



U.S. Navy Human Health Risk Assessment Guidance

Chapter 3 – Overview of the Human Health Risk Assessment Process

Table of Contents

3.0	Introduction	3-1
3.1	Goals and Use of a Human Health Risk Assessment	3-3
3.2	Exiting the Human Health Risk Assessment Process	3-3
3.2.1	Exit Criteria	3-3
3.2.2	Background Information on Exit Criteria	3-4
3.3	Planning/Scoping	3-5
3.4	Tiered Approach.....	3-5
3.5	Tier IA – Risk-Based Screening.....	3-8
3.6	Tier IB – Site-Specific Risk-Based Screening.....	3-8
3.7	Tier II – Baseline Risk Assessment	3-8
3.8	Tier III – Risk Evaluation of Remedial Alternatives	3-9
3.9	Risk Communication	3-9
3.10	Risk Management.....	3-10
3.11	References.....	3-10

List of Figures

Figure 3.1	– Human Health Risk Assessment Process	3-2
Figure 3.2	– Navy Tiered Human Health Risk Assessment Process.....	3-7



3.0 Introduction

Risk assessment is an established approach to evaluate the potential for adverse health effects from exposures to toxic substances in the environment. Risk assessment is a tool which can be used to evaluate 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.

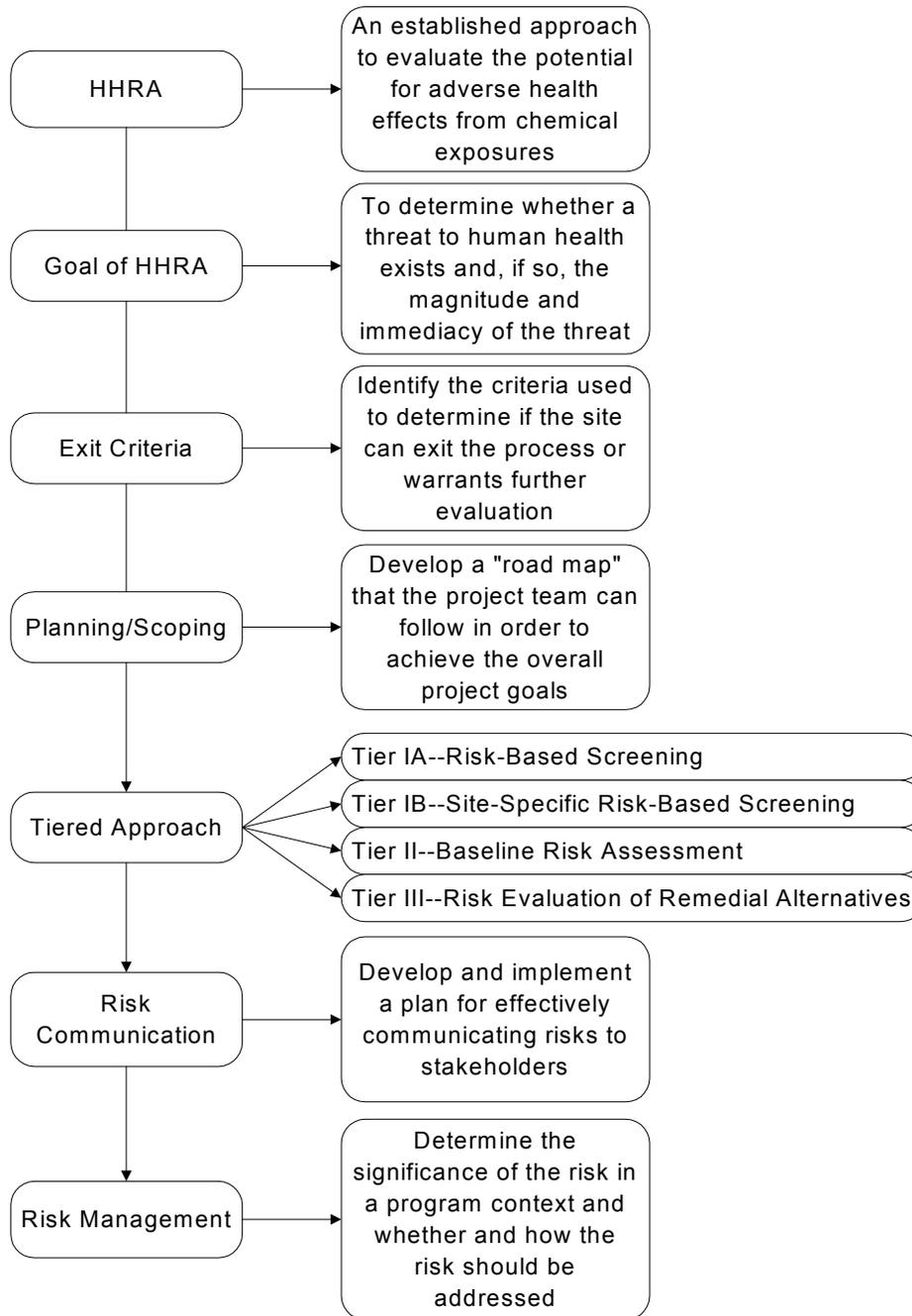
This chapter presents an overview of the HHRA evaluations that are performed as part of the site remediation process. [Figure 3.1](#) presents an overview of the human health risk assessment process. The four different types of Remedial Investigation/Feasibility Study (RI/FS) HHRA evaluations are:

