

Ecological Risk Assessment Standard Deliverables

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Abstract

There are standard deliverables which should be completed at certain steps of the ecological risk assessment (ERA) process conducted according to Navy policy (CNO, 1999). There are five standard deliverables which can span the eight-step Navy ERA process (i.e., all eight steps of the process may not be required) and typically include: (1) the Screening Problem Formulation (PF) - Step 1, (2) The Screening ERA - Steps 1 and 2, (3) The Baseline Risk Assessment PF - Step 3, (4) the Site-Specific Work Plan & Sampling and Analysis Plan (SAP) - Steps 4 to 6 and (5) the Baseline Risk Assessment or the Risk Analysis, Characterization and Conclusion - Step 7 and Risk Management- Step 8. These deliverables can be completed in a variety of combinations (e.g., merged deliverables), and/or can be included as a component of other deliverables (e.g., Remedial Investigations). For more details on the ERA process, readers should consult CNO policy and the USEPA Ecological Risk Assessment Guidance for Superfund (USEPA, 1997).

Introduction

This issue paper presents a synopsis of the standard deliverables involved in the ecological risk assessment (ERA) process, which is outlined in the Navy Policy for Conducting Ecological Risk Assessments (Chief of Naval Operations [CNO], 5 April 1999). The CNO policy, which consists of eight steps organized into three tiers, is a clarification and interpretation of the eight-step ERA process outlined in U.S. Environmental Protection Agency (USEPA) ERA guidance for the Superfund program. The major differences between the Navy ERA policy and the USEPA ERA guidance are: (1) the Navy policy provides clearly defined criteria for exiting the ERA process at specific points, (2) the Navy policy divides Step 3 (the first step of the baseline ERA) into two distinct sub-steps (Steps 3a and 3b), with a potential exit point after Step 3a (see Section IV, below), and (3) the Navy policy incorporates risk management considerations throughout all tiers of the ERA process, whereas risk management is essentially confined to Step 8 in the USEPA guidance.

As a synopsis, not all of the details of the ERA process are provided in this issue paper. Instead, the focus of the issue paper is on the deliverables produced during the ERA process and the information that should be included in each deliverable. For more detail, the reader is referred directly to the CNO policy and the USEPA Ecological Risk Assessment Guidance for Superfund (USEPA, 1997).

The standard deliverables described in this issue paper are generally produced at defined exit or decision points, which generally follow the completion of a tier, step, and/or set of steps in the ERA process. The major tiers of the ERA process include:

1. Screening ERA (Tier 1; Steps 1 and 2)
2. Baseline ERA (Tier 2; Steps 3-7)
3. Evaluation of remedial alternatives/risk management (Tier 3; Step 8)

Some of the deliverables recommended in this issue paper go beyond those explicitly called for by the ERA process. Also, this issue paper identifies, but does not discuss, the deliverables associated with Tier 3 (Step 8) as this tier/step is generally considered to be distinct from the actual assessment of risk. Not all of the identified deliverables will be required for every site and some may be required more than once. Sites which meet an exit criteria at an early step will not require the deliverables associated with later steps (since the ERA process terminates). Sites at which a presumptive remedy (such as capping an existing landfill) is implemented may also skip certain steps (and the deliverables associated with those steps). Sites with sufficient data on which to assess risk may not require Steps 4-6 and the deliverables associated with these steps, while more complex sites may require multiple rounds of data and thus multiple iterations of Steps 4-6. The deliverables identified in this issue paper are as follows:

Tier	Step	Within RI Process*	Outside of RI Process
1	Step 1 - Screening Problem Formulation	RI Work Plan	Technical Memo
1	Step 2 - Screening Risk Characterization	Draft RI Report	Stand-alone document
2	Step 3a - Refinement of Conservative Exposure Assumptions	Draft RI Report	Stand-alone document
2	Step 3b - Baseline Problem Formulation	Draft RI Report	Stand-alone document
2	Steps 4 - 6 - Site-Specific Studies	Stand-alone Work Plan	Stand-alone Work Plan
2	Step 7 - Baseline Risk Characterization	Final RI Report	Stand-alone document
3	Step 8 - Evaluation of Remedial Alternatives/Risk Management	Feasibility Study (FS)	FS or stand-alone document
* In some cases, some or all of the activities associated with Tier 1 may be conducted as part of a Preliminary Assessment or a Site Investigation rather than as part of the Remedial Investigation (RI).			

