

Reviewing Ecological Risk Assessment Deliverables

Abstract

Navy Remedial Project Managers (RPMs) are responsible for reviewing Ecological Risk Assessments (ERAs) that are conducted and written by contractors. The goal of this paper is to give RPMs some tools to help them efficiently and effectively review ecological risk assessment deliverables.

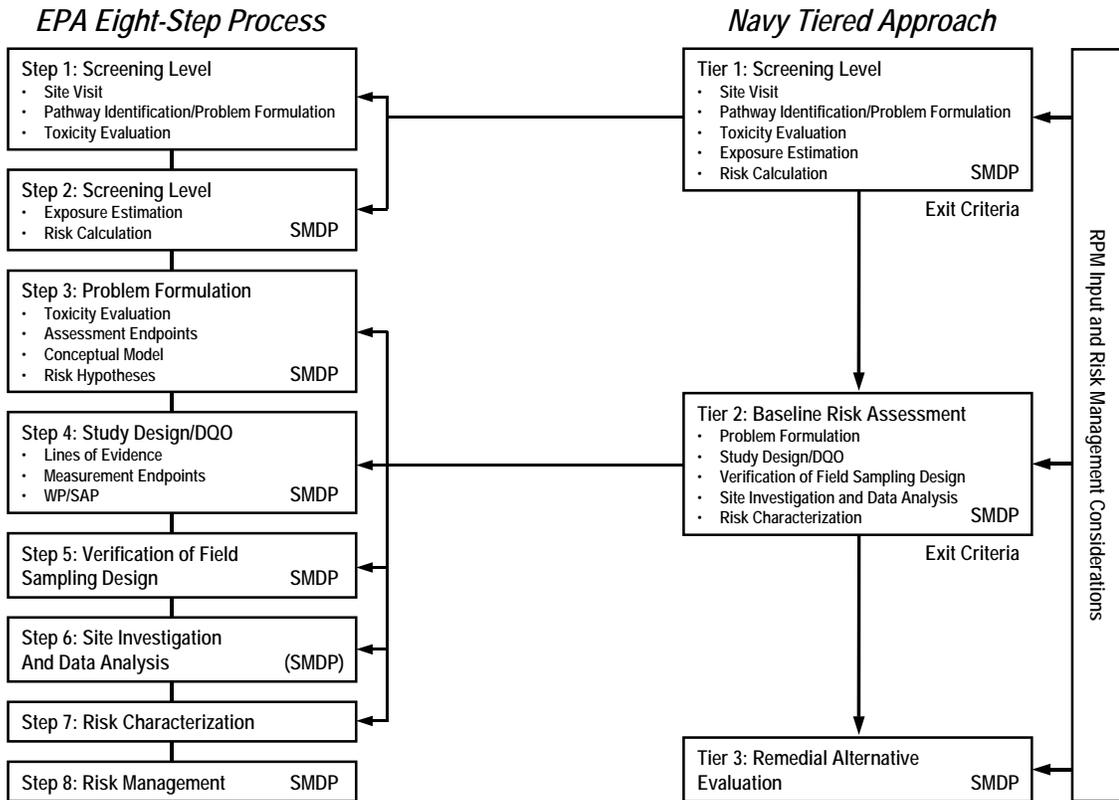
Ecological risk assessment is the process used to determine potential risk to populations of receptors due to contamination at a hazardous waste site. It uses conservative assumptions when site-specific information is not available, and the ultimate product is a risk range for each contaminant that can be used with the results of the Human Health Risk Assessment (HHRA) in developing preliminary remediation goals in the Remedial Investigation (RI) report.

This paper begins with a brief overview of Navy policy, followed by a breakdown of the steps in the ERA process and what the RPM should look for when each step is presented to them. Finally, standard deliverables are discussed along with common issues in the ERA process and strategies RPMs can use to overcome them. This paper is not intended to be a detailed technical description of the ERA process or any component thereof. There are many excellent technical documents available, some of which are referenced in this paper. Rather it is intended to provide RPMs the information necessary to review documents and determine whether or not they are written in a way that will optimize negotiation success with stakeholders and avoid any unnecessary delay due to non-technical issues within deliverables, while ensuring they comply with Navy policy and guidance.

