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From: Chief of Naval Operations (N45)
To: Commander, Naval Facilities Engineering Command

Subj: CONDUCTING HUMAN HEALTH RISK ASSESSMENTS UNDER THE ENVIRONMENTAL RESTORATION PROGRAM

Encl: (1) Navy Policy for Conducting Human Health Risk Assessments (HRAs) under the Environmental Restoration Projects

1. Enclosure (1) is provided in response to questions raised by members of the Installation Restoration risk assessment working group on how to conduct human HRAs.

2. Enclosure (1) describes a three-tiered approach with criteria for exiting the HRA process. Use of Navy's tiered process will reduce the time and cost necessary for conducting risk assessments under the Environmental Restoration Program. While the Navy's tiered process is consistent with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) implementing guidelines and the Environmental Protection Agency's Risk Assessment Guidance for Superfund (RAGS), it's efficacy for any other HRA must be determined on a case-by-case basis.

3. For further information or questions, please contact Wanda L. Holmes of my staff at (703) 604-5420 or DSN 664-5420 or email holmes.wanda@hq.navy.mil.

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NAVY POLICY FOR CONDUCTING
HUMAN HEALTH RISK ASSESSMENTS
RELATED TO THE INSTALLATION RESTORATION PROGRAM

BACKGROUND

This document provides Navy's policy on Human Health Risk Assessment (HHRA) and how HHRAs shall be implemented in the Environmental Restoration Program. HHRAs shall be scientifically based, defensible, and cost effective.

APPLICABILITY

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

POLICY

Navy policy for conducting HHRAs identifies a three-tiered approach which includes criteria for exiting from or proceeding with the human health risk assessment process, emphasizes frequent interactions and concurrence among the Navy project team (Remedial Project Managers (RPMs), regulators, contractors and stakeholders) and is fully consistent with the Environmental Protection Agency (EPA) Risk Assessment Guidance for Superfund (RAGS). The Navy HHRA policy consists of following tiers: Tier 1, Screening Risk Assessment; Tier 2, Baseline Human Health Risk Assessment; and Tier 3, Evaluation of Remedial Alternatives (Figure 1). This tiered approach is fully integrated with the Environmental Restoration Program.

Data needs for conducting HHRAs shall be considered early in the project scoping (i.e., during the planning stages of the Site Inspection and Remedial Investigation phases) to ensure that the sampling strategies meet the requirements to conduct and complete the risk assessment process and provide the data necessary to support risk management decisions for a site. The Data Quality Objectives (DQO) process shall be employed throughout the scoping and design of the HHRA to ensure appropriate data quality and exit strategies.

HUMAN HEALTH RISK ASSESSMENT PROCESS

TIER 1, SCREENING RISK ASSESSMENT

The role of the Tier 1 Screening Risk Assessment (SRA) is to identify Contaminants of Potential Concern (COPC) that may pose unacceptable risks to human health, thus focusing efforts and funds on those constituents most likely to drive human health risks. The Tier 1, SRA consists of two parts: Tier 1A, Risk Based Screening (RBS) and Tier 1B, Site Specific Risk-Based Evaluation (SSRBE) (optional). Tier 1A must be completed before continuing the HHRA process. A site visit, development of the conceptual site model (CSM), complete pathway, and problem formulation should be conducted using the DQO process. In most cases Tier 1 uses existing data.

