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30 June 2016

ENVIRONMENTAL QUALITY

STANDARD SCOPES OF WORK FOR ENVIRONMENTAL RISK ASSESSMENTS

ENGINEER PAMPHLET

AVAILABILITY

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DEPARTMENT OF THE ARMY
U.S. Army Corps of Engineers
Washington, D.C. 20314-1000

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No. 200-1-2

30 June 2016

Environmental Quality
STANDARD SCOPES OF WORK FOR ENVIRONMENTAL RISK ASSESSMENTS

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APPENDICES

Microsoft Word files of the appendices are attachments to this PDF file.

This pamphlet supersedes EP 200-1-15, dated 15 December 2001

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U.S. Army Corps of Engineers
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Environmental Quality
STANDARD SCOPES OF WORK FOR ENVIRONMENTAL RISK ASSESSMENTS

1. Purpose.

a. 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) and performance work statements (PWSs) to procure contractor services for preparing human health and ecological risk assessments for Hazardous, Toxic, and Radioactive Waste (HTRW) and Military Munitions Response Program (MMRP) projects relative to Munitions Constituents (MC). These HTRW/MMRP 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 detailed SOWs contained in Appendices A, B, C and D are a starting point only. It is both acceptable and advisable to make the SOW site-specific. The PWSs contained in Appendices E and F only require identification of the program via insertion of either HTRW or munitions constituents (MC) where shown in the text.

b. The foundation of Corps of Engineers environmental work is the Environmental Operating Principles as specified in ER 200-1-5. These seven tenets serve as guides and must be applied in all Corps business lines as we strive to achieve a sustainable environment.

2. Applicability. This EP generally applies to all HQUSACE elements and USACE commands responsible for executing HTRW or MMRP projects unless more specific guidance applies.

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

4. References.

a. 40 CFR Part 264.552/3, RCRA Corrective Action.

b. 40 CFR Part 300, National Oil and Hazardous Substances Pollution Contingency Plan.

c. Department of Defense Manual 4715.20, Defense Environmental Restoration Program (DERP) Management.

d. AR 200-1, Environmental Protection and Enhancement.

e. ER 200-1-5, Policy for Implementation and Integrated Application of the U.S. Army Corps of Engineers Environmental Operating Principles and Doctrine.

f. ER 200-3-1, Environmental Quality – Formerly Used Defense Sites (FUDS) Program Policy.

g. EM 200-1-2, Technical Project Planning (TPP) Process.

h. EM 200-1-4, Risk Assessment Handbook, Volume I: Human Health Evaluation.

i. EM 200-1-4, Risk Assessment Handbook, Volume II: Environmental Evaluation.

j. EPA/540-1-89/002, Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (Part A).

k. 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.

l. OSWER Directive 9902.3-2A, RCRA Corrective Action Plan, Final, May 1994.

5. Technical Assistance and Technical Review. The district 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 site-specific 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 Environmental and Munitions Center of Expertise (EM CX) supports all programs, and has a designated risk assessment POC for each district to give technical assistance and to review documents. Information about EM CX participation is available on-line at the EM CX intranet web site.

b. AR 200-1 gives the United States Army Institute of Public Health (USAIPH, formerly USACHPPM) responsibility to approve human health risk assessments and review environmental hazards and ecological risk assessments, on behalf of the Office of

the Surgeon General (OTSG). This requirement applies to the Army's Installation Restoration Program (IRP), Formerly Used Defense Sites (FUDS), and the Army BRAC sites.