Introduction

The Chief of Naval Operations (CNO) has released ecological risk assessment policy that is consistent with US Environmental Protection Agency (EPA) ERA policy, but has some unique characteristics that facilitate decision-making. Navy ecological risk assessment policy divides the eight steps that are laid out in the EPA’s policy into three tiers as seen in Figure 1. The three tiers are made up of (1) the screening ecological risk assessment (SERA) which encompasses Steps 1 and 2 of the EPA process, (2) the baseline ecological risk assessment (BERA) which includes Steps 3 – 7 of the EPA process, and (3) the evaluation of remedial alternatives. EPA’s Step 8 is risk management, which Navy policy incorporates throughout all three tiers.

Figure 1



Another unique aspect of Navy policy is the way that the refinement of chemicals of potential concern (COPCs) is pulled out as a separate step. This step occurs after the initial SERA and is called Step 3a – Refinement of Conservative Exposure Assumptions. It is the equivalent of the first portion of EPA’s Step 3, and is designed to focus the risk assessment before proceeding to the BERA by looking at more realistic exposure assumptions than those used in the SERA. Navy policy also points out the need to have risk managers involved in each decision point along the way, incorporating risk management considerations throughout all tiers of the ERA process. For more detail on both CNO policy and EPA guidance, access the NAVFAC Risk Assessment Workgroup website or the EPA Superfund website. The Civil Engineer Corps Officer School (CECOS) also provides a three-day training course for RPMs on ERA. Links to these resources can be found in Highlight 1.

Highlight 1

Important Websites

CNO Policy

<http://web.ead.anl.gov/ecorisk/policy/>

Navy Process

<http://web.ead.anl.gov/ecorisk/process/>

EPA Process

<http://www.epa.gov/superfund/programs/risk/ecorisk/ecorisk.htm>

CECOS Training

<https://www.cecos.navy.mil/>

The ERA process is part of the RI and must be completed in order to complete the RI report. Risk assessment is also done in the Site Inspection (SI) phase. However, the SI risk assessment is qualitative and does not necessarily follow the process as it is laid out for the RI.

Reviewing the SERA and Step 3a

The screening ecological risk assessment is performed using existing site data and conservative assumptions to focus the risk assessment for future data collection. It should not require a lot of negotiation. If there is uncertainty about the potential risk associated with a COPC at this point then it should remain in the risk assessment. The Step 3a

refinement of conservative exposure assumptions immediately follows the screen and requires a great deal of expertise on the part of Navy contractors. It is the opportunity to justify removing COPCs from further assessment based on more realistic site-specific assumptions. As the assessment moves from less site-specific information to more site-specific information the assumptions become less conservative. When there is very little site-specific information, very conservative assumptions must be used. The screen and Step 3a are often submitted as one deliverable, but it is important to understand the distinctions between the two. For a detailed discussion on these steps, see the white paper, U.S. Navy Ecological Screening and COPC Refinement for Sediment, Soil, and Surface Water at

http://web.ead.anl.gov/ecorisk/issue/pdf/Navy_Screening_White_Paper_7-22-03.pdf

The screen is made up of the preliminary conceptual site model, assessment and measurement endpoints, the ecological effects evaluation, the screening level exposure estimate, and the screening level risk calculation using the hazard quotient approach. These are all required components of risk assessment that will be used again in the baseline ecological risk assessment. The following is a brief overview of these required components.

Conceptual Site Model: The preliminary conceptual site model (CSM) includes a general description of the environmental setting, known or suspected contaminants, contaminant fate and transport mechanisms, mechanisms of ecotoxicity, likely categories of receptors, and complete exposure pathways. In those areas where information is lacking, the information gap should be documented for further investigation in the BERA, where site-specific versions of each part of the CSM will be included. If a site is expected to exit the process at the conclusion of the screen or Step 3a, it may be prudent to put more detail into the CSM at this point.

