

CESO-I

Pamphlet
No. 200-1-15

15 December 2001

Environmental Quality
STANDARD SCOPES OF WORK FOR HTRW RISK ASSESSMENTS

1. Purpose. This engineer pamphlet (EP) will give United States Army Corps of Engineers (USACE) risk assessors the recommended basic/minimum requirements for scopes of work (SOW) to procure Architect-Engineer (A-E) services for preparing human health and ecological risk assessments for Hazardous, Toxic, and Radioactive Waste (HTRW) projects. These HTRW projects are regulated under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986, and the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984. The SOWs contained in Appendices A and B are a starting point only. They can be changed by use of the Technical Project Planning (TPP) Process (EM 200-1-2) and this is acceptable and advisable.

2. Applicability. This EP applies to all HQUSACE elements and USACE commands responsible for HTRW projects.

3. Distribution Statement. Approved for public release; distribution is unlimited.

4. References.

a. Department of the Army Publications.

DA Pam 40-578

Health Risk Assessment Guidance for Installation Restoration Program and Formerly Used Defense Sites.

AR 200-1

Environmental Protection and Enhancement

b. United States Army Corps of Engineers (USACE) Publications.

EM 200-1-2

Technical Project Planning (TPP) Process.

EM 200-1-4

Risk Assessment Handbook, Volume I: Human Health Evaluation.

20020701 124

EP 200-1-15
15 Dec 01

EM 200-1-4

Risk Assessment Handbook, Volume II: Environmental Evaluation.

c. *U.S. Environmental Protection Agency (EPA) Publications.*

EPA/540/1-89/002

Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (Part A).

EPA/540/R-97/006

OSWER Directive 9285.7-75. *Ecological Risk Assessment Guidance for Superfund (ERAGS): Process for Designing and Conducting Ecological Risk Assessments.*

d. *Other Publications.*

Wentsel et al.

Tri-Service Procedural Guidelines for Ecological Risk Assessments. U.S. Army Edgewood Research, Development and Engineering Center (USAERDEC), Aberdeen Proving Ground, MD. ADA297968.

5. Technical Assistance and Technical Review. The district risk assessor should be aware of the support that is available. The risk assessor can obtain help in establishing the necessary level of effort, in establishing data collection needs, in assessing exposure and toxicity, in characterizing site risk, and in managing and communicating the risk. Assistance is also available for establishing management goals and for deriving management objectives for Ecological Risk Assessments (ERAs) at the specific site, project or installation. Help is also available for determining appropriate assessment and measurement endpoints.

a. The USACE HTRW Center of Expertise (CX) supports all programs, and has a designated risk assessment POC for each district to give technical assistance and to review documents (review by the HTRW CX is mandatory for Category B sites: all projects in the Site Inspection [SI] stage; all National Priority List [NPL] sites and Base Realignment and Closure [BRAC] sites in the Remedial Investigation/Feasibility Study [RI/FS] phase; all remediation projects that use innovative technology or are estimated to cost more than \$5M; and projects in any phase that are of special district, Major Subordinate Command [MSC] or Headquarters [HQ] USACE concern). Information about CX participation is available on-line at the CX intranet web site: <http://w3.environmental.usace.army.mil/index.html>.

b. AR 200-1 gives the United States Army Center for Health Promotion and Preventive Medicine (USACHPPM) responsibility for reviewing and approving, on behalf of the Office of the Surgeon General (OTSG), all health risk assessments within the Army's Installation Restoration Program (IRP), Formerly Used Defense Sites (FUDS), and Army BRAC sites.

Required submittals and submittal procedures are available in DA PAM 40-578. This DA PAM is available for download from the Internet at: <http://www.usapa.army.mil/gils/epubs10.html>.

c. The HTRW CX risk assessment POC can also help the district risk assessor gain access to the Army Biological Technical Assistance Group (BTAG) and the Tri-Service Ecological Risk Assessment Work Group (TSERAWG) for assistance with ERAs. The Army BTAG is made up of ecological risk assessors from the HTRW CX, USACHPPM, the United States Army Environmental Center (USAEC), and the United States Army Edgewood Chemical and Biological Center (USAECBC). In addition to the members of the Army BTAG, the TSERAWG has risk assessors from the Air Force and the Navy.

6. CERCLA/RCRA Equivalency. The CERCLA and RCRA Corrective Action programs use different terminology, but follow parallel procedures in responding to releases. In both programs, the first step after discovery of a site is to examine available data to identify releases needing further investigation. This step is called the Preliminary Assessment/Site Inspection (PA/SI) in the CERCLA process, and the RCRA Facility Assessment (RFA) in the RCRA process (done by USEPA or designated state authority). When potential risks are identified, both programs require that the nature, extent, and rate of chemical release be characterized in-depth; this process is called an RI in the CERCLA process and a RCRA Facility Investigation (RFI) in the RCRA process. Although the SOWs in this EP are written to be consistent with USEPA guidance for CERCLA projects, the district risk assessor can alter the language appropriately for use under RCRA. Generally speaking, the programs are equivalent, unless the RCRA permit specifies cleanup to below risk-based levels.