- 1.) risk-based screening;
- 2.) baseline risk assessment;
- 3.) refinement of preliminary remediation goals; and
- 4.) remedial alternatives risk evaluations.

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. Other sources of more detailed information are as follows.

- ◆ USEPA Human Health Risk Assessment Guidance – United States Environmental Protection Agency (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/superfund/programs/risk/ragsa/index.htm>.



- ◆ USEPA Guidance for Risk Characterization – United States Environmental Protection Agency. Science Policy Council. Feb. 1995. Guidance for Risk Characterization. <http://www.epa.gov/ORD/spc/rcguide.htm>.
- ◆ USEPA Guidance for Developing Risk-Based Preliminary Remediation Goals (PRGs) – United States Environmental Protection Agency. 1991. Risk Assessment Guidance for Superfund: Human Health Evaluation Manual Part B. Interim Final. Office of Emergency and Remedial Response. Washington, D.C. 9285.701A. EPA/540/R-92/003. <http://www.epa.gov/superfund/programs/risk/ragsb/index.htm>.
- ◆ USEPA Guidance for Risk Evaluation of Remedial Alternatives – United States Environmental Protection Agency. 1991. Risk Assessment Guidance for Superfund: Human Health Evaluation Manual Part C. Interim Final. Office of Emergency and Remedial Response. Washington, D.C. 9285.701A. 9285.7-01C. <http://www.epa.gov/superfund/programs/risk/ragsc/index.htm>.

3.1 Goals and Use of a Human Health Risk Assessment

The goal of a HHRA is to determine the magnitude and immediacy of potential threats to human health associated with exposure to hazardous substances. Deciding whether 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 a HHRA include the following:

- 1.) to provide 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.) to provide a basis for determining levels of chemicals that can remain onsite and still be adequately protective of public health;
- 3.) to provide a basis for comparing potential health impacts of various remedial alternatives; and
- 4.) to follow 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 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 and land use to determine if a site can exit the HHRA process or whether it warrants further evaluation. 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. *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 risk-based screening criteria (i.e., concentrations of chemicals in different media that are derived using conservative target risk goals and standard exposure scenarios) 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, iron 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 5% frequency of detection and at concentrations slightly above the detection limit) should be eliminated from further consideration in the risk assessment process (USEPA, 1989).*
- 4.) **Baseline Risk Assessment (BHHRA)** – If a BHHRA determines that the chemicals present at a site do not pose an unacceptable 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 a Remedial Project Manager (RPM) to continually re-evaluate their site, with regard to the exit criteria, to determine if it may exit the HHRA process.