Tier 1A, Risk-Based Screening

Tier 1A RBS is conducted by comparing the maximum concentration detected of each chemical of each medium (soil, surface water, and groundwater) to the appropriate risk-based concentration benchmark. Chemical constituents where at maximum concentrations that are below the benchmark values are to be eliminated from further consideration in the HHRA process. Chemical constituents exceeding the benchmark concentrations are to be retained for further evaluation. Risk-based concentration (RBC) benchmarks are based on very conservative human health exposure assumptions. Because some regulatory agencies have established RBCs for use in risk-based screening assessments, the benchmarks selected for use in Tier 1A must be agreed upon with the appropriate regulators. Tier 1A should also evaluate each chemical constituent with regards to its background levels (naturally occurring and anthropogenic in accordance with the Navy Interim Final Policy on the use of Background Chemical Levels, September 2000), detection frequency, bioavailability, and role as an essential nutrient. The product of Tier 1A is a list of chemical constituents that will be eliminated from further evaluation, and a list of COPCs to be evaluated further either in the Tier 1B, or in Tier 2. If no COPCs are identified (no unacceptable risks identified) the site should proceed to the Tier 1 exit criteria.

Tier 1B, Site Specific Risk-Based Evaluation (RAGS B)

Tier 1B SSRBE may be initiated for any chemical that is retained following the Tier 1A evaluation. The Tier 1B further evaluates these COPCs by refining the conservative assumptions employed in Tier 1A and calculating risk estimates. This evaluation may take the form of a risk-ratio analysis. The risk evaluation may use the RBCs employed in Tier 1A, or site-specific RBCs that have been back-calculated from existing site data. The Tier 1B SSRBE will have one of two outcomes: 1) COPCs will pose no unacceptable risks to human health, or 2) some or all COPCs may pose a potential unacceptable risk to human health. At the completion of Tier 1B the site should proceed to the exit criteria.

Exit criteria for Tier 1 SRA

The results of the Tier 1 SRA may support a "no further action" designation for the site and thus allow exiting the HHRA process without the need for completing Tiers 2 and 3 of the process. Alternately, the Tier 1 SRA may indicate unacceptable risks for one or more COPCs, thereby requiring the site to enter into Tier 2.

1) The site completes Tier 1A and if conducted Tier 1B and no COPCs are identified that pose unacceptable risks. A determination is made that the site poses acceptable risks to humans and the site shall be closed out for human health concerns, or

2) The site completes Tier 1A and if conducted Tier 1B and some COPCs are identified to pose potential unacceptable risks to human health. A determination is made that the site poses potentially unacceptable risks to human health and that either interim cleanup be implemented or the site moves to Tier 2.

TIER 2, BASELINE HUMAN HEALTH RISK ASSESSMENT (RAGS A)

The Baseline Human Health Risk Assessment (BHHRA), is more rigorous than the Tier 1 and thus will require additional documentation. The BHHRA shall be conducted during the Remedial Investigation phase and must be site specific. Some data collection may be needed but in some cases additional data collection is not required.

Probably the most important aspect of Tier 2 BHHRA is the study design. Study design shall re-evaluate the DQOs developed in Tier 1 to ensure that appropriate data are collected to permit risk characterization and support risk-based decision-making for the site. During study design there should be extensive communication among the Navy, the regulators and stakeholders. Specific study design topics to be discussed with the appropriate regulators and stakeholders should include current and future land use settings, data collection, exposure scenarios, and exposure concentrations used in risk estimation. As part of the Tier 2, it is critical that the RPM fully understands the basis for any risk assessment work proposed by support contractors or requested by the regulators, as well as the exposure scenarios to be evaluated. The RPM should approve such work only after sufficient justification has been provided and adequately explained and documented. This understanding of proposed work may include, but not be limited to,

- Aspects of data collection (if required);
- Analytical methods;
- Statistical analyses including Probabilistic Methods;
- Risk characterization; and
- How the study results will be used to support the risk management decisions for the site. (most important)

Specific aspects of problem formulation/study design, exposure evaluation, toxicity evaluation, and risk characterization must be negotiated among the Navy and all appropriate parties (e.g. regulators), and documented in meeting minutes and the baseline risk assessment report. If concurrence is not obtained, the RPM should document positions and elevate the matter to upper management for resolution before moving to the next step.