7. Scope of Work for Screening-Level Risk Assessment. At the PA/SI stage of CERCLA site investigations, or confirmatory sampling under a RCRA permit, a conservative screening-level risk assessment is done. This risk screening will establish whether the site poses no or negligible risks to human health and the environment, allowing a no further action decision, or it establishes the need for an RI, including a Baseline Risk Assessment (BRA) or a RFI, including a Health and Environmental Assessment (HEA). The procedures for doing the screening are found in the following USACE guidance documents: EM 200-1-4, Vol. I and II; and in the following USEPA guidance documents: EPA/540/1-89/002 and EPA/540/R-97/006. Appendix A contains a SOW (Appendix A has been provided as a Word® document for ease of use) for conducting such a screening-level risk assessment, following the USACE and USEPA guidance documents. This SOW can be modified for work within RCRA by replacing CERCLA terms with RCRA terms. The USACE risk asses-

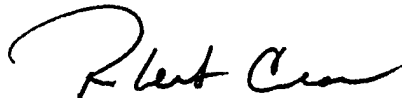
EP 200-1-15
15 Dec 01

sor should carefully evaluate the SOW, ensuring that all sections are required for the site, and make any appropriate changes.

8. Scope of Work for Baseline Risk Assessment (BRA). The BRA (or HEA during an RFI) is done during the RI/FS stage of site investigations. The BRA includes an evaluation of potential human health and ecological risks, assuming that no action is taken to minimize contamination or exposures. Appropriate guidance for the human health risk assessment is contained within RAGS and is supplemented by EM 200-1-4, Volume I. There are several perspectives appropriate for the evaluation of potential ecological risks. ERAGS, Steps 3-8 (EPA/540/R-97/006), EM 200-1-4, Volume II, and the *Tri-Service Procedural Guidelines for Ecological Risk Assessments* (Wentsel et al.) can be used together to plan and conduct the ERA. Appendix B contains a SOW (the pdf security in this EP has been set to allow the user to copy Appendix B and paste it into a Word® document) for conducting a BRA, following the appropriate guidance documents. This SOW is written to have the contractor establish the data needs according to the Technical Project Planning (TPP) Process. This aspect should be reviewed by the district risk assessor and the responsibilities for implementing TPP determined. The USACE risk assessor should carefully evaluate the SOW, ensuring that all sections are required for the site, and make any appropriate changes.

FOR THE COMMANDER:

2 Appendices
APP A -SOW for
Screening-Level Risk Assess.
APP B - SOW for Baseline
Risk Assess. (BRA)


ROBERT CREAR
Colonel, Corps of Engineers
Chief of Staff

EP 200-1-15
15 Dec 01

APPENDIX A
SCOPE OF WORK FOR SCREENING-LEVEL RISK ASSESSMENT

Screening-Level Risk Assessment

1. Introduction.

a. A section of the *Preliminary Assessment/Site Inspection (PA/SI)* Report for the site needs to be entitled *Screening-Level Risk Assessment*. Subdivide this section into *Human Health Risk Assessment (HHRA)* and *Ecological Risk Assessment (ERA)* subsections. The Screening-Level Risk Assessment is used to evaluate the site to see if it can be eliminated from further concern or if it needs additional investigation. If this is the case, a Remedial Investigation (RI), including a Baseline Risk Assessment (BRA), must be conducted.

b. Use the Technical Project Planning (TPP) Process (EM 200-1-2) for planning data collection required to prepare the screening-level risk assessment. Use of the TPP process will help to ensure that only necessary data are collected. The Contractor shall evaluate a site's location, history, and possible contaminants present, and recommend to the U.S. Army Corps of Engineers (USACE) the utility of collecting adequate samples to establish a statistically robust, significant, and defensible set of background concentrations, both naturally occurring and anthropogenic. Although not typically done at the PA/SI stage, on-site concentrations can be compared to background levels to help determine whether or not site-related chemicals pose significant risks. The work plan shall document Data Quality Objectives (DQOs) for all data collection activities. The Contractor shall ensure that quantitation limits for all dual-purpose samples (i.e., those required for both the HHRA and ERA) are low enough that site concentrations can be evaluated against levels that are known to affect potentially exposed receptors.

2. Human Health Risk Assessment (HHRA). As is done for ERAs, planning for the HHRA should include agreement on the receptor populations, and which exposure pathways and routes are to be evaluated. This effort will guide selection of health-based screening levels and allow the risk screening process to proceed smoothly. The HHRA shall conservatively evaluate the potential for adverse human health effects attributable to site contamination. This evaluation will be based on comparing site media concentrations with health-based screening levels, calculated according to protocol contained in *Risk Assessment Guidance for Superfund (RAGS) Volume I: Human Health Evaluation Manual (Part A)* (EPA/540/1-89/002). Again, use conservative exposure assumptions.

a. *Exposure Assessment.* Two primary elements of the screening-level risk assessment are identifying the appropriate receptor group or groups and selecting appropriate exposure point concentrations.

(1) You must select the population group with the highest reasonable exposure. The Contractor shall prepare a preliminary Conceptual Site Model (CSM) to help identify this group, using current and reasonable future land uses. The Contractor shall clearly justify all assumptions used.

(2) The highest detected chemical concentration in a medium shall be used as the exposure point concentration unless the range of concentrations detected, as well as the number of samples collected, allows a 95% Upper Confidence Limit (UCL) to be calculated. The Contractor shall clearly justify all assumptions used.

b. Health-Based Screening Levels. The Contractor shall evaluate the CSM for appropriate exposure pathways and exposure factors, and select or calculate the health-based screening levels that most accurately reflect site conditions. The health-based screening levels shall be selected on the basis of state and regional requirements. The following is a partial list of health-based screening levels available:

(1) United States Environmental Protection Agency (USEPA) Region 9 Preliminary Remediation Goals (PRG) Tables. These values can be accessed on the Internet at: <http://www.epa.gov/region09/waste/sfund/prg/index.htm>.

(2) USEPA Region 6 Human Health Media-Specific Screening Levels. These values can be accessed on the Internet at: http://www.epa.gov/region6/6pd/rcra_c/pd-o/./pd-n/screen.htm.