Note: If a site exits the human health risk assessment 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, 1991b). 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 BACKGROUND INFORMATION ON 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 institutional controls. The regulatory benchmarks and land use are discussed below. For more information on cancer and noncancer risks see Chapter 8 – Tier II Baseline 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 1 chance in one million [i.e., 1E-06] 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 1 chance in 1,000,000, they become less desirable, and the risk to individuals generally should not exceed 1 in 10,000 (i.e., 1E-04) (USEPA, 1991b). 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 1E-04 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, 1991b).”



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.

3.3 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 scoping process is to develop a “road map” that the project team can follow in order to achieve the overall project goals. 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-levelled 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 risk-based screening concentrations (RBCs), which are based on conservative, default exposure assumptions (e.g., residential scenario). Tier IB uses RBCs 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

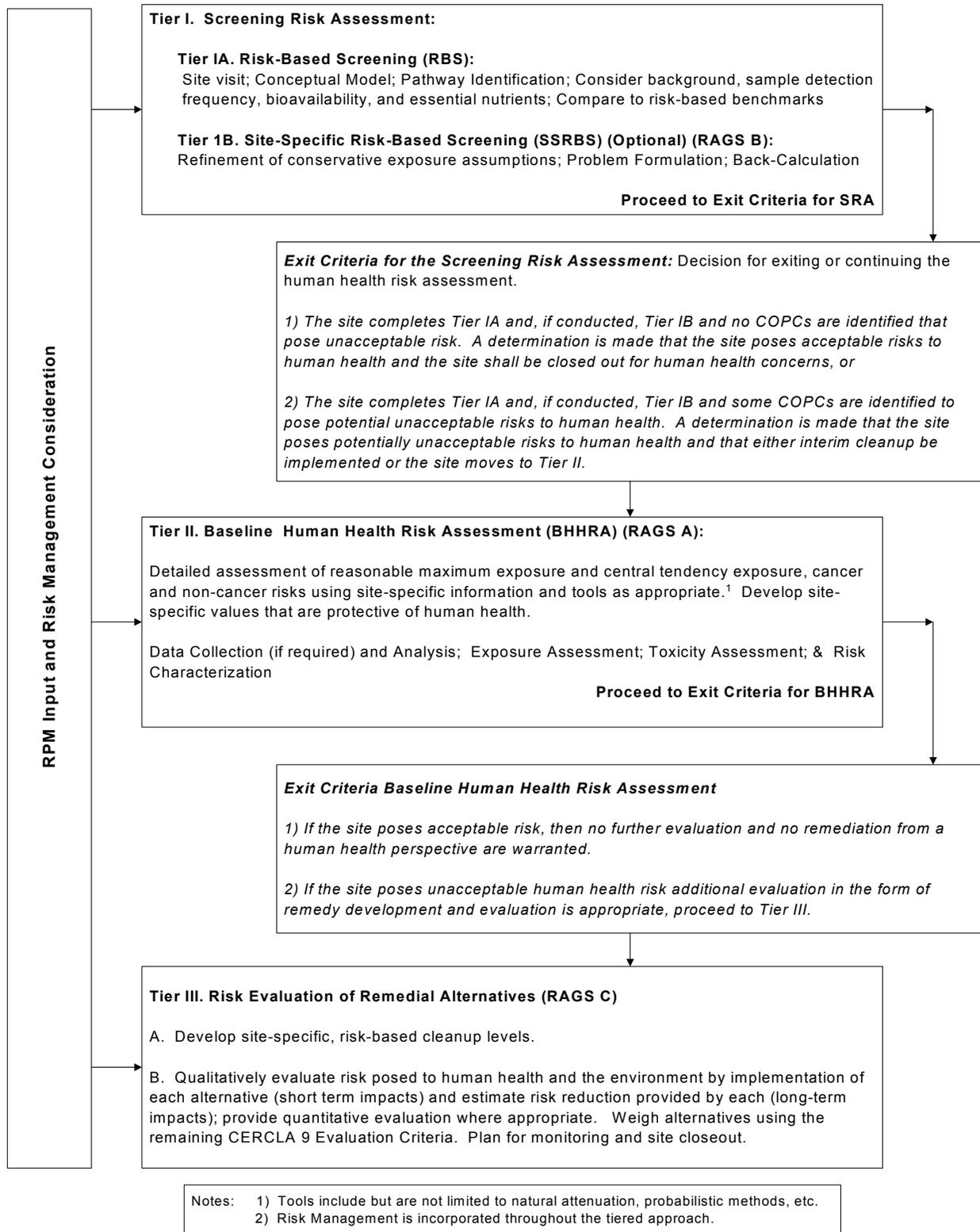


protect human health and the environment.

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. 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 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 RBCs. RBCs 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. They 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 1 in a million or 1E-06) 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. In addition, the outcomes of risk-based screening are consistent with what would occur if a complete HHRA was performed (USEPA, 1993).

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 RBCs to determine if concentrations pose an acceptable risk. However, the RBCs used in Tier IB are calculated using site-specific exposure assumptions. Some situations where it might be beneficial to develop site-specific RBCs include the following.

- ◆ Areas with extreme climates (e.g., Alaska) where standard chemical exposure factors such as exposure duration and frequency are not appropriate. For example, RBCs could be developed based on Alaska-specific residential and industrial exposure scenarios.
- ◆ Land uses with plausible exposure scenarios that different than the generic industrial worker scenario. For example, 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. For example, if a large parcel of property is going to be developed for commercial purposes, then it may be appropriate to develop site-specific RBCs that reflect the future exposure scenarios.