6. CERCLA/RCRA Equivalency.

a. 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 identify releases requiring further investigation. This step is called the Site Inspection (SI) in the CERCLA process, and the RCRA Facility Assessment (RFA) in the RCRA process (performed 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 a Remedial Investigation (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. The use of the RCRA process instead of the CERCLA process must be approved at an appropriate level within USACE or by the agency requesting the work. Certain programs such as DERP are almost exclusively performed under CERCLA despite requests from regulators to perform under a RCRA process. Where USACE is supporting another component or agency, USACE personnel should not contact regulatory agencies unless given documented permission from the component or agency project manager. Even where such permission is granted, USACE is not the point of contact for the project. That responsibility remains with the other component or agency.

b. RCRA Corrective Action differs from CERCLA requirements regarding a risk assessment. RCRA Corrective Action requires the identification of potential human and ecological receptors for current and potential future land use. A risk assessment is not required unless the permit or the designated state authority (or USEPA) specifically requires otherwise. Site specific risk assessments conducted under RCRA often rely on guidance EPA has developed for risk assessments conducted under CERCLA. To determine the site specific risk assessment requirements, the regulatory agency should be contacted to discuss the specific site. RCRA Corrective Action requires the identification of potential human and ecological receptors for current and potential future land use. A risk assessment is not required unless the permit or the designated state authority specifically requires otherwise. RCRA Corrective Action generally does not consider on-site workers as potential receptors since they are protected under OSHA.

7. Scope of Work for Screening-Level Risk Assessment. At the 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 action decision, or it establishes the need for an RI, including a Baseline Risk Assessment (BRA) or an RFI, including a Health and Environmental Assessment (HEA). The procedures for doing the screening evaluation are found in the following USACE guidance documents: EM 200-1-4, Volumes I and II; and in the following USEPA guidance documents: RAGS and ERAGS. Appendix A contains a detailed SOW for conducting such a screening-level risk assessment, following USACE and USEPA guidance. This SOW can be modified for work with RCRA by replacing CERCLA terms with RCRA terms. To determine the site specific risk assessment requirements, the regulatory agency should be contacted to discuss the specific site. The USACE risk assessor should carefully evaluate the SOW, ensuring that all sections are required for the site, and make any appropriate changes. Appendix E contains a PWS for use when the contracting vehicle is performance-based.

8. Scope of Work for Baseline Risk Assessment. The BRA (or HEA during an RFI) is conducted during the RI 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. The procedures for conducting the BRA are found in the following USACE guidance documents: EM 200-1-4, Volumes I and II; and in the following USEPA guidance documents: RAGS and ERAGS. Appendix B contains a detailed SOW for evaluation of human health risks, Appendix C contains a detailed SOW for a site-specific ERA (similar in format to the screening-level ERA used during the SI), and Appendix D contains a detailed SOW for completion of Steps 3-8 in ERAGS. By combining the SOW in Appendix B with either the SOW in Appendix C or Appendix D, a complete, detailed SOW is produced for conducting a BRA, following the appropriate guidance documents and applying the appropriate level of effort. These SOWs are written to have the contractor suggest the data needs according to the Technical Project Planning (TPP) process, and to be documented in the Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP). The district risk assessor in consultation with the project manager shall establish the actual data needs. The USACE risk assessor should carefully evaluate the SOW, ensuring that all sections are required for the site, and make any appropriate changes. Appendix F contains a PWS for use when the contracting vehicle is performance-based.

FOR THE COMMANDER:

6 Appendices
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D. PETER HELMLINGER
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Chief of Staff

APPENDIX A

SCOPE OF WORK
FOR SCREENING-LEVEL RISK ASSESSMENT

Screening-Level Risk Assessment

1. Introduction.

a. A section of the Site Inspection (SI) Report for the site needs to be entitled Screening-Level Risk Assessment. Subdivide this section into Human Health Risk Screen (HHRS) and Screening-Level Ecological Risk Assessment (SLERA) subsections. The Screening-Level Risk Assessment is used to evaluate if the site can be eliminated from further concern or if additional investigation is required due to [Hazardous, Toxic and Radioactive Waste (HTRW)] [Munitions Constituents (MC)] contamination. The risk assessment shall be in conformance with EM 200-1-4, Volume I and Volume II, the United States Environmental Protection Agency (USEPA) Risk Assessment Guidance for Superfund (RAGS) (USEPA, 1989), and the USEPA Ecological Risk Assessment Guidance for Superfund (ERAGS): Process for Designing and Conducting Ecological Risk Assessments (USEPA, 1997).