(3) USEPA Region 3 Risk-Based Concentration (RBC) Table. These values can be accessed on the Internet at: <http://www.epa.gov/reg3hwmd/risk>.

(4) USEPA Soil Screening Levels (EPA/540/R-95/128 and EPA/540/R-96/018). Guidance and procedures can be accessed on the Internet at: <http://www.epa.gov/superfund/resources/soil/>.

c. Risk Screening. The exposure point concentration shall be compared with the health-based screening level using the hazard quotient (HQ) method (dividing the exposure point concentration by the health-based screening level). To evaluate non-carcinogenic effects, the health-based screening level will be divided by 10. This procedure is to allow for the presence of multiple chemicals, while screening below a hazard index (HI) of one.

d. Characterization of Uncertainty. The uncertainties associated with the HHRA shall be clearly presented as part of the screening-level risk assessment. The potential effect of the following factors should be discussed:

- (1) Uncertainties associated with the limited chemical data base for the site.
- (2) Use of maximum chemical concentrations for exposure point concentrations.
- (3) Use of highest exposure receptors.

EP 200-1-15
15 Dec 01

(4) The application of the health-based screening value and the inherent assumptions used in its derivation.

d. Results of the HHRA. The Contractor shall summarize the HHRA, indicating the strengths and weaknesses of the screening-level assessment. The Contractor shall discuss the range of chemical concentrations detected, how far the health-based screening level or levels have been exceeded, the effects of dividing the health-based screening levels by 10, and the appropriateness of the values themselves. This information will assist in the process of deciding whether the site should be eliminated from further concern or if an RI and BRA are warranted, based on human health concerns.

3. Ecological Risk Assessment (ERA). The ERA shall conservatively evaluate the potential for adverse ecological effects ascribable to site contamination. The screening-level ERA shall be consistent with Steps 1 and 2 of the USEPA guidance, *Ecological Risk Assessment Guidance for Superfund (ERAGS): Process for Designing and Conducting Ecological Risk Assessments* (USEPA 1997).

b. Planning. Before beginning the screening-level problem formulation, the Contractor, customer, project manager, risk assessor, and other stakeholders, as directed by USACE, shall meet to establish clearly articulated Site-Specific Management Objectives (SSMOs) and to characterize the decisions to be made within the context of those objectives.

c. Step 1: Screening-Level Problem Formulation and Ecological Effects Evaluation.

(1) *Screening-Level Problem Formulation.* For the screening-level problem formulation, the Contractor shall develop a preliminary Ecological Conceptual Site Model (ECSM) for the site. Based on the site history and an initial site reconnaissance, the ESCM shall address the following five issues:

- (a) Characterization of the environmental setting and known or suspected contaminants.
- (b) Fate and transport mechanisms that might exist at the site.
- (c) Mechanisms of ecotoxicity associated with chemicals and likely categories of receptors that could be affected.
- (d) Complete exposure pathways.
- (e) Selection of appropriate endpoints supporting the SSMOs to screen for ecological risks.

(2) *Screening-Level Ecological Effects Evaluation.* The next part of the ERA is to evalu

ate preliminary ecological effects and establish chemical exposure levels that represent conservative thresholds for adverse ecological effects. The conservative thresholds are called screening ecotoxicity values. The Contractor shall locate and use an adequate benchmark as the screening ecotoxicity value. The Contractor shall evaluate the ECSM for appropriate exposure pathways, exposure factors, and the assessment endpoints (tied to the SSMOs), then select the benchmark values that most accurately reflect site conditions. The following is a partial list of sources for benchmark values:

- (a) State and Federal Ambient Water Quality Criteria (AWQC).
 - (b) USEPA, National Oceanic and Atmospheric Administration (NOAA) and Ontario sediment criteria.
 - (c) USEPA online databases (ECOTOX, AQUIRE, etc.).
 - (d) Oak Ridge National Laboratory (ORNL) benchmarks.
 - (e) U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) (military unique compounds [MUCs]).
 - (f) USEPA Region or state benchmark or guidance values.
- (3) *Uncertainty Assessment.* After the screening-level problem formulation, the Contractor shall briefly evaluate the uncertainties associated with the benchmarks used as the screening ecotoxicity values, the study design, and the selected endpoints.

c. Step 2: Screening-Level Exposure Estimate and Risk Calculation.

(1) *Screening-Level Exposure Estimate.* In this step, the Contractor shall estimate chemical exposure levels to screen for potential ecological risks. For all complete exposure pathways, the Contractor shall use the maximum detected site-related chemical concentration as the exposure point concentration. For wildlife, exposure parameters used shall be the conservative assumptions listed below:

- (a) Area use factor of 100%.
- (b) 100% bioavailability.
- (c) Most sensitive life stage present.
- (d) Average body weight—normalized ingestion rate.

EP 200-1-15
15 Dec 01

(e) 100% of the diet consists of the most contaminated dietary component.

(2) *Screening-Level Risk Calculation.* For the screening-level risk calculation, the HQ approach shall be used, comparing the dose (estimated contaminant intake) with the screening ecotoxicity value. The Contractor shall determine if the chemicals present have similar toxic mechanisms, requiring summing of the HQs to produce an HI. Justification for calculating an HI shall be clearly documented within the text of the assessment.

(3) *Scientific/Management Decision Point (SMDP).* The Contractor shall write a summary of the screening-level ERA, including the range of chemical concentrations detected, the number of chemicals exceeding their benchmarks, the degree of the exceedance of the benchmark (or benchmarks), and the appropriateness of the benchmarks themselves. In addition, the Contractor shall relate the results back to the SSMOs, and ensure that the information provided assists the risk manager in making one of the following decisions:

(a) That there is adequate information to conclude that ecological risks are negligible and, therefore, no need for remediation on the basis of ecological risk.