It is important to note that a Tier IB evaluation, unlike a Tier IA 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, risk-based concentrations involves some effort but will result in more sites being screened out from further consideration than if standard RBCs 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 Risk Assessment



The Tier II Baseline Risk Assessment (BHHRA) is a quantitative analysis of the potential adverse health effects (current or future) caused by releases of chemicals at a site. 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 additional response action is necessary at the site;
- ◆ modify preliminary remediation goals (PRGs); and
- ◆ support selection of the "no-action" remedial alternative, where appropriate.

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

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

3.8 Tier III – Risk Evaluation of Remedial Alternatives

The purpose of Tier III, Risk Evaluation of Remedial Alternatives (RERAs), is to evaluate the 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 Feasibility Study (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, 1991a). 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 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). At some sites there may be few remedial alternatives; the potential short-term and long-term human health exposure pathways may be limited. For these sites, a qualitative evaluation of the risks of remedial alternatives may be sufficient. At other sites, a complete deterministic risk assessment may be appropriate.

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), 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.

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

- 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/superfund/programs/risk/ragsa/index.htm>.
- USEPA. 1991a. Risk Assessment Guidance for Superfund: Volume 1 – Human Health Evaluation Manual (Part C, Risk Evaluation of Remedial Alternatives). Interim. Office of Emergency Response, Washington, D.C. Publication 9285.7-01C. <http://www.epa.gov/superfund/programs/risk/ragsc/index.htm>.
- USEPA. 1991b. Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions. Washington, D.C. OSWER Directive 9355.0-30. <http://www.epa.gov/superfund/programs/risk/baseline.htm>.
- USEPA. 1993. Region III Technical Guidance Manual Risk Assessment. Selecting Exposure Routes and Contaminants of Concern by Risk-Based Screening. United States Environmental Protection Agency, Region III, Hazardous Waste Management Division, Office of Superfund Programs, Philadelphia, PA 19103-2029. EPA/903/R-93-001. <http://www.epa.gov/reg3hwmd/risk/guide2.htm>.
- USEPA. 1995. Guidance for Risk Characterization. U.S. Environmental Protection Agency Science Policy Council. <http://www.epa.gov/ORD/spc/rcguide.htm>.
- USNAVY. 2001. Chief of Naval Operations Memorandum: Conducting Human Health Risk Assessments Under The Environmental Restoration Program. Ser N453E/1U595168. February 12, 2001.