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 Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP) (USEPA 2005) 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 HHRS and SLERA) are low enough that site concentrations can be evaluated against levels that are known to affect potentially exposed receptors, or evaluate the impact on the assessment if the laboratory is not able to quantify at those levels.

2. Human Health Risk Screen (HHRS). Planning for the HHRS should include agreement on the receptor populations, and which exposure pathways and routes are to be evaluated. This effort will lead to a Conceptual Site Model (CSM), guide selection of health-based screening levels and allow the risk screening process to proceed smoothly. The HHRS 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.

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) The Contractor must select the population group with the highest reasonable exposure frequency and duration to site contaminants. The Contractor shall prepare a preliminary CSM to help identify this group, using current and reasonable future land uses (see EM 200-1-12). 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 may be selected on the basis of regional and/or state requirements. It must be noted that state screening levels are not mandated at this stage of a CERCLA investigation and are not to be applied as cleanup triggers. Sources of risk-based screening levels include:

(1) United States Environmental Protection Agency (USEPA). Regional Screening Level (RSL) Summary Tables

(2) State screening levels.

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 when 10 or more chemicals are evaluated in the assessment. This procedure of screening below a hazard index (HI) of one is to conservatively account for additivity of effects from multiple chemicals.

d. Characterization of Uncertainty. The uncertainties associated with the HHRS 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 database and biasing sampling toward worst-case locations at the site.

(2) Use of maximum chemical concentrations for exposure point concentrations.

(3) Use of highest exposure receptors.

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

e. Results of the HHRS. The Contractor shall summarize the HHRS, indicating the strengths and weaknesses of the screening-level assessment. The Contractor shall discuss the range of chemical concentrations detected, degree of health-based screening level exceedance, 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. Screening-Level Ecological Risk Assessment (SLERA). The SLERA shall conservatively evaluate the potential for adverse ecological effects ascribable to site contamination. The SLERA shall be consistent with Steps 1 and 2 of the ERAGS guidance (USEPA 1997). Additional clarification of the SLERA process and appropriate procedures is provided by the Tri-Services Environmental Risk Assessment Working Group (TSERAWG) document A Guide to Screening-Level Ecological Risk Assessment (TSERAWG, 2008).

a. 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 characterize the decisions to be made within the context of those objectives. The Contractor shall utilize the Army Checklist for Important Ecological Places to assist in evaluation of appropriate SSMOs. Reference Technical Document for Ecological Risk Assessment: Process for Developing Management Goals (USA BTAG 2005).

b. 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 of those contaminants.

(c) Mechanisms of ecotoxicity associated with those contaminants 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 SLERA is to evaluate 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 Ecological Soil Screening Levels (Eco-SSL) Guidance and Documents;

(c) USEPA, National Oceanic and Atmospheric Administration (NOAA) and Ontario sediment criteria;

(d) Oak Ridge National Laboratory (ORNL) benchmarks;

(e) U.S. Army Institute for Public Health (USAIPH) for military unique compounds (MUCs); and

(f) USEPA Region or state benchmarks 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 1;

(b) 100% bioavailability;

(c) Most sensitive life stage present;

(d) Average body weight—normalized ingestion rate; and

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

(2) Screening-Level Risk Calculation. For the screening-level risk calculation, the hazard quotient approach, which compares point estimates of TRVs and exposure values, is standard practice. Hazard quotients are calculated using the following equation:

$$HQ = \text{Exposure Value} / TRV$$

Where the exposure value is either a concentration (mg substance/kg media or mg substance/L water) or an estimated dose (mg substance/kg body weight-day) and the TRV is either a concentration or an estimated dose representing the threshold of a safe exposure. Thus, for each contaminant and environmental medium, the hazard quotient (HQ) is expressed as the ratio of a potential exposure level to the applicable toxicity-based benchmark (TSERAWG, 2008).

