From: Chief of Naval Operations  
To: Commander, Naval Facilities Engineering Command  

Subj: NAVY POLICY FOR CONDUCTING ECOLOGICAL RISK ASSESSMENTS  

Ref: (a) Department of the Navy Environmental Policy Memorandum 97-04; Use of Ecological Risk Assessments, ltr of 16 May 97  
(b) EPA Interim Final Ecological Risk Assessment Guidance for Superfund, 5 Jun 97  

End: (1) Navy Policy for Conducting Ecological Risk Assessments  

1. Reference (a) is Navy policy for conducting ecological risk assessments. Reference (b) is Environmental Protection Agency (EPA) guidance that defines an eight-step process for conducting ecological risk assessments.  

2. Enclosure (1) is provided in response to concerns received from the field to amplify reference (a) and to clarify our interpretation of the EPA eight-step process of reference (b). The EPA eight-step process does not clearly define exit points at which an ecological risk assessment can be considered complete for the intended purpose. Enclosure (1) describes a three tiered process for Navy, which includes all the elements of the EPA eight-step process but provides opportunities to exit the process at lower steps when appropriate. Use of the Navy tiered process will reduce the time and cost necessary for conducting ecological risk assessments.  

3. My point of contact is Wanda L. Holmes who can be reached at (703)604-5420, DSN 664-5420 or e-mail: holmes.wanda@hq.navy.mil.  

Copy to: (see next page)
Subj: NAVY POLICY FOR CONDUCTING ECOLOGICAL RISK ASSESSMENTS

Copy to:
LANTNAVFACENGCOM
PACNAVFACENGCOM
SOUTHWESTNAVFACENGCOM
SOUTHNAVFACENGCOM
NORTHNAVFACENGCOM
ENGFLDACT CHES
ENGFLDACT WEST
ENGELDACT NW
N FE SC
NAVY POLICY  
FOR  
CONDUCTING ECOLOGICAL RISK ASSESSMENT

BACKGROUND

This policy document complements the Department of the Navy Environmental Policy Memorandum 97-04; Use of Ecological Risk Assessment (ltr 16 May 1997). The purpose of this document is to provide clarification of the Navy’s policy on Ecological Risk Assessment (ERA) and the manner in which ERAs shall be implemented for Navy in the Environmental Restoration Program. The goal of Navy policy is to ensure to the fullest extent possible that ERAs conducted are scientifically based, defensible, and done in a manner that is cost effective while protecting human health and the environment.

APPLICABILITY

Policies and procedures contained herein apply to Ecological Risk Assessments funded under Environmental Restoration, Navy (ER,N) and Base Realignment and Closure (BRAC).

POLICY

Navy policy for conducting ERA’s identifies a three-tiered approach which emphasizes frequent interactions and concurrence among the Navy project team (Remedial Project Managers (RPM), Remedial Technical Managers (RTM), regulators, and contractors) and identifies specific decision points and criteria for exiting from or proceeding on with the risk assessment process. This tiered approach enhances the 8-step process identified in the Environmental Protection Agency (EPA) Interim Final Ecological Risk Assessment Guidance for Superfund, 5 June 1997, and consists of following tiers: Tier 1, screening Risk Assessment; Tier 2, Baseline Ecological Risk Assessment; and Tier 3, Evaluation of Remedial Alternatives (Figure 1). The tiered approach is also consistent with and fully integrated with the Installation Restoration Program.
Tier 1: SCREENING RISK ASSESSMENT (SRA)

The Tier 1 Screening Risk Assessment should use existing data (such as sampling or monitoring data) for all detected contaminants. The SRA should be conducted during the Site Inspection phase. No new or additional data collection activities should be implemented as part of the screening risk assessment. Thus, overall costs should be low and the SRA is expected to be completed in a relatively quick manner (no more than 2 to 3 months). The SRA employs conservative (i.e. more stringent) assumptions to evaluate existing site data and determine whether additional ecological risk assessment or accelerated site cleanup may be warranted, or that the site poses acceptable risks and a designation of no further action is appropriate.