Deliverable Types

Screening Problem Formulation (Step 1)

The screening (i.e., preliminary) problem formulation is critical to a seamless and efficient ERA. This deliverable is typically contained within the Remedial Investigation

(RI) Work Plan (WP). Ecological resources (species and habitats) present at a site are preliminarily identified (typically through a site visit and a review of any existing data) and documented. Suspected contaminants, environmental setting, and contaminant fate and transport mechanisms are also described. The screening problem formulation identifies the media to be evaluated, includes a preliminary conceptual model that identifies potentially complete exposure pathways and preliminary assessment endpoints, and determines if the existing analytical data are adequate for completing the screening ERA. If the existing analytical data are not adequate, additional sampling is proposed as part of the RI WP.

For sites where the RI is already underway or completed prior to ERA work beginning, the deliverable can be a technical memorandum that provides the information on how the ERA will be conducted. The technical memorandum should include a brief summary of the work to-date and address issues including the usability of existing data and how data gaps are to be handled in the screening ERA. The level of detail in the technical memorandum should be similar to the ERA component of a RI WP.

Screening Ecological Risk Assessment (Steps 1 and 2)

The second deliverable is the screening ERA report, which comprises Steps 1 and 2 of the ERA process. Details from the screening problem formulation (primarily the preliminary conceptual model), described in the previous section, are coupled with two preliminary screening steps to develop a simplified assessment of potential risk based upon readily available information from the site and the literature. It is purposefully biased to be conservative, minimizing the chance of concluding there is no risk when in fact there is a risk. The screening ERA report should include the results of the screening problem formulation (Step 1), as well as the components of Step 2: (1) screening effects evaluation, (2) screening exposure estimate, and (3) screening risk calculation. Screening tables identifying chemicals of potential concern (COPCs) from direct exposure and COPCs from exposure through food webs summarize the results from this phase of the ERA.

Direct exposure screening (screening risk calculation) is accomplished by comparing the maximum concentrations detected in each site medium evaluated (determined in Step 1) to agreed-upon medium-specific screening values (determined as part of the screening effects evaluation). If the maximum concentration is greater than or equal to the screening value, no screening value is available, or detection limits are higher than screening values (for non-detected chemicals), the chemical is considered a COPC for that medium and is retained for further evaluation. Potential food web exposures of selected receptor species are also estimated (screening exposure estimate) using conservative values for all applicable exposure factors (e.g., food ingestion rate) and maximum media concentrations. In general, food web exposure modeling is only conducted for chemicals that have a reasonable probability of bioaccumulating in food webs since chemicals with very low uptake factors are unlikely to be present at high enough concentrations in food items to represent a risk. Chemicals for which exposures

equal or exceed their ingestion-based, toxicological screening values are retained as COPCs for that exposure pathway and receptor.

The screening ERA can be included in the RI WP if all necessary data are available at that time or, more commonly, can be included in the draft RI report, although the screening tables can be provided to the regulators for their concurrence prior to the submittal of the RI report. If the RI has already been completed, the screening ERA is submitted as a stand-alone document.

The end of Step 2 generally corresponds to the first decision/exit point (although a site may exit after Step 1 if no complete exposure pathways are identified). Sites which meet the exit criteria do not require further evaluation and the ERA process terminates. Sites which do not meet the exit criteria continue on to Step 3.

Baseline Risk Assessment Problem Formulation (Step 3)

The third deliverable in the ERA process is the baseline risk assessment problem formulation, which is a refined problem formulation that focuses the ERA on areas, receptors, pathways and chemicals where there is a reasonable potential for ecological risk, as identified in the screening ERA. Although it is only the first step of the Baseline ERA, it is often useful to submit the baseline problem formulation as a separate deliverable for regulator review to allow for agreement on the “risk drivers” (if any).

In the first part of this step (Step 3a), a refined evaluation of media concentrations and exposure estimates is conducted using more realistic assumptions (or site-specific data) and additional methodologies. Examples of more realistic exposure assumptions include using central tendency estimates (rather than maximums) for media concentrations, bioaccumulation factors, and exposure parameters. Examples of additional methodologies include consideration of upgradient and background concentrations, detection frequency, and bioavailability.

If risk estimates (and their associated uncertainty) are acceptable following Step 3a, the site will meet the conditions of the next exit criterion and the ERA process will terminate. If the Step 3a evaluation does not support an acceptable risk determination, the site continues to Step 3b.

In Step 3b, the preliminary conceptual model presented in the screening ERA is refined based on the results of Step 3a to develop a revised list of receptors, COPCs, assessment endpoints, measurement endpoints, and risk hypotheses. Based upon the revised conceptual model, the lines of evidence to be used in characterizing risk (if present) are determined. An important function of this deliverable is to provide an opportunity for regulatory input and approval on conceptual model components prior to continuing with the Baseline ERA process.

