



U.S. Navy Human Health Risk Assessment Guidance

Chapter 1 – Introduction

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1.0 Introduction

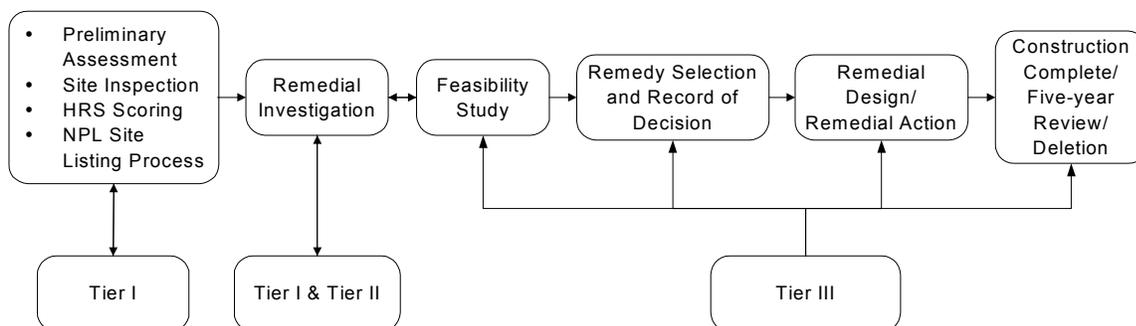
The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA, or "Superfund"), as amended, established a national program for responding to releases of hazardous substances to the environment. The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) is the 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 (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, 2001b).

Risk Assessment is a key step in the IR 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 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 or exposure pathways), 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 Remedial Project Managers (RPMs) to focus resources on those sites that pose a significant risk to human health and/or the environment.

Every effort has been made to provide examples and specific recommendations in this guidance document. There may be site-specific situations however, when some of these recommendations may not be appropriate. In those cases, the underlying logic that is identified in the 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 good and consistent risk evaluation practices for evaluating potential human health risks. Other objectives include the following:

- 1.) ensure that remedial project managers (RPMs) are aware of current risk assessment requirements, policies, and tools;
- 2.) provide a mechanism to gather and transfer information on risk assessment and risk management;
- 3.) identify barriers to risk-based decision-making and develop strategies to address these barriers;
- 4.) provide a basis for working toward consistent Navy-wide risk-based decision processes based on a three-tiered approach;
- 5.) help reduce costs by matching the level of effort expended with the complexity of the site; and
- 6.) increase 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 the 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 human health risk assessment process including the goals, tiered approach, risk communication, and risk management.
- ◆ **Human Health Risk Assessment Guidance** – Provides detailed information to aid in managing, planning, designing, conducting, and effectively communicating the results of HHRAs as identified in:
 - ❖ **Chapter 4 – Strategically Managing the HHRA Process**
 - ❖ **Chapter 5 – Planning/Scoping**
 - ❖ **Chapter 6 – Data Quality Objectives for Risk Assessment**
 - ❖ **Chapter 7 – Tier IA and Tier IB – Risk-Based Screening**
 - ❖ **Chapter 8 – Tier II – Baseline Risk Assessment**
 - ❖ **Chapter 9 – Other Tools: Using Probabilistic Risk Assessment to Further Characterize Risks**
 - ❖ **Chapter 10 – Tier III – Risk Evaluation of Remedial Alternatives**
 - ❖ **Chapter 11 – Risk Communication Principles and Techniques**



❖ **Chapter 12 – Risk Management**

- ◆ **Issue Summaries** – Provides information on a range of HHRA-related topics.
- ◆ **Tools and Resources** – Lists, and briefly describes, HHRA tools and resources (e.g., models, statistical software, and databases).
- ◆ **Case Studies** – Provides examples that demonstrate practical application of the concepts presented in the guidance.
- ◆ **Discussion Forum** – Provides an interactive site where individuals can ask and answer risk assessment related questions.

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, 2001a). The purpose of this policy is to provide clarification of the Navy's policy on human health assessments and the manner in which HHRAs are to be implemented for the Navy in the IR Program. The primary goal of the Navy policy is 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 and therefore the document focuses on issues that RPMs must understand and implement in order to carry out their responsibilities and incorporate risk-based decision-making into the IR process. The guidance focuses on important general issues rather than on in-depth, technical risk assessment issues. Other resources such as the issue papers, case studies, discussion groups, and United States Environmental Protection Agency (USEPA) guidance are available for RPMs who would like more detailed information.

Many of the recommendations and strategies presented in the 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/superfund/programs/risk/ragsa/index.htm>.

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

USNAVY. 2001b. Navy/Marine Corps Installation Restoration Manual (Draft) 2001 Update. Naval Facilities Engineering Command, Alexandria, VA. http://enviro.nfesc.navy.mil/erb/erb_a/restoration/ir_manual/Default.htm.