Assessment and Measurement Endpoints: Throughout this process the assessment and measurement endpoints will be important decision-making and communication tools. The SERA is the first place that these are introduced. An assessment endpoint is “an explicit

expression of the environmental value that is to be protected”, and defines “both the valued ecological entity at the site (e.g., a species, ecological resource, or habitat type) and a characteristic(s) of the entity to protect (e.g., reproductive success, production per unit area, areal extent)” (USEPA, 1997). A measurement endpoint measures the effects of site COPCs on a sensitive species and life stage to make inferences about the population represented by the assessment endpoint.

Ecological Effects Evaluation: The data for the screening ecological effects evaluation is gathered from literature. The toxicity data chosen for comparison to site data needs to be based on a No Observed Adverse Effect Level (NOAEL) for the SERA. The NOAEL is the highest concentration of a contaminant at which no adverse effects are observed. In the BERA, decisions may be made based on the Lowest Observed Adverse Effect Level (LOAEL) as well as the NOAEL. The LOAEL is the lowest concentration of a contaminant at which adverse effects are observed. One way ERAs differ from HHRAs is that ERAs protect at the population level while HHRAs protect at the individual level. The toxicity benchmarks chosen for ecological effects evaluations are used to make decisions at the population effects level. There are other types of effects data and many databases to get the required data from. Often an EPA region will have specific toxicity benchmarks for use in their region. Finding the appropriate numbers for screening your site will require both a look at what benchmarks have been previously used in your region, as well as some research into any new or updated benchmarks.

Exposure Estimate: The screening level exposure estimates should be conservative. By using conservative assumptions that represent exposure levels greater than those one would expect to find at the site, we can feel confident that there is very little chance of coming to the conclusion that there is acceptable risk at the site when in fact the risk is not acceptable. When reviewing a screening ecological risk assessment it is typical to find that conservative assumptions, which may not reflect actual conditions at the site, have been used.

Risk Calculation: Using the screening benchmarks gathered during the screening level effects evaluation and the dose calculated from the screening level exposure estimate, a Hazard Quotient (HQ) is calculated as shown in Highlight 2. The HQ review is straightforward and important in the screen because it gives the answer to the question of what COPCs will be carried forward to Step 3a and the BERA. Those contaminants with an HQ greater than 1 are COPCs to be carried forward. The conservative exposure estimate for these COPCs is greater than the screening benchmark. Those contaminants with an HQ less than 1 are considered to have acceptable risk and do not need to be carried into the BERA. These COPCs exit the process at the end of Step 2. There are two other groups of contaminants that will be carried forward into the BERA. The first is those contaminants that are known to bioaccumulate in the food chain, and the second is those contaminants for which there is not enough toxicological information to make a decision using a HQ calculation.

Highlight 2

$$\text{Hazard Quotient} = \frac{\text{Exposure Estimate}}{\text{Screening Benchmark}}$$

Step 3a – Refinement of Conservative Assumptions: Step 3a takes a more realistic look at preliminary COPCs by doing refinement level risk calculations and refinement level exposure estimates using the hazard quotient approach. The same parameters are used to come up with an exposure estimate here as were used in the SERA, but in Step 3a the values used are more realistic and drawn either from site-specific information or from published values derived from literature (e.g. the estimate of site use may be adjusted from 100% to 50% if the home range and feeding range of an assessment endpoint are more than twice as big as your site). Using the refined exposure estimates, the hazard quotients are recalculated using the same method that was used in the SERA. Risk due to background contamination is also considered at this step. Navy background policy states that COPCs occurring below naturally occurring or man-made background levels should be identified during Step 3a. These COPCs should not be assessed further in the BERA. There may be potential risk due to background levels of COPCs, which should be discussed in the risk characterization.

See http://web.ead.anl.gov/ecorisk/policy/pdf/Final_Navy_Background_Policy.pdf for a copy of this policy.

Avoid including Step 3a refinement in Steps 1 and 2. Trying to give a preview of Step 3a during the screen may cause unnecessary negotiations and time delays. This is because extra time will be spent negotiating points that are not necessary for the screen and will most likely be renegotiated in Step 3a. It is important to keep the steps distinct, since separate decisions must be made in each step.