The criteria for exiting the Tier 1 Screening Risk Assessment includes:

1) The site passes the screening risk assessment; there is either an absence of complete exposure pathways to ecological receptors, or an absence of unacceptable risks. If the site passes the screen then the determination is made that the site poses acceptable risks to ecological resources and the site shall be closed out for ecological concerns.

2) The site fails the screening risk assessment; the site must have both a complete exposure pathway and unacceptable risks. If the site fails the screen then either interim cleanup (if more cost advantageous) may be implemented or the site moves to the second tier.

In many cases, the site will not successfully pass the screening risk assessment. However, many chemicals evaluated in the screening assessment may be eliminated from further consideration in either the baseline risk assessment or in an accelerated site cleanup on the basis of either incomplete exposure pathways or acceptable risk.

Tier 2, BASELINE ECOLOGICAL RISK ASSESSMENT (BERA)

The Baseline Ecological Risk Assessment, which is more rigorous and less conservative than the screening risk assessment, will require additional documentation as well
as further data collection and evaluation. The ERA shall be conducted during the Remedial Investigation phase.

The first activity (Step 3a) of the BERA is to refine the conservative exposure assumptions employed in the Tier 1 SRA, and recalculate the risk estimates. This reevaluation may include considerations of background, sample detection frequency, bioavailability and realistic exposure scenarios.

The criteria for exiting Step 3a Refinement includes:

1) Re-evaluation of data supports a no further action designation for the site and thus allow exiting of the ERA process without completing the entire BERA.

2) If the re-evaluation of the assumptions still indicates an unacceptable risk, then the Tier 2 BERA is continued.

Probably the most important aspects of Tier 2 BERA are project planning and study design/verification. These activities, which represent Step 3-5 of the EPA ecological risk assessment guidance, include extensive communication among and concurrence (if obtainable) from the regulators and stakeholders prior to proceeding from one step to another. As part of this tier, it is critical that the RPM fully understands the basis for any ecological risk assessment work proposed by support contractors and requested by the regulators. The RPM should approve such work only after sufficient justification for the work has been provided and adequately explained. This understanding of proposed work may include, but not be limited to,

- Aspects of data collection;
- Analytical methods;
- Assessment and measurement endpoints;
- Statistical analyses including Probabilistic Methods;
- Risk characterization;
- And most importantly how the study results will be used to support the risk management decisions for the site.

Specific aspects of problem formulation, study design, and risk characterization must be negotiated among the Navy and all appropriate parties (i.e. regulators), and documented through the use of the Scientific Management Decision
Advancement from one step of the BERA to the next will be dependent upon successful concurrence between the Navy and all appropriate parties. If concurrence is not obtained, document opposing positions and elevate to upper management before moving to the next step. Multiple iterations of BERA are not warranted.

At the conclusion of Tier 2 the BERA will provide a characterization of ecological risks posed by the site, and will support the RPM in making one of the following two risk management decisions:

1) No further evaluation and no remediation from an ecological perspective are warranted because the site does not pose unacceptable risk.

2) The site poses unacceptable ecological risks and additional evaluation in the form of remedy development and evaluation (Tier 3) is appropriate.

Tier 3: EVALUATION OF REMEDIAL ALTERNATIVES

Tier 3 is the evaluation of the remedial alternatives (including no action) with regards to; 1) the effectiveness of reducing risks to acceptable levels; 2) ecological impacts related to remedy implementation; and 3) residual risks. The Tier 3 evaluation of remedial alternatives is conducted during the Feasibility Study and focuses on the NCP Nine Evaluation Criteria for selection of the remedy. This is an important tier that is not always adequately considered (with regards to ecological risk and impacts) in the remedy selection process. If remedial alternatives are not adequately evaluated from an ecological perspective, the outcome of the remediation may be more detrimental to the environment than if the site had not been remediated. The ecological remedy evaluation should be conducted in conjunction with the human health remedy evaluation. The selected remedy from an ecological perspective should also be protective of human health.

At the conclusion of the Tier 3 evaluation of remedial alternatives, the RPM will have an evaluation that identifies for each alternative considered (including no-action) its risk reduction effectiveness and residual risk, potential environmental impacts, cost, technical merits and...
benefits, and acceptance by the Navy and the stakeholders. This evaluation will then assist the Navy in selecting the final remedy for the site.