The Tier 2 assessment shall employ both the Reasonable Maximum Exposure (RME) and the Central Tendency Exposure (CTE) parameters to estimate risk and shall be calculated using realistic exposure assumptions. The Tier 2 BHHRA should characterize risk under current and probable future land use scenarios. Do not evaluate unrealistic exposure scenarios that are not likely to take place at the site.

At the end of Tier 2 the BHHRA will provide a characterization of human health risks that the site poses and whether those risk are acceptable or unacceptable.

Exit Criteria for Tier 2 BHHRA

1) The site does not pose unacceptable risk to human health. A determination is made that no further evaluation and no remediation from a human health perspective are warranted, and the site exits the HHRA process, or

2) The site poses unacceptable risks to human health. A determination is made that additional evaluation in the form of remedy development and evaluation is appropriate, and the site proceeds in the HHRA process to Tier 3.

TIER 3: EVALUATION OF REMEDIAL ALTERNATIVES (RAGS C)

Initiation of Tier 3 is based on a determination of unacceptable risks to human health. Tier 3 is the evaluation of the remedial alternatives (including no action) with regards to: 1) their effectiveness in reducing risks to acceptable levels; 2) the nature and magnitude of potential impacts to natural resources and human health that could result from remedy implementation; and 3) residual risks. Tier 3 is conducted during the Feasibility Study, which focuses on evaluating remedial alternatives using the Nine Evaluation Criteria for remedy selection as identified in the National Contingency Plan. This is a very important tier that is not always adequately considered in the remedy selection process. If remedial alternatives are not adequately evaluated from a natural resource injury perspective, the outcome of the remediation may be more detrimental to the environment than if the site had not been remediated.

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

Navy Human Health Risk Assessment Tiered Approach

RPM Input and Risk Management Consideration

Tier 1. Screening Risk Assessment:

Tier 1A. Risk-Based Screening (RBS):
Site visit; Conceptual Model; Pathway Identification; Consider background, sample detection frequency, bioavailability, and essential nutrients; Compare to risk-based benchmarks

Tier 1B. Site-Specific Risk-Based Screening (SSRBS) (Optional) (RAGS B):
Refinement of conservative exposure assumptions; Problem Formulation; Back-Calculation

Proceed to Exit Criteria for SRA

Exit Criteria for the Screening Risk Assessment: Decision for exiting or continuing the human health risk assessment.

1) The site completes Tier 1A and if conducted Tier 1B and no COPCs are identified that pose unacceptable risk. A determination is made that the site poses acceptable risks to human and the site shall be closed out for human health concerns, or

2) The site completes Tier 1A and if conducted Tier 1B and some COPCs are identified to pose potential unacceptable risks to human health. A determination is made that the site poses potentially unacceptable risks to human health and that either interim cleanup be implemented or the site moves to Tier 2.

Tier II. Baseline Human Health Risk Assessment (BHHRA) (RAGS A):

Detailed assessment of reasonable maximum exposure and central tendency exposure, cancer and non-cancer risks using site-specific information and tools as appropriate[1]. Develop site-specific values that are protective of human health.

Data Collection (if required) and Analysis; Exposure Assessment; Toxicity Assessment; & Risk Characterization

Proceed to Exit Criteria for BHHRA

Exit Criteria Baseline Human Health Risk Assessment

1) If the site poses acceptable risk, then no further evaluation and no remediation from an human health perspective are warranted.

2) If the site poses unacceptable human health risk additional evaluation in the form of remedy development and evaluation is appropriate, proceed to Tier 3.

Tier 3. Risk Evaluation of Remedial Alternatives (RAGs C)

A. Develop site-specific, risk-based cleanup levels.

B. Qualitatively evaluate risk posed to the human health and 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 alternatives using the remaining CERCLA 9 Evaluation Criteria. Plan for monitoring and site closeout.

Notes:
1) Tools include but are not limited to natural attenuation, probabilistic methods, etc.
2) Risk Management is incorporated throughout the tiered approach.

Figure 1