(b) That the information is not adequate to make a decision at this point, and the ecological risk assessment process will continue to Step 3 (a baseline ERA).

(c) That the information points to a potential for adverse ecological effects, and a more thorough assessment is warranted.

(d) The USEPA (1999) guidance, *Ecological Risk Assessment and Risk Management Principles for Superfund Sites* should be consulted to assist in this aspect. If it appears that further assessment is warranted, the Contractor shall clearly identify those chemicals that need to be carried forward, those pathways found to be complete and significant, and the potentially affected receptors. This information will help focus the Problem Formulation for the baseline ERA.

(4) *Refinement of the Screening-Level ERA.* If the results of the screening-level HHRA indicate no significant human health risks, but there are potential ecological risks, the screening-level ERA will be refined. Since the screening-level ERA uses very conservative assumptions, the Contractor shall evaluate the list of chemicals detected and the corresponding HQs generated to determine if the use of site-specific exposure parameters would cause the HQs to drop to or near unity. Additionally, the Contractor shall evaluate on-site concentrations against both naturally occurring and anthropogenic background concentrations, if site-specific background concentrations are available (note that this step is not included in ERAGS, but may be used to minimize the number of Chemicals Of Potential Ecological Concern [COPECs] carried through the baseline ERA). For this refinement, the Contractor shall reevaluate the following parameters, as appropriate, and recalculate HQs for those pathways indicating a risk:

- (a) Area use percentage (home range).
- (b) Bioavailability < 100%.
- (c) Diet composition < 100% from the most contaminated media.
- (d) Food concentration.
- (e) Detection frequency.

3. Examples of Guidance. The following documents are provided for reference. Additional documentation may be used as required.

a. Department of the Army Publications.

DA Pam 40-578

Health Risk Assessment Guidance for Installation Restoration Program and Formerly Used Defense Sites.

AR 200-1

Environmental Protection and Enhancement.

b. U.S. Army Corps of Engineers (USACE) Publications.

EM 200-1-2

Technical Project Planning (TPP) Process.

EM 200-1-4

Risk Assessment Handbook, Volume I: Human Health Evaluation.

EM 200-1-4

Risk Assessment Handbook, Volume II: Environmental Evaluation.

c. U.S. Environmental Protection Agency (USEPA) Publications.

EPA/540/1-89/002

*Risk Assessment Guidance for Superfund: Vol. 1 - Human Health Evaluation Manual (Part A).
Office of Emergency and Remedial Response.*

EPA/600/3-89/013

EP 200-1-15
15 Dec 01

Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference. Office of Research and Development.

EPA/600/P-95/002Fa, b, and c
Exposure Factors Handbook.

EPA/600/Z-92/001
Guidelines for Exposure Assessment. 57 FR 22888.

EPA/630/R-95/002F
Guidelines for Ecological Risk Assessment. Final.

EPA/540/R-95/128
Soil Screening Guidance: Technical Background Document.

EPA/540/R-96/018
Soil Screening Guidance: User's Guide.

EPA/540/R-97/006
Ecological Risk Assessment Guidance for Superfund (ERAGS): Process for Designing and Conducting Ecological Risk Assessments. Interim Final.

USEPA
OSWER Directive 9285.7-01B. *Human Health Evaluation Manual, Part B: Development of Risk-Based Preliminary Remediation Goals.* Office of Emergency and Remedial Response.

USEPA
OSWER Directive 9285.7-09A. *Guidance for Data Useability in Risk Assessment (Part A).* Final report. Office of Emergency and Remedial Response.

USEPA
OSWER Directive 9285.7-081. *Supplemental Guidance to RAGS: Calculating the Concentration Term.* Office of Solid Waste and Emergency Response.

USEPA
OSWER Directive 9285.7-09B. PB92-963362. *Guidance for Data Useability in Risk Assessment.*

USEPA
OSWER Directive 9285.7-28 P. *Ecological Risk Assessment and Risk Management Principals for Superfund Sites.*

USEPA

On-Line Database: *Integrated Risk Information System (IRIS)*.
<http://www.epa.gov/ngispgm3/iris/index.html>

d. Other Publications.

Wentsel et al.

R.S. Wentsel, *Tri-Service Procedural Guidelines for Ecological Risk Assessments*. U.S. Army Edgewood Research, Development and Engineering Center (ERDEC), Aberdeen Proving Ground, MD, ADA297968.

EP 200-1-15
15 Dec 01

APPENDIX B
SCOPE OF WORK FOR BASLEINE RISK ASSESSMENT

Baseline Risk Assessment

1. Introduction.

a. A section of the Remedial Investigation (RI) Report for the site shall be entitled *Baseline Risk Assessment* (BRA). This section shall be further subdivided into *Human Health Risk Assessment* (HHRA) and *Ecological Risk Assessment* (ERA) subsections. The Contractor shall use all available site information to prepare the BRA. All topics required by this section of the scope of services as described below shall be addressed in the BRA. Where a specific topic can not be applied to this site, the Contractor shall document that it was adequately considered, and justify its omission. The Contractor will consider United States Environmental Protection Agency (USEPA) regional or state requirements for using the *Risk Assessment Guidance for Superfund* (RAGS), *Volume I: Human Health Evaluation Manual, Part D* (EPA/540/R-97/033).

b. Use the Technical Project Planning (TPP) Process (EM 200-1-2) for planning data collection required to prepare the BRA. Use of the TPP process will ensure that only necessary data are collected. The Contractor shall propose sample locations, depths, and numbers required to prepare the HHRA and, as noted below, for the ERA. Base the sampling scheme on the Conceptual Site Model (CSM) and the Ecological Conceptual Site Model (ECSM). Data Quality Objectives (DQOs) for all data collection activities shall be clearly documented in the work plan (WP)/Sampling and Analysis Plan (SAP), and contain the following information: sample location, sample depth (if appropriate), analytical method requirements, quantitation limit requirements, and identification of data use. The Contractor shall evaluate analytical quantitation capabilities against protective levels and identify the effects on the BRA when the required quantitation limits cannot be achieved. The Contractor shall ensure that quantitation limits for all dual-purpose samples (i.e., those required for both the HHRA and ERA) are low enough to evaluate site concentrations against the lower of the two levels.