It may be appropriate to present the screen and Step 3a in the same document, but there are distinct decision points for each. Communication is enhanced when stakeholders know what step of the process is being presented. While the screen and Step 3a may be in the same document there still need to be different decisions for each. There are Scientific Management Decision Points (SMDPs) with exit criteria at both Step 2 and Step 3a. SMDPs are the points throughout the process where risk managers are brought in to work with risk assessors and make coordinated decisions before moving to the next step. At SMDPs, management decisions are made based on the conclusions of the ERA. For both Step 2 and Step 3a, one of the primary results of the SMDP is a decision on what COPCs will remain in the ERA for further evaluation due to either unacceptable risk or not enough information to make a risk determination, and what COPCs have been determined to have no unacceptable risk and will exit the process.

Reviewing the Baseline Ecological Risk Assessment

BERA documents build off of the SERA and Step 3a. The CSM, Assessment Endpoints, and Measurement Endpoints that were first presented in the SERA and expanded in the Step 3a will be further expanded in the BERA. The refined exposure assumptions from Step 3a will be carried over into the BERA for further risk characterization. There will be two significant sets of deliverables for the BERA. The first occurs at the end of Step 4 and will include the Work Plan (WP), Sampling and Analysis Plan (SAP), and other necessary pre-field work documentation. The second set of deliverables occurs at Steps 6 and 7, and will be the results of sampling and analysis along with risk characterization.

For many smaller sites, the WP and accompanying documents will be inclusive of sampling for both the Human Health Risk Assessment and the ERA. For these smaller or simpler sites, the Risk Characterization may only appear within the RI report and not as a separate deliverable.

The work plan should set the stage for the sampling plan. The work plan includes a general overview of the site along with a summary of any previous site investigations, the CSM and assessment and measurement endpoints, identification of the investigations needed to determine risk to the assessment and measurement endpoints, a description of the assumptions used, and any major sources of uncertainty. These items lead directly to the formation of the sampling plan because all samples should tie back directly to each of the work plan components. No sample should be taken unless it is directly related to the CSM or an assessment or measurement endpoint. The conceptual model for the site has been in formation since the first deliverable, and by this point it should be detailed and complete.

The SAP includes the field sampling plan and the QAPP. Both should be detailed and specific about all of the logistics of sampling and analysis. Throughout the WP and SAP there should be an emphasis on following the Data Quality Objectives (DQO) process. The DQOs must follow the 7-step process described by the EPA in their Guidance for the Data Quality Objectives Process (1994). This process can be found at <http://www.epa.gov/swrust1/cat/epaqag4.pdf>.

The WP and the SAP should also clearly state how the data will be interpreted. It is important to include plans for data interpretation before the data is actually gathered because this will facilitate decision making in risk characterization. The key foundation is having a good Conceptual Site Model and an understanding of the assessment endpoints, along with developing DQOs that ask the right questions and are measurable, and having decision points or an exit strategy.

Risk analysis (Step 6) and characterization (Step 7) are based on the evaluation and results of the BERA. The risk characterization includes the risk estimation based on the interpretation of the data that was specified in the WP and SAP, the risk description that includes the risk range bounded by the NOAEL and LOAEL and narrative description of other risk factors, and an analysis of the uncertainty associated with the risk.

Risk management occurs outside of the risk assessment and requires active participation on the part of the RPM. Using the results of the risk characterization, the risk managers can determine the appropriate preliminary remediation goals (PRGs) in the RI, and then use risk information in the evaluation of remedial alternatives in the Feasibility Study (FS).

Standard Deliverables

The steps in an ERA may be presented in various ways but there are some standard deliverables that are common to most sites. Standard deliverables are not prescribed in guidance but do coincide with the SMDPs and can be a useful tool. These deliverables provide the basis for risk managers to make decisions. A set of standard deliverables is listed in the white paper “Ecological Risk Assessment Standard Deliverables” that can be found at http://web.ead.anl.gov/ecorisk/issue/pdf/StandDeliverable_Prev1-10-02.pdf. For a given site some variation in standard deliverables may be appropriate for the ERA. However, the standard deliverables provide structure to the decision points, which can be of assistance to many ERAs. Because each site is unique, the appropriate deliverables to document the decision points are determined by the RPM with input from the project team according to CNO policy and EPA guidance. Standard deliverables can be integrated into documents or done according to the project team method of documenting decisions. Most SMDPs require some sort of deliverable.

