs to the risk assessment.

- **Relevance of Toxicity Values** – The use of surrogate toxicity values, where chemical-specific values are not available, and the use of toxicity values developed for more (or less) bioavailable forms of a chemical than are present at a site can affect risk estimates. In general, the uncertainty associated with the toxicity values used to calculate risk should be considered when deciding which end of the risk range will be used to determine whether or not remedial action is warranted. For example, oral toxicity factors are typically used as surrogates for a dermal toxicity factors when evaluating dermal exposure because the USEPA has not developed dermal toxicity factors. In this case, if the dermal pathway contributes significantly to the overall risk, then risk

assessors should assist RPMs in selecting which end of the risk management range should be applied to the site based on the degree of uncertainty associated with the surrogate dermal toxicity factors.

- **Land Use** – Residential land use should not be used as the basis for making remedial decisions at every site. Rather, remedial decisions should be based on current and plausible future land use. For example, industrial, recreational, and agricultural land use should be used, when appropriate. In general, future land use assumptions should be based on current land use conditions. In instances where it is difficult to use current land use to predict future land use (e.g., a vacant lot), risk managers should consult base master-development plans and other land use planning documents to assist in determining the most plausible future land use for a site. It is important to note that if the appropriate future land use for a site is not residential, then it typically will be necessary to implement institutional controls (ICs) (e.g., a deed restriction) and perform long-term monitoring at the site.

- **Presence of Sensitive Populations** – If sensitive subpopulations (e.g., children at a school/daycare/playground, the elderly, or tribal members who partake in subsistence fishing, etc.) will be at the site on a regular basis, then it may be appropriate to use the lower end of the risk range to determine whether or not remedial action is warranted.

- **Risks to Ecological Receptors** – Impacts to ecological receptors may need to be considered and may prompt remedial action in cases where there is not a threat to human health.

- **Use of Nonstandard Exposure Parameters** – The Record of Decision (ROD) should clearly identify and justify the use of any non-standard exposure parameters and the need for remedial action, if baseline risks are within the generally-acceptable risk range (i.e., a cancer risk less than $1x10^{-4}$ and a hazard index less than 1). The ROD should also include a table listing the final remediation levels and the corresponding risk level for each chemical of concern (COC).

Community Involvement– *Input from Community/Restoration Advisory Boards should be considered throughout the site investigation process and included in risk management decisions. Note: In some cases the results of a Tier I or Tier II risk evaluation depend on land-use controls (LUCs), such as ICs or future land use decisions. It is important to understand the benefits of LUCs, as well as the restrictions that accompany them. Implementing LUCs for a site can be beneficial, because it allows the risk assessment to reflect actual future land use which can lower the cost of the remediation if a land use other than residential is specified. This is due to the fact that exit criteria for land uses other than residential (e.g., industrial) are typically less stringent. Although LUCs may present a viable option as part of a remedy, it is important to consider the long-term, life-cycle costs of LUCs (e.g., long-term monitoring). The implementation of LUCs is a risk management decision and long-term costs of LUCs should be weighed against the additional costs of cleanup to unrestricted use.*

12.2 Risk Management Guidelines for Selecting a Remedy

If it is determined that a site warrants remedial action, then an appropriate remedy must be selected for the site, based on the nine evaluation criteria which are identified in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The first two of these criteria are called Threshold Criteria and are associated with evaluating the risks to human health and the environment associated with the remedy. They are: 1) overall protection of human health and the environment, and 2) compliance with Applicable or Relevant and Appropriate Requirements (ARARs). These criteria must be met at every site. The other seven criteria are associated with Balancing Criteria (e.g., long-term effectiveness, implementability, cost, etc.), and Modifying Criteria (i.e., state and community acceptance). This section identifies the risk management guidelines that should be considered when evaluating a remedy with respect to the Threshold Criteria.

The process of identifying remedial alternatives for a site is often performed concurrently with other steps in the remedial process (e.g., site investigation, risk assessment, etc.). However, once it has been determined that a site warrants remedial action, the process of selecting an appropriate remedy, or remedies, intensifies, and risk management decisions may be required. The following considerations should be taken into account when making risk management decisions during the remedial selection process.

- **Compliance with Chemical-Specific ARARs** – ARARs are generally considered protective of human health even if they are outside the risk range, unless there are extenuating circumstances (e.g., exposure to multiple contaminants or pathways of exposure).