2. Data Evaluation. Before they are used in the BRA, all analytical data shall be reviewed, and appropriate data qualifiers applied, as required (see USEPA 1992a). Then review project DQOs to determine if the data collected are of sufficient quantity and quality, according to their intended use. The Contractor shall then present the chemical data in a table that contains chemicals analyzed, concentrations detected, the sample quantitation limits, data qualifiers, and the frequency of detection, and these data will be footnoted to identify applicable Quality Assurance/Quality Control (QA/QC) results and any limits on data use.

3. Human Health Risk Assessment (HHRA). The HHRA shall assess the risks and hazards to human receptors from site contaminants in the event no action is taken to remove contaminants or stop them from migrating. In the process of evaluating exposures, the Contractor shall consider all current and *reasonable* future land use scenarios and evaluate risks and hazards to adults, children, and sensitive subpopulations, as appropriate. The HHRA shall be consistent with the USEPA guidance, *Risk Assessment Guidance for Superfund* (RAGS), *Volume*

I: Human Health Evaluation Manual (EPA/540/1-89/002), and EM 200-1-4, *Risk Assessment Handbook, Volume I: Human Health Evaluation*. Additionally, USEPA regional and state guidance shall be used as required and deemed appropriate.

a. Selection of Chemicals of Potential Concern (COPCs). The Contractor shall select COPCs according to the protocol in RAGS, USEPA regional, or state guidance, as required or appropriate.

b. Exposure Assessment. Exposure will be assessed on the basis of the CSM that was developed during the TPP process. The CSM shall be updated to include any information that has been realized during the field effort and shall be the basis for assessing the exposure. All source areas, intermedia transport mechanisms, receptors, and exposure routes shall be evaluated in this section.

(1) While assessing exposure, the Contractor shall use available monitoring data, analyze potential chemical releases in detail, estimate exposure point concentrations, evaluate the environmental fate and transport of chemicals released both qualitatively and quantitatively, and identify exposed populations. Other relevant data that can assist the Contractor in assessing exposure include activity patterns, land use zoning, community development plans, landowner intentions, public water availability, restrictions on private wells, location of nearest potable well, quality and quantity of groundwater, etc. As specified in RAGS, exposure point concentrations shall be expressed as the 95 percent Upper Confidence Limit (95% UCL) on the arithmetic mean, or be represented by the results of fate and transport modeling. The Contractor shall determine the data distribution (i.e., normal, log-normal, or non-parametric) and apply statistics appropriate for that distribution. The Contractor shall consider ingestion, inhalation, and dermal contact exposure routes from the following potentially affected environmental media at each site:

- (a) Soil.
- (b) Ground water.
- (c) Surface water/suspended sediment.
- (d) Sludge/bottom sediment.

(2) The Contractor shall assess exposures according to protocol contained in RAGS, using the algorithms provided, or justify changes deemed necessary. Exposure parameters shall be taken from the *Exposure Factors Handbook* (EPA/600/P-95/002Fa, b, and c) or from alternate sources that are deemed appropriate. All exposure parameters used shall be documented in the text, including justification for their use. At a minimum, the Reasonable Maximum Exposure (RME) and Central Tendency Exposure (CTE) will be calculated. One example of each calculation shall be provided, and the results of all calculations shall be presented in a table.

c. Toxicity Assessment. A toxicological profile is required for all chemicals retained as COPCs. Attach them in an appendix to the end of the RI Report. These toxicity profiles shall minimally include a summary of the study or studies used to derive the reference dose (RfD) or cancer slope factor, confidence, weight of evidence, and indicated effect. The toxicological profiles need not be written for this HHRA, but may be taken from published sources, such as the Agency for Toxic Substances and Disease Registry (ATSDR). The hierarchy for toxicity values to be used in the HHRA shall be as follows:

- (1) USEPA Integrated Risk Information System (IRIS).
- (2) USEPA National Center for Environmental Assessment (NCEA).
- (3) U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) (military unique chemicals [MUCs]).
- (4) ATSDR Minimum Risk Levels (MRLs).
- (5) USEPA Water Quality Criteria Documents.
- (6) USEPA Health Effects Assessment Summary Tables (HEAST).
- (7) USEPA Health Advisories.

d. Risk Characterization. Risk characterization is required for the individual and composite carcinogenic risk and noncarcinogenic hazard of human exposure to site COPCs. Risk shall be calculated in accordance with RAGS protocol. The contractor shall clearly identify, in a table, risks and Hazard Quotients (HQs) associated with each chemical for each route of exposure. That table will also sum the risks or calculate a hazard index (HI) for all chemicals, pathways, and receptors. The Contractor shall identify how the aggregate carcinogenic risks relate to the EPA's acceptable risk range of 1E-06 to 1E-04. Also, where an HI exceeds unity, the Contractor shall segregate the individual HQs and recalculate HIs by target organ, as specified in RAGS.

e. Uncertainty Analysis. Various approaches can be taken to describe the uncertainties of the assessment, ranging from descriptive to quantitative. The method selected shall be consistent with the level of complexity of the assessment. The Contractor shall evaluate all uncertainties associated with sampling and analysis, fate and transport, exposure assessment, toxicity assessment, and risk characterization, indicating the strengths and limitations of the HHRA. The discussion shall point out sources of uncertainties, estimate the degree of uncertainty associated with each source, and estimate of the effect (over- or under-estimation of risk) of that uncertainty. The Contractor shall also briefly discuss potential options that could be used to reduce the most significant uncertainties in the assessment. At a minimum, the following two

points shall be addressed: whether or not the performance of a quantitative uncertainty analysis (e.g., sensitivity analysis or probabilistic assessment) on one or more aspects of the study would improve the assessment; and the potential success or feasibility, or both, of investigating site-specific measures of bioavailability.