(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 SLERA. If the results of the screening-level HHRS indicate no significant human health risks, but there are potential ecological risks, the SLERA 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). See TSERAWG, 2008 for instructions. 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 (realistic uptake factors)

(e) Detection frequency

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

a. Required publications.

TSERAWG, 2008
A Guide to Screening-Level Ecological Risk Assessment. TG-090801.

USA BTAG, August 2005
Technical Document for Ecological Risk Assessment: Process for Developing Management Goals.

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.

EM 200-1-12
Conceptual Site Models.

USEPA, December 1989
EPA/540/1-89/002. Risk Assessment Guidance for Superfund: Vol. 1 - Human Health Evaluation Manual (Part A). Office of Emergency and Remedial Response.

USEPA, June 1997
EPA/540/R-97/006. Environmental Response Team. Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments.

USEPA, October 1999
OSWER Directive 9285.7-28 P. Ecological Risk Assessment and Risk Management Principles for Superfund Sites.

USEPA, March 2005
EPA-505-B-04-900A. DoD: DTIC ADA 427785. Uniform Federal Policy for Quality Assurance Project Plans; Evaluating, Assessing, and Documenting Environmental Data Collection and Use Programs. Part 1: UFP-QAPP Manual. Final Version. Intergovernmental Data Quality Task Force.

b. Related publications.

40 CFR Part 300
National Oil and Hazardous Substances Pollution Contingency Plan.

Army Regulation 200-1
Environmental Protection and Enhancement.

USA BTAG, January 2002.
Technical Document for Ecological Risk Assessment: Planning for Data Collection.

USEPA, September 1990
Publication 9285.7-05FS. Guidance for Data Useability in Risk Assessment: Quick Reference Fact Sheet.

USEPA, March 1991
OSWER Directive 9285.6-03. Timothy Fields, Jr. Memo, Human Health Evaluation Manual, Supplemental Guidance: "Standard Default Exposure Factors".

USEPA, April 1992
OSWER Directive 9285.7-09A. Guidance for Data Useability in Risk Assessment (Part A). Final report. Office of Emergency and Remedial Response.

USEPA, May 1992
PB92-963362. Guidance for Data Useability in Risk Assessment (Part B). Final

USEPA, May 1992
Publication 9285.7-081. Supplemental Guidance to RAGS: Calculating the Concentration Term.

USEPA, May 1992
EPA/600/Z-92/001 Guidelines for Exposure Assessment.

USEPA, December 1993
EPA/600/R-93/187a. Wildlife Exposure Factors Handbook, Volume I of II.

USEPA, May 1995
OSWER Directive No. 9355.7-04. Land Use in the CERCLA Remedy Selection Process.

USEPA, October 1995
New Policy on Evaluating Health Risks to Children.

EPA, May 1996
EPA/540/R-95/128. Soil Screening Guidance: Technical Background Document.

USEPA, July 1996
EPA/540/R-96/018. Soil Screening Guidance: User's Guide.

USEPA, May 1998
EPA/630/R-95/002F. Guidelines for Ecological Risk Assessment.

USEPA, September 2002
EPA 540-R-01-003. Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites.

USEPA, December 2002
OSWER 9285.6-10. Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites.

USEPA, December 2003
OSWER Directive 9285.7-53. Human Health Toxicity Values in Superfund Risk Assessments.

USEPA, April 2006
EPA/600/R-06/038. Assessing Risks to Populations at Superfund and RCRA Sites Characterizing Effects on Populations.

USEPA, September 2011
EPA/600/R-09/052. Exposure Factors Handbook.

USEPA IRIS
On-Line Database: Integrated Risk Information System (IRIS).

ECO Update Bulletin Series **

USEPA, September 1991 **
Publication 9345.0-05I.. Vol. 1, No.1. ECO Update, The Role of BTAGs in Ecological Assessment.

USEPA, December 1991 **
Publication 9345.0-05I. Vol. 1, No. 2. ECO Update, Ecological Assessment of Superfund Sites: An Overview.

