

# Reviewing Ecological Risk Assessment Deliverables

## Abstract

The goal of this paper is to give remedial project managers (RPMs) some tools to help efficiently and effectively review ecological risk assessment (ERA) deliverables to ensure they meet Navy policy and project objectives. This paper is a combination of the earlier *Ecological Risk Assessment Standard Deliverables* issue paper and the original *Reviewing Ecological Risk Assessment Deliverables* issue paper.

Ecological risk assessment is the process used to determine potential risk to populations of ecological 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.

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. 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 nontechnical issues within deliverables, while ensuring compliance with Navy policy and guidance.

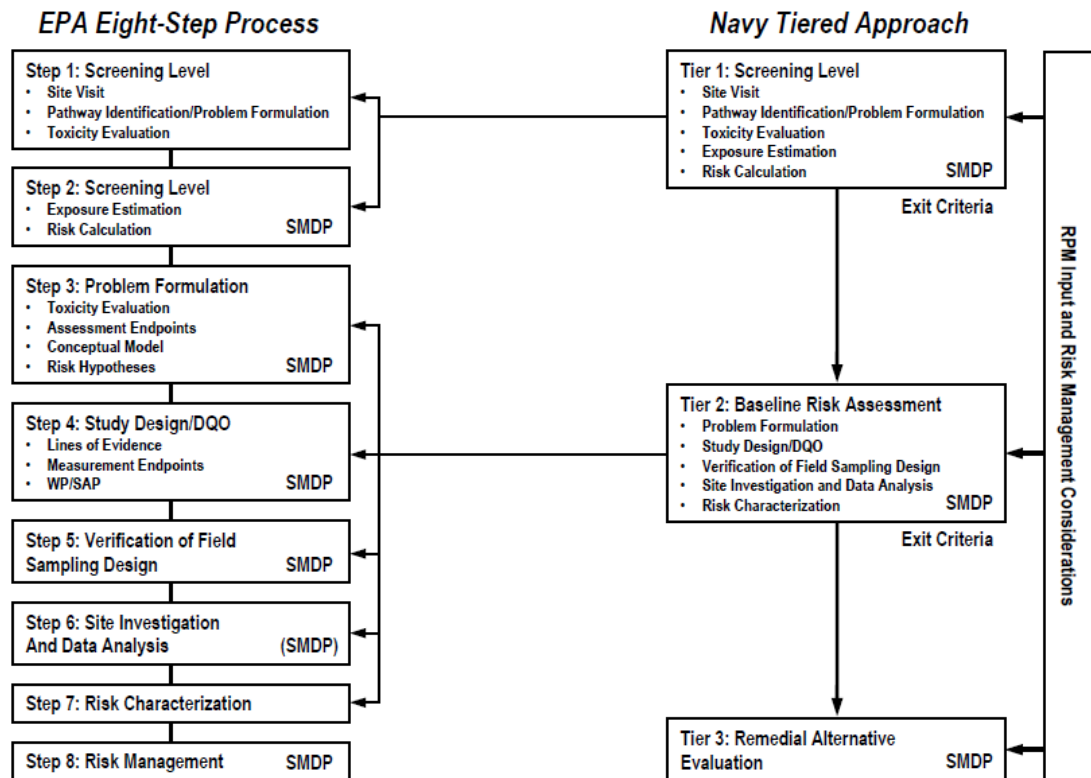
## Introduction

The Chief of Naval Operations (CNO) has released [ecological risk assessment policy](#) that is consistent with the US Environmental Protection Agency (EPA) [ecological risk assessment guidance](#), but has some unique characteristics that facilitate decision-making.

The Navy [ecological risk assessment process](#) 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.

Navy and EPA Ecological Risk Assessment Comparison

Figure 1



Navy policy stresses the importance of refining the list of contaminants of potential concern (COPCs) by pulling it out into a separate sub-step. This occurs after the initial SERA and is called Step 3a – Refinement of Conservative Exposure Assumptions. It is the equivalent of the first component of EPA’s Step 3, and is designed to focus the risk assessment when beginning 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 Environmental Restoration and BRAC website](#) or the [EPA Superfund website](#). The Civil Engineer Corps Officer School (CECOS) also provides a three-day training course for RPMs on ERA.

The ERA process is usually done as a part of the RI and must be completed in order to complete the RI report. Although the risk assessment screen can also be done in the Site Inspection (SI) phase, in most cases, it is completed within the RI.