4. Ecological Risk Assessment (ERA). The contractor shall conduct a baseline ERA for the site. The ERA determines whether or not there are actual or potential ecological risks attributable to contamination at the site. The ERA shall be based on the Site-Specific Management Objectives (SSMOs), the ECSM, the list of Chemicals Of Potential Ecological Concern (COPECs), and the Scientific/Management Decision Point (SMDP) established at the end of the Preliminary Assessment/Site Inspection (PA/SI). The ERA shall be conducted in accordance with steps 3 through 8 of *Ecological Risk Assessment Guidance for Superfund (ERAGS): Process for Designing and Conducting Ecological Risk Assessments* (USEPA 1997). Additionally, use the following guidance as appropriate: *Risk Assessment Handbook, Volume II: Environmental Evaluation* (EM 200-1-4), *Guidelines for Ecological Risk Assessment* (EPA/630/R-95/002F), *Tri-Service Procedural Guidelines for Ecological Risk Assessments* (Wentsel et al. 1996), and guidance from the applicable USEPA region and state.

a. Step 3: Problem Formulation. Problem formulation is a process for generating and evaluating hypotheses about why human activities may have caused ecological effects. It establishes the goals, breadth, and focus of the baseline ERA (USEPA 1997). The Contractor shall use the TPP Process (EM 200-1-2) during problem formulation to ensure that data collected are of adequate quality and quantity for their intended use. Problem formulation for the baseline ERA shall include the following activities:

- Refinement of preliminary COPECs.
- Refinement of the ECSM.
- Selection of assessment endpoints directly linked to the SSOMs.
- Development of risk hypotheses for each assessment endpoint.

(1) *Refinement of Preliminary COPECs.* The SMDP from the screening-level ERA in the PA/SI should have indicated what COPECs need to be carried into the baseline ERA. Because the screening-level ERA uses very conservative assumptions, the Contractor shall evaluate the list of COPECs and the corresponding HQs generated to determine if the use of site-specific exposure parameters would cause the HQs to drop to or near unity. Additionally, the Contractor shall evaluate on-site concentrations against both naturally occurring and anthropogenic background concentrations, if site-specific background concentrations are available (note that this step is not included in ERAGS, but may be used to minimize the number of COPECs carried through the baseline ERA). For this evaluation, the Contractor shall reevaluate the following wildlife exposure parameters (see EPA/600/R-93/187a) and recalculate HQs for those pathways indicating a risk from the screening-level ERA:

EP 200-1-15
15 Dec 01

- (a) Area use percentage (home range).
- (b) Bioavailability < 100%.
- (c) Diet composition < 100% from the most contaminated media.
- (d) Food concentration.
- (e) Detection frequency.

(f) Based on this evaluation, the Contractor shall propose which COPECs need not be carried forward, and shall clearly document the rationale for their exclusion.

(2) *Refinement of the ECSM.* The Contractor shall review and revise the preliminary ECSM developed during the PA/SI to identify the source areas, fate and transport mechanisms of the COPECs, receptors exposed to site chemicals, and exposure routes expected to be complete. The detail required for the ECSM will be determined by the COPECs present, an evaluation of site use (both current and reasonable future), and the quality and quantity of available habitat (both on-site and adjacent off-site). The Contractor shall ensure that adequate information on the COPECs is available to determine potential risks. Due consideration shall be given to threatened and endangered species that may be on-site and sensitive habitats on-site or adjacent off-site. Mechanisms of ecotoxicity available from the PA/SI shall be reevaluated to ensure their relevance to the exposure pathways identified as complete. If necessary, a literature search shall be conducted to evaluate toxicity information on these chemicals relative to any potential receptors identified, and to guide the sampling, analysis, and quantitation limit requirements for the data collection effort.

(3) *Selection of Assessment Endpoints.* Guided by the SSMOs and the ECSM, the Contractor shall propose the assessment endpoints to be evaluated in the baseline ERA. By definition, assessment endpoints are explicit expressions of the actual environmental value to be protected, including both the ecological entity and an attribute of that entity. In selecting assessment endpoints, give special consideration to ecological relevance, regulatory policy goals and societal values, and susceptibility to the COPECs.

(4) *Risk Hypotheses.* Ecological risk hypotheses for the baseline ERA are basically questions about the relationships among assessment endpoints and their predicted responses when exposed to contaminants (EPA/540/R-97/006). These testable hypotheses will provide the basis for developing the study design and for evaluating the results of the site investigation in the analysis phase. The most basic question to be answered by the ERA is whether COPECs are causing or have the potential to cause adverse effects on the assessment endpoints. Based on the ECSM, the Contractor shall propose the risk hypotheses to be answered by the baseline ERA.