USEPA, March 1992 **
Publication 9345.0-05I. Vol. 1, No. 3. ECO Update, The Role of Natural Resource Trustees in the Superfund Process.

USEPA, May 1992 **
Publication 9345.0-05I. Vol. 1, No. 4. ECO Update, Developing a Work Scope for Ecological Assessments.

USEPA, August 1992 **
Publication 9345.0-05I. Vol. 1, No. 5. ECO Update, Briefing the BTAG: Initial Description of Setting, History, and Ecology of a Site.

USEPA January 1996 **
EPA/540/F-95/037. Vol. 3, No. 1. ECO Update, Ecological Significance and Selection of Candidate Assessment Endpoints.

USEPA, January 1996 **
EPA 540/F-95/038. Vol 3, No. 2. ECO Update, Ecotox Thresholds. PB95-96334. Publication 9345.0-12FSI.

APPENDIX B

SCOPE OF WORK
FOR BASELINE 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 BRA is used to evaluate risks/hazards from exposure to [Hazardous, Toxic and Radioactive Waste (HTRW)] [Munitions Constituents (MC)] contamination under baseline (no action) conditions. 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 cannot be applied to this site, the Contractor shall document that it was adequately considered, and justify its omission. The risk assessment shall be in conformance with EM 200-1-4, Volume I and Volume II, the United States Environmental Protection Agency (USEPA) Risk Assessment Guidance for Superfund (RAGS) series (USEPA, 1989, 1991a, 1991b, 2004, 2009), and the USEPA Ecological Risk Assessment Guidance For Superfund (ERAGS): Process for Designing and Conducting Ecological Risk Assessments (USEPA, 1997b). The Contractor will consider USEPA regional or state requirements for using the Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual, Part D (USEPA, 2009).

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). See Conceptual Site Models (EM 200-1-12). Data Quality Objectives (DQOs) for all data collection activities shall be clearly documented in the Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP) (USEPA 2005), 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, with appropriate data qualifiers applied, as required (see, ER 200-1-7, EM 200-1-10, DoD 2010, USEPA 1992, 2002b, 2002c). 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, sample detection and quantitation limits, data qualifiers, and the frequency of detection. The 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 baseline risks and hazards to human receptors from [site contaminants] [MC] 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 RAGS guidance, Volume I: Human Health Evaluation Manual (USEPA 1989), and EM 200-1-4, Volume I. 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 the protocol in RAGS, USEPA regional, or state guidance, as required or appropriate. Per Department of Defense Manual 4715.20 (DoD, 2012), risk assessments should not quantify exposure to naturally occurring substances present at concentrations unaffected by current or past site activities. (See also EPA 2002a)

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 complete or potentially complete 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, and identify exposed populations. As specified in RAGS, exposure point concentrations shall be expressed as the 95 percent Upper Confidence Limit (95% UCL) on the

arithmetic mean. The Contractor shall use ProUCL Software for calculation of the UCL.

(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 site-specific where possible, taken from the Exposure Factors Handbook: 2011 Edition (US EPA, 2011), or taken 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. The hierarchy for toxicity values to be used in the HHRA shall be as specified in DoD Instruction 4615.18, shown below:

(1) Tier 1 – USEPA Integrated Risk Information System (IRIS).

(2) Tier 2 – EPA Provisional Peer-Reviewed Toxicity Values (PPRTVs). Note that Screening PPRTVs (or Appendix PPRTVs) are not to be used for the assessment.

(3) Tier 3 – Other Toxicity Values. Tier 3 includes additional EPA and non-EPA sources of toxicity information. Priority should be given to sources of information that use sound science and are the most current, peer-reviewed, transparent, and publicly available. Example sources for Tier 3 include the California State EPA Toxicity Criteria Database, the U.S. Department of Human and Health Services Minimal Risk Levels, and the EPA's Health Effects Assessment Summary Table (HEAST) (USEPA 1997a). Values may also be found by using an Internet search engine to search for "toxicity values" for a specific chemical.

