U.S. Navy Human Health Risk Assessment Guidance

Chapter 2 – Regulatory Framework

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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 Contingency Plan (NCP), and how Navy Lead Agency authority is implemented throughout the process.

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

- National Contingency Plan (40 CFR 300), http://www.epa.gov/epahome/cfr40toc.htm.
- Navy/Marine Corps Installation Restoration Manual, Naval Facilities Engineering Command, Alexandria, Virginia, 2000. http://enviro.nfesc.navy.mil/esc414/Techinfo/techinfo.htm.
- United States Environmental Protection Agency (USEPA) web sites.
    - CERCLA – (U.S. House of Representatives, U.S. Code, Title 42, Chap. 103), http://www.epa.gov/superfund/action/law/cercla.htm.
    - SARA – (U.S. House of Representatives, U.S. Code, Title 42, Chap. 103), http://www.epa.gov/superfund/action/law/sara.htm.
    - NCP – (40 CFR 300) http://www.epa.gov/docs/epacfr40/chapt-I.info/subch-J.htm
    - Superfund - http://www.epa.gov/superfund/programs/er/hazsubs/supers.htm.
- Risk Assessment Guidance for Superfund: Human Health Evaluation Manual Part A. USEPA, Office of Emergency & Remedial Response, 1989. EPA/540/1-89/002 http://www.epa.gov/superfund/programs/risk/ragsa/index.htm.

2.1 Comprehensive Environmental Response, Compensation and Liability Act

The Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (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. The Superfund Amendments and Reauthorization Act (SARA) amended CERCLA on October 17, 1986 (U.S. House of Representatives, U.S. Code, Title 42, Chap. 103 (a)). The 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/oilspill/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 and relevant or appropriate requirements (ARARs) (unless a waiver is obtained);

Balancing Criteria – Are 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 – Are 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

2.3.1 Introduction

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

Step 2 - Site Inspection

Step 3 – Hazard Ranking System (HRS) Scoring

Step 4 – National Priorities List (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

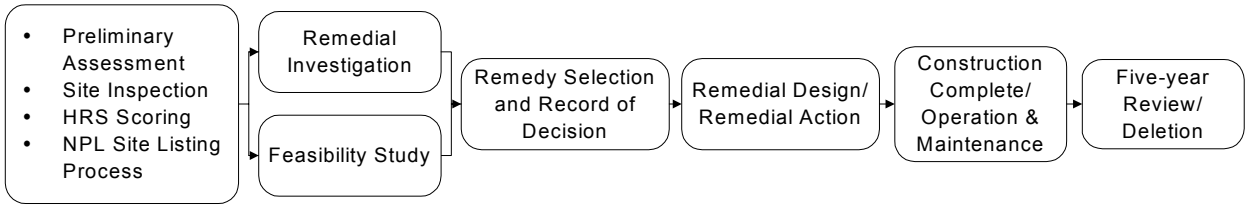
Step 9 – Operation and Maintenance

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



2.3.2 STEP 1 – PRELIMINARY ASSESSMENT

The Preliminary Assessment (PA) is used to evaluate potential releases of hazardous substances from a site. The PA is a limited-scope investigation performed on every CERCLIS 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 Site Inspection (SI) is performed. The USEPA publication *Guidance for Performing Preliminary Assessments Under CERCLA* (http://www.epa.gov/superfund/whatissf/sfproces/pasi.htm) (USEPA, 1991), and the electronic scoring program (http://www.epa.gov/superfund/resources/pascore/index.htm) provide more information on conducting Pas (USEPA, 1991).

2.3.3 STEP 2 – SITE INSPECTION

The Site Inspection (SI) provides the data needed for HRS scoring and documentation. The SI provides more information for evaluating 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, or 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, or expanded SI, is conducted. The USEPA publication *Guidance for Performing Site Inspections Under CERCLA* (http://www.epa.gov/superfund/whatissf/sfproces/pasi.htm) provides more information on conducting Sis (USEPA, 1992).

2.3.4 STEP 3 – HAZARD RANKING SYSTEM

The Hazard Ranking System (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 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 ground water 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 an important requirement 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 *(EPA 9345.1-07)* (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).

2.3.5 STEP 4 – NATIONAL PRIORITIES LIST SITE LISTING PROCESS

Sites are listed on the NPL based on their HRS score and public comments (http://www.epa.gov/superfund/action/law/npl_hrs.htm). The NPL is a management tool that publicly identifies sites or other releases that appear to warrant remedial actions. The NPL is updated periodically.

2.3.6 STEP 5 – REMEDIAL INVESTIGATION/FEASIBILITY STUDY

After a site is listed on the NPL, a remedial investigation/feasibility study (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 (USEPA, 1989). 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 are conducted concurrently — data collected in 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 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, the baseline risk assessment, refinement of preliminary remediation goals, and the remedial alternatives risk evaluation. 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/whatissf/sfproces/rifs.htm) (USEPA, 1988d).

2.3.7 STEP 6 – RECORD OF DECISION

The Record of Decision (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, 1988e).

2.3.8 STEP 7 – REMEDIAL DESIGN/REMEDIAL ACTION

Remedial Design (RD) is the phase in Superfund site cleanup where the technical specifications for cleanup remedies (including engineering controls and/or institutional controls) and technologies are designed. Remedial Action (RA) follows the remedial design 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, 1988c).

2.3.9 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 is completed (USEPA, 1988a).

2.3.10 STEP 9 – OPERATION AND MAINTENANCE

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, ground water extraction treatment, ground water 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 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, ground water activities, or through natural attenuation (USEPA, 1988b).

2.3.11 STEP 10 – FIVE-YEAR REVIEW

Section 121(c) of CERLCA 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).

2.3.12 Step 11 – National Priorities List Site Deletions

The USEPA may delete a final NPL site if it determines that no further response 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 where no further response 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 no further response 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 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 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.

2.5 References

USEPA. 1988a. Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA; Interim Final. NTIS PB89-184626, EPA 9355.3-01. http://www.epa.gov/superfund/action/process/ccl.htm.

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