The baseline problem formulation deliverable is typically included as part of the RI report. If the RI has already been completed, it can be submitted as a stand-alone

document. A meeting with the regulators may be useful at this stage to discuss results to this point and possible next steps.

Site-Specific Work Plan & Sampling and Analysis Plan (SAP) (Steps 4 to 6)

A decision point is reached after the Baseline ERA problem formulation (Step 3) is completed. The main purpose of this decision point is to decide if additional data are needed to refine the risk estimates and/or to reduce uncertainties. If so, a site-specific WP and SAP are developed which focus on the required data as identified in the baseline problem formulation/ conceptual model. The site-specific WP and SAP might include the following studies, or others, depending upon site-specific circumstances and data requirements:

- Ecological studies such as benthic and terrestrial community studies.
- Laboratory studies such as toxicity tests or bioaccumulation tests. The media is collected from the site and laboratory organisms are used.
- Bioavailability studies, such as Acid Volatile Sulfide/Simultaneously Extracted Metals (AVS/SEM) sediment analyses.
- Collection of additional analytical chemistry data such as those used to develop background concentrations, fill analytical data gaps, or determine tissue residues in biota.

The WP or SAP should discuss how the data are to be evaluated and how inferences will be drawn from the studies as related to the assessment endpoints. Also included in the site-specific WP and SAP are data quality objectives (DQOs), which outline a series of planning steps to ensure that the type, quantity, and quality of the data to be collected during the investigation are adequate to support an ERA. The specific goals of the general DQO process are to:

- Clarify the study objective and define the most appropriate types of data to collect.
- Determine the most appropriate field conditions under which to collect the data.
- Specify acceptable levels of decision errors that will be used as the basis for establishing the quantity and quality of data needed to support risk management decisions.

The Site-Specific WP and SAP are submitted for agency review and approval, prior to sampling and analysis, as a stand-alone document.

Baseline Ecological Risk Assessment (Step 7)

The last deliverable in the ERA process is the Baseline ERA report, which synthesizes the information gathered during the entire ERA process into a comprehensive document that presents the final risk analysis, characterization and conclusions on ecological risk. Risk is evaluated and characterized using both qualitative and quantitative means, as appropriate, based on the methodologies agreed to in previous steps of the ERA process (e.g., the site-specific WP). Conclusions are made on whether or not there is a reasonable potential for ecological risk at the site, and if there is potential risk, the magnitude of that risk. The ERA should clearly communicate the conclusion on risk and the process and steps used to reach that conclusion. It should also provide a discussion of the uncertainties associated with the risk conclusions. The ERA is finalized and included in the final RI Report (or as a stand-alone document if the RI has already been completed).

If risks and uncertainties are acceptable following the completion of Step 7, the ERA concludes that no remediation or other action is required at the site from an ecological perspective. If the Baseline ERA concludes that unacceptable risks are attributable to the site, activities associated with Tier 3 (Step 8) will be required to address those risks. These activities, such as developing risk-based clean-up levels and evaluating possible remedial alternatives, are conducted outside of the risk assessment, typically as part of a FS.

Point of Contact

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Acronyms

AVS/SEM – Acid Volatile Sulfides/Simultaneously Extracted Metals
CNO – Chief of Naval Operations
COPC – Chemical of Potential Concern
DQO – Data Quality Objectives
ERA – ecological risk assessment
FS – Feasibility Study
RI – Remedial Investigation
SAP – Sampling & Analysis Work Plan
USEPA – United States Environmental Protection Agency
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

Bioavailability: the degree to which a chemical in environmental media can be assimilated, or taken up by, an organism

Conceptual model: Component of the problem formation (see below) which addresses the following; (1) a description of the site environmental setting and known or suspected contaminants, (2) probable contaminant fate and transport mechanisms, (3) mechanisms of ecotoxicity associated with contaminants for receptors, (4) identification of complete exposure pathways and (5) a selection of endpoints to screen for ecological risk.

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.

Problem formulation: Step in the ERA where the assessor develops the conceptual model (see above).

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.

References

CNO (Chief of Naval Operations). 1999. Navy Policy for Conducting Ecological Risk Assessments. April 5, 1999.

U.S. Environmental Protection Agency (USEPA). 1997. Ecological risk assessment guidance for Superfund: process for designing and conducting ecological risk assessments. Interim Final. EPA/540/R-97/006.