Key Issues in Deliverables A key question to ask regarding any ERA deliverable is whether or not it fits within the scope of Navy policy and guidance. To determine the answer to this question, look at the document and determine what step of the three-

tiered/eight step ERA process it fulfills. Use resources like the Navy ERA website <http://web.ead.anl.gov/ecorisk/> to determine whether a deliverable is in compliance with Navy policy. A deliverable should state clearly what step of the process it completes. Generally, documents that do not specifically meet the requirements of a given step of the process are not productive because they make it more difficult to get regulatory concurrence. It is also important to confirm that no steps are skipped.

Another important question is whether statements made in the deliverable are logical, and whether the conclusions make sense based on the data presented. Although conducting an ERA requires specific areas of scientific expertise, the risk assessment should also be written to be logical and comprehensible to the layman. The ERA is an important communication tool to all stakeholders. Statements should reflect what you know about the site as the RPM. It should be clear to you how all of the data is being used for decision-making and how the conclusions are supported by the data. As you review the deliverable, it is important to note any assumptions that are not clearly defined. For example, if a particular type of sampling has been omitted from the risk assessment it is important to include the reason why (e.g. tissue analysis has been omitted because there was not enough of the test species available at the site to get the necessary quantity of tissue for sampling.)

SMDPs for the elimination of COPCs occur at the end of Step 2 (SERA risk characterization), Step 3a (Refinement of Conservative Exposure Assumptions), and Step 7 (BERA risk characterization). These decisions are based on the conclusion of “no unacceptable risk” to assessment endpoints, usually based on a hazard quotient of <1. At Step 2, decisions are made based on a screening of limited information and conservative assumptions. In many cases this step eliminates few if any chemicals. At this stage in the risk assessment, there is very little chance of determining that there is no significant risk if in fact there is significant risk. Step 3a requires the refinement of some of the conservative assumptions to more realistic or site-specific assumptions. If there is not enough information to understand site-specific exposures, then the COPC is not eliminated. In some cases looking at more realistic exposures allows for the elimination

of COPCs. In many cases the refinement of assumptions helps focus the BERA. At the end of Step 7 (BERA risk characterization), increased understanding of the site allows some COPCs that were previously retained to be eliminated. Accepting that there is risk and continuing with the risk assessment requires basic documentation. Eliminating COPCs requires specific supporting data. Proper expertise on the project team is crucial when COPCs are being eliminated. For all remaining COPCs cleanup goals must be determined in the Remedial Investigation Report

Review for Decision Making

Throughout the ERA process it is important to consider the best way to facilitate decision-making. As an RPM, when you review the ERA submittals, consider whether the document facilitates or complicates decision-making.

One way to facilitate decision-making for the site is by making sure that the ERA and the HHRA are coordinated in a cost-effective manner. The ERA is not done in a vacuum. The HHRA must be taken into consideration, especially when it comes time to deploy a sampling event. Work plans for sampling events can be inclusive of the needs of both the human health and the ecological risk assessment. Some examples of things to be considered include types of fish tissue and detection limits. At a surface water site, fish tissue may be necessary to determine bioaccumulation in both the ERA and the HHRA. Money and time can be saved when the same sampling event can be deployed once for both studies. However, the types of fish or sampling methods (e.g. whole body v. fillet) may need to be different for the two studies. A second common issue that comes up when looking to use the same data for both an HHRA and an ERA is that of acceptable detection limits. The analysis used must be sensitive enough to give acceptable data at levels lower than the screening benchmarks being used for the site. In many cases the benchmarks used for comparison in the screening ERA will be lower, but there are some contaminants for which the HHRA may require lower detection limits. A detailed discussion of detection limits is available in the issue paper, Laboratory Detection and

Reporting Limit Issues Related to Risk Assessments at
http://web.ead.anl.gov/ecorisk/issue/pdf/Final_Detection_04_02.pdf

