



## U.S. Navy Human Health Risk Assessment Guidance

# Chapter 4 – Strategically Managing the Human Health Risk Assessment Process

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## 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:

- ◆ Regulatory Framework;
- ◆ 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;
- ◆ Exit Criteria;
- ◆ Negotiation Strategies;
- ◆ Risk Communication; and
- ◆ Risk Management.

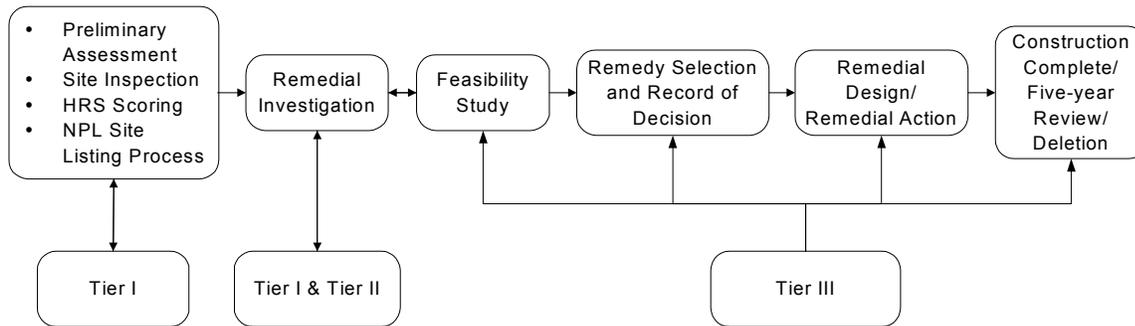
More in-depth discussions of each of these topics are presented in other chapters of this guidance.

## 4.1 Regulatory Framework

Risk Assessment is a key step in the Installation Restoration (IR) 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 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 risk assessment (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 Contingency Plan (NCP) in the case of releases and threatened releases on or from DOD properties. The Navy/Marine Corps Installation Restoration Manual (March 2000), Section 1.1.5, entitled “Lead Agency Authority” delegates NAVFACENGCOM responsibility to plan and implement response actions at all Navy and Marine Corps installations.

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 Priority 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 EPA are unable to reach an agreement on selection of a remedial action, EPA 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 EPA 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

The purpose of the project planning 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” and avoid key data gaps and 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 RI/FS process.



Project planning 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).

## 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 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. The CSM can also be used as an effective tool in the scoping process, to communicate site conditions to regulators and stakeholders.

## 4.5 Data Quality Objectives for Risk Assessment

Data Quality Objectives (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, amount, and quality of data collected at a site are appropriate to meet project objectives. 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.). Three key risk assessment DQO issues are as follows.

- 1.) **Adequate Site Characterization** – The foundation of a credible risk assessment are the 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 risk-based concentrations (RBCs). For some analytical methods, the detection limits for non-detected data (if taken at the detection limit) may exceed the RBCs. 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, in order to ensure that the appropriate analytical methods are selected.
- 3.) **Background Samples** – The purpose of a site risk assessment is to estimate the incremental risks associated with 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).*



## 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 a human health risk assessment, 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 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 (BHRA)** – If a BHRA 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, 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, 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.*

#### **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 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 United States Environmental Protection Agency (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, 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 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, 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.

## **4.8 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 different stakeholders who have different objectives and concerns. This may lead to a difficult and lengthy remedial process. Risk Communication is a science-based approach for effectively addressing these concerns, and helps streamline the remedial process by gaining stakeholder acceptance. The following seven cardinal rules were developed by EPA (Covello and Allen) to facilitate risk communication:



- 1.) accept and involve the public as a legitimate partner;
- 2.) plan carefully and evaluate performance;
- 3.) listen to your audience;
- 4.) be honest, frank, and open;
- 5.) coordinate and collaborate with other credible sources;
- 6.) meet the needs of the media; and
- 7.) speak clearly and with compassion (USEPA, 1988).

Although time and energy must be invested to promote public involvement, the investment pays significant dividends in community understanding and goodwill. Involving stakeholders in the risk assessment process will help to achieve the following.

- ◆ **Identify Overlooked Local Knowledge** - Community members may have useful information about the site's history, chemical uses, human activities, and past, current, and future land uses.
- ◆ **Streamline Efforts** - Community members may have special issues or concerns that, if incorporated into the risk assessment planning at the outset, will reduce the likelihood that the risk assessment and cleanup plans will have to be redone.
- ◆ **Gain Acceptance** - Community members who contribute to planning the risk assessment will better understand the process and will more likely give the outcome their support (USEPA, 1999).

*Note: In some regulatory contexts (e.g., CERCLA) public involvement is required.*

## 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:



- 1.) identify sites that do not require remediation (i.e., “No Further Action Sites”); and
- 2.) evaluate remedial alternatives in order to select a remedy for a site.

## 4.10 References

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