Lead toxicity is not evaluated in the traditional manner and does not fit within the hierarchy above. The Contractor shall use the guidance provided by USEPA to assess lead toxicity/exposures using the Integrated Exposure Uptake Biokinetic (IEUBK) Model and/or the Adult Lead Model, as required or deemed appropriate. See Lead at Superfund Sites.

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 [40 CFR 300.430(e)(2)(i)(A)(2-5)]. 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.

APPENDIX C

SCOPE OF WORK FOR SCREENING-LEVEL ECOLOGICAL RISK ASSESSMENT

4. Ecological Risk Assessment (ERA). The ERA shall evaluate the potential for adverse ecological effects ascribable to site contamination. The ERA will generally follow Steps 1 and 2 of the ERAGS guidance (USEPA, 1997b), but will be conducted using realistic exposure assumptions. Additional clarification of the ERA process and appropriate procedures is provided by the Tri-Services Environmental Risk Assessment Working Group (TSERAWG) document A Guide to Screening-Level Ecological Risk Assessment (TSERAWG, 2008), Guidelines for Ecological Risk Assessment (USEPA, 1998), and guidance from the applicable USEPA region and state.

a. Problem Formulation. Before beginning problem formulation, the Contractor shall review the results of the screening-level ecological risk assessment (SLERA) performed during the Site Inspection. This involves the Site-Specific Management Objectives (SSMOs), the ECSM and the Chemicals of Potential Ecological Concern (COPECs). This information will guide selection of assessment endpoints for this ERA.

(1) Establishing Assessment Endpoints. Based on the results of the SLERA, the Contractor shall establish the assessment endpoints, or the valued resources requiring protection at the site (see TSERAWG, no date). Unless threatened or endangered species are on-site, the assessment endpoints will be selected such that protection is afforded at the population, community, or ecosystem level of organization.

(2) Establishing Measurement Endpoints. Measurement endpoints are, by definition, measurable responses to a stressor that are related to the valued characteristics chosen as the assessment endpoints. Measurement endpoints for this ERA will be media concentrations of COPECs that are related to the assessment endpoints via either toxicity benchmarks or intake of contamination through diet.

b. Exposure Estimate, Risk Calculation, and Risk Description.

(1) Exposure Estimate. In this step, the Contractor shall estimate chemical exposure levels to screen for potential ecological risks. For all assessment endpoints with complete exposure pathways, the Contractor shall use the 95% UCL of medium-specific site data as the exposure point concentration. Appropriate exposure parameters used shall be taken from the Wildlife Exposure Factors Handbook (USEPA, 1993) or other appropriate

sources. The Contractor shall clearly document and justify all assumptions made in selection of the exposure parameters

(2) Risk Calculation. For the risk calculation, the hazard quotient approach, which compares point estimates of toxicity reference values (TRVs) and exposure values, is standard practice. Hazard quotients are calculated using the following equation:

HQ = Exposure Value / TRV

Where the exposure value is either a concentration (mg substance/kg media or mg substance/L water) or an estimated dose (mg substance/kg body weight-day) and the TRV is either a concentration or an estimated dose representing the threshold of a safe exposure. Thus, for each assessment endpoint, contaminant and environmental medium, the hazard quotient (HQ) is expressed as the ratio of a potential exposure level to the applicable toxicity-based benchmark (TSERAWG 2008).

(3) Risk Description. The Contractor shall provide an assessment of the potential for ecological risks by describing the extent, magnitude and potential ecological significance of site contamination, as well as an evaluation of the uncertainties of the assessment. This will involve describing the location and areal extent of contamination above the threshold for adverse effects, the degree to which the threshold has been exceeded, and the potential for natural recovery of the ecosystem. This should also involve a discussion of on-site versus surrounding habitat as well as an evaluation of the potential for site contamination to adversely affect receptors at the population, community, or ecosystem level of organization. The USEPA (1999) guidance, Ecological Risk Assessment and Risk Management Principles for Superfund Sites should be consulted to assist in this aspect. 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 points to a potential for adverse ecological effects, and a more thorough assessment is warranted.