(5) *Step 3 SMDP.* At this SMDP, the Contractor shall present the proposal for the final list of COPECs, assessment endpoints, and the risk hypotheses. To develop the site study and establish the level of effort necessary to evaluate potential site risks, agreement must be reached on the following four components of the ECSM: the list of COPECs, the assessment endpoints, exposure pathways assumed to be complete, and the testable hypotheses that will be answered by the baseline ERA. This will facilitate identification of the measurement endpoints and current data gaps to be evaluated by the field effort.

b. Step 4: Study Design and the DQO Process. This step in the ERA process will establish field and laboratory procedures for the investigation and will document DQOs for all data to be collected.

(1) *Establishing Measurement Endpoints.* The Contractor shall propose measurement endpoints, based on the assessment endpoints agreed to at the Step 3 SMDP. Measurement endpoints are, by definition, measurable responses to a stressor that are related to the valued characteristics chosen as the assessment endpoints. Measurement endpoints can be measures of exposure (i.e., media concentration of COPECs, including spatial and temporal aspects relevant to the level of analysis) or measures of effect (also associated with the level of analysis). The relationship between the measurement endpoint and the assessment endpoint must be clearly described, must be based on scientific evidence, and should allow potential harm to be evaluated at the population, community, or ecosystem level of organization. The measurement endpoints shall be selected to determine the answers to the risk hypotheses agreed to at the SMDP. In general, there are generally five lines of evidence that can be used to answer these questions:

(a) Comparing estimated or measured exposure levels with Reference Toxicity Values (RTVs) derived from the literature (i.e., the HQ method).

(b) Comparing site tissue residues with tissue residues from a reference area.

(c) Comparing toxicity test results with toxicity test results from a reference area.

(d) Comparing observed effects on site receptors with those observed in a reference area.

(e) Comparing measures of population or community health with those observed in a reference area.

(f) The Contractor shall propose the lines of evidence necessary to evaluate all complete pathways from COPECs to receptors, to be presented at the Step 4 SMDP for agreement. Additionally, the Contractor shall propose how the data and the various lines of evidence will be interpreted, and how inferences will be drawn from the measurement to the assessment endpoints. Agreement prior to the field effort will ensure that the baseline ERA will provide the

information appropriate for making risk management decisions.

(2) *Determination of Data Needs.* Based on the information above, the Contractor shall propose the data required for evaluation of potential ecological threats. All data available from previous site investigations shall be evaluated to determine appropriate sampling locations, in an attempt to establish gradients of contamination and corresponding ecological impacts wherever possible. Additionally, the Contractor shall evaluate the existing data for usability to determine what data gaps exist, and the sampling required to fill those gaps. Finally, DQOs shall be assigned for all required samples, establishing how the lines of evidence will be evaluated, the sampling and analytical requirements, and the analytical quantitation limits required.

(3) *Step 4 SMDP.* The SMDP at the end of Step 4 will obtain agreement on the following three items: the measurement endpoints, site investigation methods for both field and laboratory, and the data reduction/interpretation techniques. The Contractor shall document the above and the applicable DQOs in the WP/SAP (including the DQOs for HHRA samples), ensuring that all DQOs are complete and clearly defined, that sampling for the ERA and HHRA are coordinated (i.e., not duplicated), and that the analytical quantitation limits are adequate for their intended use.

c. *Step 5: Field Verification of Sampling Design.* Before the WP/SAP are made final, it may be necessary to verify that the proposed field effort is practical and appropriate. If it has not already been done, the Contractor shall verify the sampling design, the risk hypotheses, complete exposure pathways, and the measurement endpoints for appropriateness and field implementability. The Contractor shall document any aspect of the field effort that might be problematic, propose a solution, and obtain concurrence from the USACE.

d. *Step 6: Site Investigation and Analysis Phase.* This step in the ERA process implements the field effort outlined in the WP/SAP and analyzes the data that result, characterizing actual exposures and ecological effects, leading to the risk characterization in Step 7.

(1) *Site Investigation.* The site investigation will implement the WP/SAP developed in Step 4 and verified in Step 5 (if required). If the Contractor determines that deviations from the WP/SAP are required because of changes in field conditions or concentrations/locations of COPECs, they shall be proposed to the USACE for consideration at an SMDP. Upon agreement, the RI Report shall include the reason for the change and how the change affects the baseline ERA.

(2) *Step 6 SMDP.* This SMDP is required only if it is necessary to alter the WP/SAP, as noted above. Agreement shall be reached on the appropriateness of the changes, as well as on how the information will be used in the baseline ERA.

(3) *Analysis of Ecological Exposures and Effects.* In the analysis phase of the ERA, the

data on existing and potential exposures and ecological effects at the site are technically evaluated (EPA/540/R-97/006). The procedures for characterizing exposures and ecological effects were documented in the WP/SAP (SMDP at the end of Step 4).

(a) *Characterizing Exposures.* The exposure analysis combines the spatial and temporal distributions of the selected endpoints with those of the COPECs to evaluate exposures. The result of the exposure analysis is an exposure profile. This profile quantifies the magnitude and spatial and temporal patterns of exposure as they relate to the assessment endpoints and risk hypotheses developed during problem formulation (EPA/540/R-97/006).

(b) *Characterizing Ecological Effects.* The ecological effects characterization shall include a summary of the types of adverse effects on biota associated with exposure to COPECs and shall evaluate of relationship between magnitude of exposures and adverse effects.

(c) *Exposure-Response Analysis.* The Contractor shall describe the relationship between the magnitude, frequency, or duration of exposures to the COPECs and the magnitude of any responses. The relationship between exposure and response shall be described to the extent possible and the linkage between the measurement and assessment endpoints shall be clearly explained. The Contractor shall provide identification of the effects (i.e., potential or observed), and a discussion of the confidence in these relationships, either qualitatively or quantitatively, as allowed by the data.