NATURAL RESOURCES

If there are natural resources potentially impacted by Navy releases then involve proper trustees during the ecological risk assessment process, to the extent practicable. Trustee involvement is encouraged in our cleanup program but Navy is the lead agency and the Navy and appropriate parties (i.e. regulators only) shall make all final decisions.

EXISTING ECOLOGICAL RISK ASSESSMENTS

Baseline ecological risk assessments that are already underway should meet the substantive requirements of Tier 1, 2 and 3.

Screening Risk Assessments already underway should meet the substantive requirements of Tier 1, SRA (Steps 1 and 2) including: problem formulation and conceptual model development, exposure estimation, preliminary risk calculation, and COC determination.

Baseline Ecological Risk Assessments that are already underway should meet the substantive requirements of Tier 2, BERA (Step 3.7) including: refinement of the screening risk assessment (conceptual model or problem formulation), determination of the data quality objectives and study design, development of the field investigation/data analysis, and characterization of risk.

Evaluations of remedial alternatives that are already underway should meet the substantive requirements of Tier 3 utilizing the data from the screening and baseline ERAs.
Navy Ecological Risk Assessment Tiered Approach

**Tier 1. Screening Risk Assessment (SRA):** Identify pathways and compare exposure point concentrations to benchmarks.

- Step 1: Site visit; Pathway Identification/Problem Formulation; Toxicity Evaluation
- Step 2: Exposure Estimate; Risk Calculation (SMDP)

Proceed to Exit Criteria for SRA

**Exit Criteria for the Screening Risk Assessment:** Decision for exiting or continuing the ecological risk assessment.

1) Site passes screening risk assessment: A determination is made that the site poses acceptable risk and shall be closed out for ecological concerns.

2) Site fails screening risk assessment: The site must have both complete pathway and unacceptable risk. As a result, the site will either have an interim cleanup or moves to the second tier.

**Tier 2. Baseline Ecological Risk Assessment (BERA):** Detailed assessment of exposure and hazard to "assessment endpoints" (ecological qualities to be protected). Develop site specific values that are protective of the environment.

- Step 3a: Refinement of Conservative Exposure Assumptions (SRA) --- Proceed to Exit Criteria for Step 3a
- Step 3b: Problem Formulation - Toxicity Evaluation; Assessment Endpoints; Conceptual Model; Risk Hypothesis (SMDP)
- Step 4: Study Design/DQO - Lines of Evidence; Measurement Endpoints; Work Plan and Sampling & Analysis Plan (SMDP)
- Step 5: Verification of Field Sampling Design (SMDP)
- Step 6: Site Investigation and Data Analysis [SMDP]
- Step 7: Risk Characterization

Proceed to Exit Criteria for BERA

**Exit Criteria Step 3a Refinement**

1) If re-evaluation of the conservative exposure assumptions (SRA) support an acceptable risk determination then the site exits the ecological risk assessment process.

2) If re-evaluation of the conservative exposure assumptions (SRA) do not support an acceptable risk determination then the site continues in the Baseline Ecological Risk Assessment process. Proceed to Step 3b.

**Exit Criteria Baseline Risk Assessment**

1) If the site poses acceptable risk then no further evaluation and no remediation from an ecological perspective is warranted.

2) If the site poses unacceptable ecological risk and additional evaluation in the form of remedy development and evaluation is appropriate, proceed to third tier.

**Tier 3. Evaluation of Remedial Alternative (RAGs C)**

a. Develop site specific risk based cleanup values.

b. Qualitatively evaluate risk posed to the environment by implementation of each alternative (short term) impacts and estimate risk reduction provided by each (long-term) impacts; provide quantitative evaluation where appropriate. Weigh alternative using the remaining CERCLA 9 Evaluation Criteria. Plan for monitoring and site closeout.

Notes: 1) See EPA's 8 Steps ERA Process for requirements for each Scientific Management Decision Point (SMDP).

2) Refinement includes but is not limited to background, bioavailability, detection frequency. Etc.

3) Risk Management is incorporated throughout the tiered approach.

Figure 1