A second way to facilitate decision-making is to be certain that the Navy is comfortable with what is being proposed before sending a deliverable to regulatory agencies for review. Review all documents internally before forwarding them to regulatory agencies and if possible get someone else to review deliverables also. There are many options for secondary review. Possible secondary reviewers include: remedial technical managers (RTMs), the Ecological Risk Technical Assistance Team (ERTAT), other RPMs, or other technical support. Regardless of who does the secondary internal review, it is important that the internal reviews are complete before the document goes to the regulators and stakeholders. Decision-making is complicated if documents are sent out for external review before internal Navy reviews are complete. It is difficult to make necessary changes once the document has been released. As you do your internal review, consider what items are of interest to stakeholders. Stakeholders are most often interested in the goal of the document, risk questions, the conclusions of the document, and the basic information necessary for decision-making. Review to confirm that the main body of the document contains the information you plan to use to make decisions at the site with supporting information in appendices referenced throughout the document, and that the conclusions presented logically flow from the data and analysis presented.

Summary

The overview of Navy policy, discussion of the steps in the ERA process, and presentation of common issues included in this paper are intended to give RPMs the basic information they need to efficiently and effectively review ecological risk assessment deliverables. The review strategies that were presented here can improve risk assessment efficiency and assist RPMs as they negotiate with stakeholders.

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Acronyms

BERA – Baseline Ecological Risk Assessment
CNO – Chief of Naval Operations
COPC – Chemical of Potential Concern
CSM – Conceptual Site Model
DQO – Data Quality Objective
EPA – United States Environmental Protection Agency
ERA – Ecological Risk Assessment
ERTAT – Ecological Risk Technical Assistance Team
FS – Feasibility Study
HHRA – Human Health Risk Assessment
HQ – Hazard Quotient
LOAEL – Lowest Observed Adverse Effect Level
NOAEL - No Observed Adverse Effect Level
PRG – Preliminary Remediation Goal
RI – Remedial Investigation
RPM – Remedial Project Manager
RTM – Remedial Technical Manager
SAP – Sampling and Analysis Plan
SERA – Screening Ecological Risk Assessment
SMDP – Scientific Management Decision Point
QAPP – Quality Assurance Project Plan
WP – Work Plan

Glossary

Bioaccumulation: the process by which chemicals are taken up by an organism either directly from exposure to a contaminated medium or by consumption of food containing the chemical.

Chemical of Potential Concern (COPC) – a potentially site-related chemical occurring or suspected in water, soil, or sediment due to current or historical site operations.

Conceptual Site Model (CSM) – a series of working hypotheses about origin, distribution, and transport of site-related chemicals through the environment; routes and scenarios of exposure of ecological receptors to site chemicals; and how site chemicals may effect specific ecological components.

Data quality objectives (DQOs): qualitative and quantitative statements that define the type, quality, and quantity of data necessary to support defensible risk management decision-making. Used to develop an effective sampling plan that avoids the collection of data that are inconsequential

Ecological risk assessment (ERA): process that identifies stressors (e.g., chemical, physical) that may alter ecosystems and quantifies the probable severity of adverse effects on those ecosystems.

Exposure pathway: Route, dictated by site-specific conditions and habitats, by which an ecological receptor might contact a contaminant or ecological stressor.

Hazard Quotient (HQ): The ratio of an exposure level to a substance to a toxicity value selected for the risk assessment for that substance.

Human health risk assessment (HHRA): process that identifies stressors (e.g., chemical, physical) that may affect human health and quantifies the probable severity of adverse effects on humans.

Lowest Observed Adverse Effect Level (LOAEL): the lowest level of a stressor evaluated that has a statistically significant adverse effect on the exposed organisms compared to control or reference organisms.

No Observed Adverse Effect Level (NOAEL): the highest level of a stressor evaluated that causes no statistically significant difference in effect compared to control or reference organisms.

Receptor: any organism, population, or community that may become exposed to a stressor (e.g., chemical, physical).

Risk drivers: the stressor or mechanism perceived as being the primary source of environmental risk and the potential focus the site assessment.

Scientific Management Decision Point (SMDP): a point during the risk assessment process when the risk assessor communicates the results of the assessment at that stage to the risk manager. At this point the risk manager determines whether the information is sufficient to arrive at a decision regarding risk management strategies and/or the need for additional information to move forward in the risk assessment process.

Uncertainty: imperfect knowledge about the present or future state of specific factors, parameters, or models.

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