(d) *Evidence of Causality.* It is very important to evaluate the strength of the causal association between COPECs and effects on the selected endpoints. Demonstrating a correlation between a contaminant gradient and ecological impacts is a key component of establishing causality, but is not required. The Contractor shall use the procedures and methods outlined in ERAGS (EPA/540/R-97/006) and the Guidelines (EPA/540/R-97/033) to assist in describing the cause and effect relationships.

e. *Step 7: Risk Characterization.* As stated in ERAGS, "unless the site investigation during Step 6 discovers unexpected information, the risk assessment should move smoothly through the risk characterization phase, because the data interpretation procedures were specified in the WP/SAP." The Risk Characterization includes two major steps: risk estimation and risk description.

(1) *Risk Estimation.* To estimate risk, integrate the exposure profiles and the exposure-effects information gathered during the field effort, and assess the uncertainties associated with the process. All assumptions, defaults, uncertainties, use of professional judgment, and any other inputs to the risk estimate shall be clearly identified and easy to find.

(2) *Risk Description.* The risk description shall consist of a summary of the results of the risk estimation and an assessment of confidence in the risk estimates through a discussion of the

EP 200-1-15

15 Dec 01

weight of evidence. An analysis and discussion of all identifiable uncertainties shall also be included.

f. Step 8: Risk Management. At the end of the baseline ERA, the Contractor shall provide information to the risk manager or managers to assist them in decision-making. In addition to summarizing the baseline ERA, the Contractor shall adequately address the six principals and the four questions from USEPA.

5. Results of the BRA. The Contractor shall present a summary of the results and uncertainties of both the HHRA and the ERA, the relationship of the two assessments, and an evaluation of the severity of any risks or hazards indicated. Any conflicts between the HHRA and ERA (e.g., significant human health risk but no indication of ecological risk) should be clearly discussed, so that the effects of giving one or the other preference are easily understood. This information is intended to help the risk manager or managers to determine the need for a no further action decision, a removal action, or to proceed to a Feasibility Study for site remediation.

6. Examples of Guidance. The following documents are provided for reference. Additional documentation may be used as required or appropriate.

a. Department of the Army Publications.

DA Pam 40-578

Health Risk Assessment Guidance for Installation Restoration Program and Formerly Used Defense Sites.

AR 200-1

Environmental Protection and Enhancement.

b. U.S. Army Corps of Engineers (USACE) Publications.

EM 200-1-2

Technical Project Planning (TPP) Process.

EM 200-1-4

Risk Assessment Handbook, Volume I: Human Health Evaluation.

EM 200-1-4

Risk Assessment Handbook, Volume II: Environmental Evaluation.

c. U.S. Environmental Protection Agency (USEPA) Publications

EPA/540/1-88/001

OSWER Directive 9285.5-1. *Superfund Exposure Assessment Manual*. Office of Emergency and Remedial Response.

EPA/540/1-89/002

Risk Assessment Guidance for Superfund: Vol. 1 - Human Health Evaluation Manual (Part A). Office of Emergency and Remedial Response.

EPA/540/G-89/004

OSWER Directive 9355.3-01. *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA*. Office of Emergency and Remedial Response.

EPA-540/R-95-036

Health Effects Assessment Summary Tables (HEAST), NTIS PB95-921199.

EPA/540/R-95/128

Soil Screening Guidance: Technical Background Document.

EPA/540/R-96/018

Soil Screening Guidance: User's Guide.

EPA/540/R-97/006

Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments.

EPA/540/R-97/033

OSWER Directive 9285.7-01D. *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual, Part D*.

EPA/600/3-89/013

Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference. Office of Research and Development.

EPA/600/R-93/187a

Wildlife Exposure Factors Handbook, Volume I of II.

EPA/600/P-95/002Fa, b, and c

Exposure Factors Handbook.

EPA/600/Z-92/001

Guidelines for Exposure Assessment. 57 FR 22888.

EP 200-1-15
15 Dec 01

EPA/630/R-95/002F

Guidelines for Ecological Risk Assessment.

EPA/630/R-97/001

Guiding Principles for Monte Carlo Analysis.

USEPA

National Oil and Hazardous Substances Pollution Contingency Plan. Final Rule. Office of Solid Waste and Emergency Response. 55 FR 8660.

USEPA

OSWER Directive 9285.7-01B. *Human Health Evaluation Manual, Part B: Development of Risk-Based Preliminary Remediation Goals.* Office of Emergency and Remedial Response.

USEPA

OSWER Directive 9285.7-01C. *Human Health Evaluation Manual, Part C: Risk Evaluation of Remedial Alternatives.* Office of Emergency and Remedial Response.

USEPA

OSWER Directive 9285.7-09A. *Guidance for Data Useability in Risk Assessment (Part A).* Final report. Office of Emergency and Remedial Response.

USEPA

OSWER Directive 9285.7-081. *Supplemental Guidance to RAGS: Calculating the Concentration Term.*

USEPA

PB92-963362. *Guidance for Data Useability in Risk Assessment (Part B).* Publication No. 9285.7-09B.

USEPA

OSWER Directive 9285.7-28 P. *Ecological Risk Assessment and Risk Management Principals for Superfund Sites.*

USEPA

On-Line Database: *Integrated Risk Information System (IRIS).*
<http://www.epa.gov/ngispgm3/iris/index.html>

d. Other Publications.

Wentsel et al.

R.S. Wentsel, et al. *Tri-Service Procedural Guidelines for Ecological Risk Assessments.* U.S.

EP 200-1-15
15 Dec 01

Army Edgewood Research, Development and Engineering Center (ERDEC), Aberdeen Proving Ground, MD. ADA297968.