## Standard Deliverables

There are standard deliverables associated with the ERA process. These deliverables provide the basis for risk managers to make decisions. The standard deliverables, which span the Navy tiered ERA process, typically include:

1. Screening ERA report - Steps 1 and 2
2. Baseline ERA Step 3a - Refinement of conservative assumptions
3. Baseline ERA Problem Formulation consisting of Work Plan (WP) and Sampling and Analysis Plan (SAP)/UFP-QAPP - Step 3b - 5
4. The Baseline ERA Report – Step 6-7

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). However, a deliverable should state clearly what step of the process it completes and it is important to confirm that no steps are skipped. The statements made in the deliverable need to be logical, and the conclusions need to make sense based on the data presented. Although conducting an ERA requires specific areas of scientific expertise, the risk assessment should also be written in a way to be comprehensible to the layman. As you review each deliverable, it is important to note any assumptions that are not clearly defined. Generally, documents that do not specifically meet the requirements of a given step of the process are less productive because they can make it more difficult to get regulatory concurrence.

## Screening Ecological Risk Assessment Problem Formulation

As part of the first deliverable, the Screening (i.e., preliminary) Problem Formulation (PF) (Step 1 of the EPA ERA process) is critical to a seamless and efficient ERA. In many cases, the SERA PF is not a standalone deliverable but it is important to document the PF activities and findings clearly and concisely in the SERA report. The screening-level problem formulation consists of six components that need to be documented in the SERA. These include:

1. Description of environmental setting and contaminants known or suspected at the site due to past Navy operations
2. Description of potential contaminant fate and transport mechanisms at the site
3. Ecotoxicity evaluation of potential chemical contaminants at the site
4. Identification of potentially complete ecological exposure pathways at the site
5. Selection of screening-level assessment and measurement endpoints
6. Selection of ecological effects screening benchmarks

The first four of these components are addressed as part of your Conceptual Site Model (CSM).

The CSM includes a general description of the environmental setting of the site that should be completed using information from both historic sources (reports, maps, photos) and the initial site visit. It should include the site layout and topography, habitat descriptions, descriptions of disturbed/man-made areas, current, historic, and future land uses, observations of plants and animals present at the site, and a description of soil/sediment/water types.

The list of chemical contaminants known or suspected at the site should be compiled from previous investigations and based upon historic operations at the site. If no prior sampling has been done, the list of suspected contaminants is based on the historical site operations. The use of full spectrum analyses to validate the list of suspected contaminants should be carefully evaluated and based upon any uncertainties that arise concerning the historical operations at the site. If the knowledge of site operations is not well documented and no historical data is available, full suite analyses should be conducted. It is the Navy's responsibility to provide sufficient historical documentation to justify the use of anything less than full suite analyses in the screening level risk assessment problem formulation.

Potential chemical contaminant migration pathways should be identified for the site. These pathways could include air or wind-borne transport, erosion, surface water runoff, ground water, food-chain transport (bioaccumulation/ingestion of contaminated media), etc. Discussion of chemical fate in the environment should consider the propensity for physical and biological degradation of contaminants, including the formation of daughter products, and the likelihood that some chemical constituents will be readily metabolized or sequestered by organisms.

The toxicity mechanisms of potential chemical contaminants should be evaluated to help in understanding potential exposure pathways and focusing the selection of appropriate screening-level assessment and measurement endpoints. It is important to understand whether a constituent's mode of action makes it particularly toxic to certain groups of organisms (e.g. mammals vs. fish, or vertebrates vs. invertebrates), and what the potential toxic effects are (e.g. death, growth reduction, reproductive/developmental effects).

The CSM should include all complete exposure pathways. The exposure pathway is the route by which the chemical contaminant is taken-up by the receptor. In order for an exposure pathway to be classified as complete, there must be a source of chemical contaminants, a transport pathway from the chemical contaminants to the receptor, and a route of entry into the receptor. Examples of potential exposure routes are direct ingestion of media, root uptake by plants, direct contact/dermal absorption from water, soil, or sediment, and food-chain uptake. A key component of identifying potential risk is that there must be chemical contaminants present, and there must be complete exposure pathways. If there are no complete exposure pathways, there is no risk, even if chemical contaminants are present at the site. The exposure pathway evaluation should include consideration of potential future exposure pathways, as well as current exposure pathways. For instance, if no current pathway exists because a contaminant is located in

subsurface soil or sediment beyond the reach of ecological receptors, the likelihood that those subsurface soils/sediments could become exposed due to erosion or displacement of surface soils/sediments should be considered.

In those areas where information is lacking, the information gap should be documented for further investigation in the BERA, where the CSM will be updated using more site-specific data. A CSM is an active and evolving document that is updated throughout the course of an ecological risk assessment.

Based on the completed CSM, you will determine your screening-level assessment and measurement endpoints. 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., survival, growth, reproductive success)” (USEPA, 1997). A measurement endpoint measures the effects of site COPCs on the assessment endpoint to make inferences about the risk to the population represented by the assessment endpoint. Screening-level measurement endpoints must be consistent with the identified toxicity mechanisms and exposure pathways. Throughout this process the assessment and measurement endpoints will be important decision-making and communication tools.