- **Current and Future Land Use** – Land use plays an important part in developing preliminary remediation goals (PRGs) and final remediation levels (FRLs) for a site. For example, risk-based PRGs for residential land use sites will typically be more protective (i.e., the chemical and media-specific concentrations will be lower) than risk-based PRGs for industrial land use sites. USEPA guidance states that, "the most appropriate future land use for a site should be selected so that the appropriate exposure pathways, parameters, and equations can be used to develop risk-based PRGs" (USEPA, 1991b). Consequently, residential land use should not be assumed for every site. Other land uses, such as industrial, recreational, and agricultural, should be used to develop PRGs and FRLs, if appropriate. In general, future land use assumptions should be based on current land use conditions. In instances where it is difficult to use current land use to predict future land use (e.g., a vacant lot), risk managers should consult base master-development plans and other land use planning documents to assist in determining the most plausible future land use for a site. It is important to note that if the appropriate future land use for a site is not residential, then it typically will be necessary to implement institutional controls (e.g., a deed restriction) and perform long-term monitoring at the site.

- **Institutional or Engineering Controls** – PRGs and FRLs should reflect ICs or engineering controls (ECs) that are part of the remedy. For example, if a deed restriction is in place that limits land use to commercial purposes, then PRGs and FRLs should be based on a conceptual site model (CSM) that reflects this land use. Another example is an EC, such as a cap, that would eliminate or severely reduce potential exposure to COCs. The PRGs and FRLs should be based on a CSM that reflects the implementation and maintenance of the EC.

  Note: If the remedy depends on ICs or ECs, it is important to consider the long-term, life-cycle costs (e.g., long-term monitoring) versus the additional costs of cleanup to unrestricted use.

- **Site-Specific Background Concentrations** – Site-specific background concentrations of chemicals should be used during the Tier I and Tier II risk evaluations to eliminate chemicals that are present at or below background concentrations from further consideration in the risk assessment. However, in some situations this step may have been omitted. Therefore, it is important that the PRGs and FRLs are compared to background concentrations to ensure that they are not below background concentrations. Additional information about monitoring and enforcing LUCs is available from the Department of Defense (DOD, 2003).

- **Multi-Media Fate and Transport Issues** – The CSM should be re-evaluated during the remedy selection process to determine if PRGs or FRLs need to be developed for media that may not have been evaluated, or were determined to not be of concern, in the Tier I or Tier II risk evaluations. For example, the results of the baseline human health risk assessment (BHHRA) may have indicated that, for a site with soil and groundwater issues, exposures to soil were of concern while exposures to groundwater were not of concern. In this instance, PRGs and FRLs would be developed for exposures to soil and not groundwater. However, in some cases potential migration of contaminants in soil to groundwater may be of concern and should be considered when developing the PRGs and FRLs for soil.

- **Risk Management Range** – For chemicals lacking MCLs or non-zero MCLGs, PRGs and FRLs should be established at concentrations that achieve 1×10^{-6} excess cancer risk or a hazard quotient of 1 (for noncarcinogens) modified, as appropriate, based on exposure, uncertainty, and technical feasibility factors (USEPA, 1991b). It should be noted, however, that the risk goals identified in the NCP, and further clarified in the USEPA Memo, "Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions," are not discrete values that, if exceeded, automatically indicate that remedial action is warranted at a site (USEPA, 1991a). For example, a site with a cumulative cancer risk greater than 1×10^{-4} may be considered protective of human health based on site-specific conditions and, therefore, remedial action is not warranted. This situation may occur when several conservative assumptions have been made that don't necessarily reflect the reasonable future use of the site (e.g., risk results may be elevated due to incidental soil ingestion at a site that is intended to be paved in the future). Conversely, in other situations, a site with cumulative cancer risk less than 1×10^{-4} may not be considered protective of human health and, therefore, remedial action is warranted. For example, this situation may occur when future use of the site indicates that sensitive receptors such as children and the elderly may be present.

  Note: If the Tier I or Tier II evaluations and the comparison of exposure concentrations to chemical-specific standards indicates that there is no unacceptable risk to human health or the environment and that no remedial action is warranted, then the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) Section 121 cleanup standards for selection of a Superfund remedy, including the requirement to meet ARARs, are not triggered.

- **Multiple Descriptors of Risk** – Risk managers should incorporate multiple risk descriptors, such as the central tendency exposure (CTE) and RME risk estimates from a Tier II BHHRA or Probabilistic Risk Assessment (PRA), to assist in developing PRGs and FRLs for a site. This is consistent with USEPA Policy which states, that Information should be presented on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors (e.g., central tendency, high end of individual risk, population risk, important subgroups, if known) consistent with the guidance on Risk Characterization, USEPA risk assessment guidelines, and program-specific guidance. In decision-making, risk managers should use information appropriate to their program legislation (USEPA, 1995).