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

a. Required publications.

Department of Defense (DoD) 2009
DoD Instruction 4715.18. Emerging Contaminants (ECs).

DoD, 2010
DoD Quality Systems Manual for Environmental Laboratories. Version 4.2.

DoD, 2012
DoD Manual Number 4715.20. Defense Environmental Restoration Program (DERP) Management.

TSERAWG, September 2008a
A Guide to Screening-Level Ecological Risk Assessment. TG-090801.

TSERAWG, no date
Selection of Assessment and Measurement Endpoints for Ecological Risk Assessment TG-090802.

ER 200-1-7
Chemical Data Quality Management for Environmental Restoration Activities.

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.

EM 200-1-10
Guidance for Evaluating Performance-Based Chemical Data.

EM 200-1-12
Conceptual Site Models.

USEPA, December 1989
EPA/540/1-89/002. Risk Assessment Guidance for Superfund: Vol. 1 - Human Health Evaluation Manual (Part A). Office of Emergency and Remedial Response.

USEPA, December 1991
EPA/540/R-92/003. Publication 9285.7-01B. Risk Assessment Guidance for Superfund, Human Health Evaluation Manual, Part B, Development of Risk-Based Preliminary Remediation Goals, Interim.

USEPA, December 1991
EPA/540/R-92-004. Risk Assessment Guidance for Superfund, Human Health Evaluation Manual, Part C, Risk Evaluation of Remedial Alternatives, Interim.

USEPA, April 1992
EPA/540/R-92/003. Guidance for Data Useability in Risk Assessment (Part A). Final report.

USEPA, December 1993
EPA/600/R-93/187. Wildlife Exposure Factors Handbook, Volume I of II.

USEPA, 1997a
EPA 540-R-97-036. Health Effects Assessment Summary Tables (HEAST), 1997 Update (or latest version).

USEPA, 1997b
EPA/540/R-97/006. Environmental Response Team. Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments.

USEPA, 1998
EPA/630/R-95/002F. Guidelines for Ecological Risk Assessment.

USEPA, October 1999
OSWER Directive 9285.7-28 P. Ecological Risk Assessment and Risk Management Principals for Superfund Sites.

USEPA, December 2001
Publication 9285.7-47. Risk Assessment Guidance for Superfund, Human Health Evaluation Manual, Part D, Volume I - Human Health Evaluation Manual (Part D, Standardized Planning, Reporting and Review of Superfund Risk Assessments) Final.

USEPA, September 2002
EPA 540-R-01-003. Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites.

USEPA, November 2002
EPA/240/R-02/004. Guidance on Environmental Data Verification and Data Validation.

USEPA, December 2002
EPA/240/R-02/009. EPA QA/G-5. Guidance for Quality Assurance Project Plans.

USEPA, July 2004
EPA/540/R/99/005. Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment), Final.

USEPA, March 2005
EPA-505-B-04-900A. Uniform Federal Policy for Quality Assurance Project Plans; Evaluating, Assessing, and Documenting Environmental Data Collection and Use Programs. Part 1: UFP-QAPP Manual. Final Version. Intergovernmental Data Quality Task Force.

USEPA, January 2009
EPA-540-R-070-002. Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment), Final.

USEPA, October 2011
EPA/600/R-09/052F. Exposure Factors Handbook: 2011 Edition.

USEPA
ProUCL Software. Latest version.

USEPA
On-Line Database: Integrated Risk Information System (IRIS).

USEPA
On-Line Database: Provisional Peer Reviewed Toxicity Values (PPRTVs).

b. Related publications.

40 CFR Part 300
National Oil and Hazardous Substances Pollution Contingency Plan.

TSERAWG, February 2008b
Tri-Services Handbook for the Assessment of the Vapor Intrusion Pathway.

TSERAWG, October 2011
Tri-Service Position Paper on Background Levels in Risk Assessment.

Army Regulation 200-1.
Environmental Protection and Enhancement.