In addition to finding the assessment and measurement endpoints, the benchmarks used to screen site concentrations for the screening ecological effects evaluation are gathered from literature. The toxicity data chosen for comparison to site data should 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. Decisions may be made based on the Lowest Observed Adverse Effect Level (LOAEL) if a NOAEL is not available. The LOAEL is the lowest concentration of a contaminant at which adverse effects are observed. There are other types of effects data and many databases to get the required data from and 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. There should be upfront agreement between the RPM and the regulator on the benchmarks that will be used in the SERA.

## **Reviewing the Screening Ecological Risk Assessment Report**

The information from the SERA problem formulation, including the initial CSM, assessment and measurement endpoints, and the ecological effects screening benchmarks, are documented in the SERA report. Therefore, it is important to ensure that in reviewing the SERA report, it includes the findings in the SERA problem formulation along with the screening level exposure estimate, and the screening level risk calculation using the hazard quotient approach. These are all required components of the SERA and must be stated in a clear concise manner in the SERA report. The conclusion of the SERA report will then establish the scientific management decision points (SMDPs) for the site.

**Exposure Estimate:** The screening level exposure estimates are meant to be conservative. By using conservative assumptions that represent worst case levels that could be found 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. Examples of these conservative estimates include using the minimum body weight and maximum ingestion rates for species exposure, the most sensitive life stage for life stage exposure estimates, and assuming 100% for area-use factors. When reviewing a Screening Ecological Risk Assessment it is important to ensure that these ultra conservative assumptions, which may not reflect actual conditions at the site, have been used. These conservative inputs required by the SERA, provide a baseline for future risk assessment and decision making, and allow us to narrow the list of COPCs with confidence that those we remove pose no unacceptable risk once agreed upon by the regulators.

**Risk Calculation:** Using the screening benchmarks gathered during the screening level

**Highlight 1**

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

effects evaluation and the dose calculated from the screening level exposure estimate, a Hazard Quotient (HQ) is calculated as shown in Highlight 1. 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 BERA Step 3a. Those contaminants with an HQ greater than 1 are COPCs to be carried forward (i.e. 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 and are clearly documented in the SERA report. The SERA should also document 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 are not enough toxicological data to make a decision using a HQ calculation.

**Scientific Management Decision Point (SMDP):** SMDPs represent agreement points between the Navy and the regulators regarding a variety of important ERA components including problem formulation, assessment and measurement endpoints, work and sampling plans, and final reports. For the SERA, the final report acts as the SMDP and documents these agreements. It is important to review the SERA to ensure all the agreement points are documented clearly in the SERA report.

The SERA report is typically included in the RI, 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 SERA report 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 3a.

## **Reviewing the BERA Step 3a - Refinement of Conservative Assumptions**

The second deliverable in the ERA process is referred as Step 3a and is the refinement of the conservative assumptions used in the SERA to refine the list of COPCs. This is the first step in developing the BERA problem formulation in that it takes a more site specific 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 drawn either from site-specific information or from more site appropriate 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). Examples of additional factors include consideration of background concentrations, detection frequency, and bioavailability. Using the refined exposure estimates, the hazard quotients are recalculated using the same method that was used in the SERA. 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. If risk estimates (and their associated uncertainty) for all COPCs 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, the Baseline ERA Problem Formulation.

The SERA and Step 3a are often submitted as one deliverable, but it is important to understand the distinctions between the two. If you are going to submit the screen and Step 3a together, be sure to separate your steps and data for reporting. If the screen and Step 3a are in the same document there still needs to be different decisions for each. It is important to list the COPCs from the SERA before the more site-specific adjustments are applied in Step 3a. A second, reduced, list of COPCs from Step 3a can be provided in this deliverable as long as it is separate from the SERA list of COPCs.

## **Reviewing the Baseline Ecological Risk Assessment Problem Formulation**

The third deliverable, the BERA Problem Formulation (PF) builds off of the SERA and Step 3a and is the completion of the rest of step 3 (3b), and step 4 of the process. The CSM, assessment endpoints, and measurement endpoints that were first presented in the

SERA and refined in the Step 3a will be further refined in the BERA PF. Based upon the revised CSM, the lines of evidence to be used in characterizing risk are determined. An important function of this deliverable is to provide an opportunity for regulatory input and approval on conceptual site model components prior to continuing with the Baseline ERA process.

