



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

# Chapter 12 – Risk Management

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## 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. 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 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 managers are responsible for determining the significance of the risks at a site and whether 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.

## 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, 1991b)" identifies key points that should be considered when making risk management decisions at a site. 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  $1E-04$  and the non-carcinogenic hazard index is less than 1, action generally is not warranted unless there are adverse environmental impacts. However, if 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  $1E-04$ , although EPA generally uses  $1E-04$  in making risk management decisions. A risk estimate that is greater than  $1E-04$  may be considered acceptable, if justified based on site-specific conditions. A risk*



manager may also decide that a baseline risk level less than  $1E-04$  is unacceptable due to site specific reasons and that remedial action is warranted.

- ◆ **Consider ARARs** – Applicable or relevant and appropriate requirements (ARARs) may be used, in addition to calculated risks, to determine whether a site warrants remediation.
- ◆ **Evaluate Current and Future Exposures** – Both current and likely future exposures should be assessed to determine whether or not a site poses an unacceptable risk to human health and the environment.
- ◆ **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 (e.g., a deed restriction) and perform long-term monitoring at the site.
- ◆ **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 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  $1E-04$  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.

*Note: In some cases the results of a Tier I or Tier II risk evaluation depend on land use controls (LUCs), such as institutional controls 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 remedy selection criteria which are identified in the National 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 ARARs. These criteria must be met at every site. The other seven criteria are non-risk-related and are associated with issues such as cost, feasibility, and long-term effectiveness. 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 performed concurrently with other steps in the remedial process (i.e., 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 risk assessment



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 such as 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, 1991a).” 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 institutional or engineering controls 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 engineering control, 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 of the engineering control.

*Note: If the remedy depends on institutional control or engineering controls, 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.
- ◆ **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 risk assessment (BHRA) 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 Maximum Contaminant Levels (MCLs) or non-zero Maximum Contaminant Level Goals (MCLGs), PRGs and FRLs should be established at concentrations that achieve 1E-06 excess cancer risk or a hazard quotient of 1 (for noncarcinogens) modified, as appropriate, based on exposure, uncertainty, and technical feasibility factors (USEPA, 1991a). 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, 1991b). For example, a site with a cumulative cancer risk greater than 1E-04 may be considered protective of human health based on site-specific conditions and, therefore, remedial action is not warranted. Conversely, in other situations, a site with cumulative cancer risk less than 1E-04 may not be considered protective of human health and, therefore, remedial action is warranted.

*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 CERCLA (Comprehensive Environmental Response, Compensation and Liability Act) 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 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, “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, 1994).”
- ◆ **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 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/>.
- ◆ **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 carcinogenic and noncarcinogenic risks are below their respective regulatory benchmarks or PRGs/FRLs, but chemical-specific standards (e.g., MCLs or MCLGs) are exceeded;
- ◆ the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure (RME) for both current and future land use is greater than 1E-04;
- ◆ the non-carcinogenic hazard index is greater than one; and
- ◆ there are adverse environmental impacts (USEPA, 1991b).

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, 1991b). In addition, the CERCLA Section 121 cleanup standards for selection of a remedy, including the requirement to meet ARARs, are not triggered (USEPA, 1991b).

### 12.3.2 SITE CLOSEOUT

The last step in the remedial process is site closure. 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. 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 institutional controls, action RODs without institutional controls, etc.) can be found in the 1999 *Environmental Site Closeout Process Guide* (<http://web.ead.anl.gov/ecorisk/closeout/>).

## 12.4 References

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