- **Community Involvement**– Input from Community/Restoration Advisory Boards should be considered throughout the site investigation process and included in risk management decisions.

- **Impact of Ecological PRGs** – Ecologically-based PRGs should also be considered along with human health-based PRGs, FRLs, and ARARs when evaluating remedial alternatives at a site. Ecologically-based PRGs may impact the selection of a remedial alternative at some sites because the ecologically-based PRGs may be lower (i.e., more protective) than their corresponding human health-based PRGs (e.g., copper). It is important to note that remedies based on ecologically-based PRGs and FRLs should consider the "Net Environmental Benefit" of the alternative. That is, RPMs should evaluate the injury that will occur to the environment at a site as a result of implementing the remedy versus the injury to the environment resulting from "No Further Action." See the Navy Guidance on Performing Ecological Risk Assessments for more information on ecologically-based PRGs: http://web.ead.anl.gov/ecorisk/.

- **Points of Compliance** – The final remediation levels for each chemical in a specific medium will be identified in the ROD. In addition, the point (or area) of compliance will also be identified for each medium. In some cases, the location of the point of compliance is not always obvious. Often the point of compliance is set at the source area where the hazardous substances are present or at the property boundary. For groundwater, the USEPA recommends that the final cleanup levels generally should be attained throughout the entire contaminant plume, except when remedies involve areas where waste materials will be managed in place. In the latter case,

cleanup levels should be achieved at and beyond the edge of the waste management area when waste is left in place. In some cases, such as where several distinct sources are in close geographic proximity, it may be appropriate to move the point of compliance to encompass the sources of release. In such cases, the point of compliance may be defined to address the problem as a whole, rather than source-by-source (USEPA, 1997).

12.3 Exit Criteria and Site Closeout

12.3.1 Exit Criteria

Decisions to take remedial actions at a site depend on human health risks, ecological risks, and chemical-specific ARARs (e.g., MCLs). Remedial action generally is warranted when:

- the cumulative carcinogenic site risk to an individual based on RME for either current or future land use is greater than 1×10^{-4}; or
- the non-carcinogenic hazard index is greater than 1; or
- the carcinogenic or noncarcinogenic risks are below their respective regulatory benchmarks or PRGs/FRLs, but chemical-specific standards (e.g., MCLs or non-zero MCLGs) are exceeded; or
- there is elevated ecological risk (USEPA, 1991a). See the Navy Guidance on Performing Ecological Risk Assessments for discussion of ecological risk estimates: http://web.ead.anl.gov/ecorisk/

Remedial action is generally not warranted when the Tier I or Tier II evaluations and the comparison of exposure concentrations to chemical-specific standards indicate that there is not an unacceptable risk to human health or the environment (USEPA, 1991a). Exit strategies following completion of Tier I and Tier II evaluations are discussed in Chapter 7, Section 7.2 and Chapter 8, Section 8.2 where preparation of risk assessments is discussed. In addition, the CERCLA Section 121 cleanup standards for selection of a remedy, including the requirement to meet ARARs, are not triggered if site risks are at or below levels that allow unrestricted use and unrestricted exposures (USEPA, 1991a). However, the USEPA guidance regarding the conditions that require use of ARARs is written broadly and may be interpreted differently by various parties.

12.3.2 Site Closeout

Site closeout implies that the Navy has completed active management and monitoring of the restoration site, and that no additional environmental restoration funds are expected to be expended at the site unless the need for additional remedial action is demonstrated. At this point, there should be no additional risk assessment or risk management that needs to be performed. The Environmental Site Closure Process refers to the steps that occur after a cleanup decision has been made and the remedial action is scheduled to begin. Detailed information on the closeout process (e.g., no action RODs, action RODs with ICs, action RODs without ICs, etc.) can be found in the Navy's Guidance for Documenting Site Closeout Milestones (NAVFAC, 2006) and the DoD/EPA Joint Guidance on Streamlined Site Closeout and NPL Deletion Process for DoD Facilities (DoD/EPA, 2005).

12.4 Additional Resources

Additional resources related to risk management and site closeout include the following:

- The Department of the Navy Environmental Restoration Program (NERP) Manual (USNAVY 2006)

- Department of the Navy Guidance to Documenting Milestones Throughout the Site Closeout Process (NAVFAC, 2006)
- DoD/EPA Joint Guidance on Streamlined Site Closeout and NPL Deletion Process for DoD Facilities (DoD/EPA, 2005)

12.5 References

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