The outcome of the BERA PF, i.e. completing Steps 3 & 4 of the ERA process, consists of the BERA Work Plan (WP) and Sampling and Analysis Plan (SAP) which documents the project requirements and identifies the sampling and analysis requirements to be performed. Generally, the information in these two plans are submitted as part of the UFP-QAPP developed in accordance with [Uniform Federal Policy for Quality Assurance Project Plans \(UFP QAPP\) Manual Guidance](#) using the UFP-QAPP Manual Worksheet format. Key worksheets to review include:

- Worksheet 10: Used to present the CSM. The CSM has been in formation since the first deliverable, and by this point should be detailed and complete. Ensure no sample will be taken unless it is directly related to the CSM or an Assessment or Measurement Endpoint.
- Worksheet 11: Describes the problem to be addressed and the approach for evaluating or addressing it, and is titled Project Quality Objectives (PQO)/Systematic Planning Process (SPP). PQOs (sometimes referred to as Data Quality Objectives (DQOs)) are qualitative and quantitative statements, and are developed using the SPP as part of Step 3 and 4 of the ERA process. Information relative to the DQO process is available online at: <http://www.epa.gov/quality/dqos.html>. It is important that the PQOs relate to the key receptors, pathways of concern and COPCs identified from Step 3a.
- Worksheet 15: Is presented in table format and identifies relevant sample variables such as the COPCs, laboratory analysis methods, sample media type, project action limits (PALs) and laboratory limits. This should be reviewed to ensure that the data to be collected will meet the PQOs.
- Worksheet 17: Explains the sampling design and rationale, including a discussion of which samples will be taken (primary, quality control (QC), etc), how they will be taken, and why they are being taken. Review to ensure there is clear rationale on how the number of proposed samples and locations will provide sufficient data to meet the PQOs.

The Site-Specific WP/SAP or UFP-QAPP is submitted for agency review and approval, prior to sampling and analysis, as a stand-alone document. In some cases, the sites may have one set of project documents (i.e. the WP/SAP) that may include information for both the Human Health Risk Assessment (HHRA) and the ERA. In addition, the BERA may only appear within the RI report and not as a separate deliverable.



In order to facilitate effective decision making in risk characterization, the WP/SAP must clearly state how the data will be used prior to being generated. This information is based on a clear and accurate CSM, a well written UFP-QAPP, an understanding of the assessment endpoints that are measurable, and inclusion of decision points or an exit strategy.

## **Reviewing the Baseline Ecological Risk Assessment Report**

The Baseline Environmental Risk Assessment (BERA) Report is the fourth deliverable and occurs at the end of Step 7. The BERA report synthesizes the information gathered during the entire ERA process into a comprehensive document that presents the final risk analysis (Step 6) characterization (Step 7). Conclusions on ecological risk should be clear, concise and make sense 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). The risk characterization should include 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 with narrative descriptions of other risk factors, and an analysis of the uncertainty associated with the risk. It is important that the BERA also documents those COPCs that were dropped from the ERA due to acceptable risk and the reason/basis for the acceptable risk conclusion.

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 BERA concludes that unacceptable risks are attributable to the site, 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.

Conclusions are made on whether or not there is 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.

## **Reviewing Deliverables for Decision Making**

Throughout the ERA process it is important to consider the best way to facilitate site decision-making. As an RPM, when you review the ERA deliverables, 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 and 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 vs. fillet) may need to be different for the two studies. Another common issue that comes up when looking to use the same data for both an HHRA and an ERA is that of acceptable analytical 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 than the HHRA, 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* which is available on the ERB website under Risk Assessment.

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. This can be accomplished by reviewing all documents internally before forwarding them to regulatory agencies. There are many options for review. Beside the RPM, possible secondary reviewers include: Remedial Technical Managers (RTMs), the Risk Assessment Workgroup (RAW) members, other RPMs, or other technical support. Regardless of who does the internal review, it is important that the 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 as it is difficult to make changes once the document has been released. As you do your internal review, consider what items are of interest to stakeholders (i.e. 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. In the end, make sure that the thought process and conclusions in all deliverables are clear to you as an RPM. If they are not, ask for technical clarification or bring in additional Navy support to help.

## Point of Contact

Contact your local Risk Assessment Workgroup (RAW) representative for more information.

## Acronyms

BERA	Baseline Ecological Risk Assessment
CNO	Chief of Naval Operations
COPC	Contaminant of Potential Concern
CSM	Conceptual Site Model
DQO	Data Quality Objective
EPA	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
PAL	Project Action Limit
PQO	Project Quality Objective
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
SI	Site Inspection
SMDP	Scientific Management Decision Point
SPP	Systematic Planning Process
UFP-QAPP	Uniform Federal Policy-Quality Assurance Project Plan
QC	Quality Control
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.

**Contaminant of Potential Concern (COPC):** a potentially site-related chemical contaminant 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 affect 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.

**Feasibility Study:** to ensure that appropriate remedial alternatives are developed and evaluated in such a manner that the information can be presented to a decision-maker and an appropriate remedy selected.

**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):** SMDPs represent agreement points between the Navy and the regulators regarding a variety of important ERA components including problem formulation, assessment and measurement endpoints, work and sampling plans, and final reports.

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

## References

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