U.S. Army, November 2009
Munitions Response – Remedial Investigation/Feasibility Study Guidance.

USA BTAG, January 2002
Technical Document for Ecological Risk Assessment: Planning for Data Collection.

USA BTAG, August 2005
Technical Document for Ecological Risk Assessment: Process for Developing Management Goals.

EM 200-1-15
Technical Guidance for Military Munitions Response Actions.

USEPA, October 1988
EPA/540/G-89/004. Guidance for Conducting Remedial Investigations and Feasibility Studies under CERCLA. Office of Emergency and Remedial Response.

USEPA, September 1990
Publication 9285.7-05FS. Guidance for Data Useability in Risk Assessment: Quick Reference Fact Sheet. OSWER.

USEPA, March, 1991
OSWER Directive 9285.6-03. Timothy Fields, Jr. Memo, Human Health Evaluation Manual, Supplemental Guidance: "Standard Default Exposure Factors".

USEPA, April 1991
OSWER Directive 9355.0-30. Don Clay Memo, Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions.

USEPA, May 1922
Publication No. 9285.7-09B. Guidance for Data Useability in Risk Assessment (Part B).

USEPA, May 1992
Publication 9285.7-08. Supplemental Guidance to RAGS: Calculating the Concentration Term.

USEPA, May 1992
EPA/600/Z-92/001. Guidelines for Exposure Assessment.

USEPA, August 1994
OSWER Directive No. 9285.7-17. Role of the Ecological Risk Assessment in the Baseline Risk Assessment.

USEPA, MAY 1995
OSWER Directive No. 9355.7-04. Land Use in the CERCLA Remedy Selection Process.

USEPA October 1995
New Policy on Evaluating Health Risks to Children.

USEPA, January 1996
OSWER Directive 9835.15c. Revised Policy on Performance of Risk Assessments During Remedial Investigation/Feasibility Studies (RI/FS) Conducted by Potentially Responsible Parties.

USEPA, July 1996
EPA/540/R-95/128. Soil Screening Guidance: Technical Background Document.

USEPA, July 1996
EPA/540/R-96/018. Soil Screening Guidance: User's Guide.

USEPA, March 1997
EPA/630/R-97/001. Guiding Principles for Monte Carlo Analysis.

USEPA, July 3, 1997
Office of the Administrator, Cumulative Risk Assessment Guidance – Phase I Planning and Scoping.

USEPA, December 2001
EPA 540-R-02-002. OSWER 9285.7-45. Risk Assessment Guidance for Superfund: Volume III - Part A, Process for Conducting Probabilistic Risk Assessment.

USEPA, April 2002
OSWER 9285.6-07P. Role of Background in the CERCLA Cleanup Program.

USEPA, November 2002
EPA 530-D-02-004. OSWER Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance).

USEPA, December 2002.
OSWER 9285.6-10. Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites.

USEPA, December 2003.
OSWER Directive 9285.7-53. Human Health Toxicity Values in Superfund Risk Assessments.

USEPA, April 2006
EPA/600/R-06/038. Assessing Risks to Populations at Superfund and RCRA Sites Characterizing Effects on Populations. ERASC-006.

ECO Update Bulletin Series **

USEPA, September 1991 **
Publication 9345.0-05I. Vol. 1, No. 1. ECO Update: The Role of BTAGs in Ecological Assessment.

USEPA, December 1991 **
Publication 9345.0-05I. Vol. 1, No. 2. ECO Update: Ecological Assessment of Superfund Sites: An Overview.

USEPA, March 1992 **
Publication 9345.0-05I. Vol. 1, No. 3. ECO Update: The Role of Natural Resource Trustees in the Superfund Process.

USEPA, May 1992 **
Publication 9345.0-05I. Vol. 1, No. 4. ECO Update: Developing a Work Scope for Ecological Assessments.

USEPA, August 1992 **
Publication 9345.0-05I. Vol. 1, No. 5. ECO Update: Briefing the BTAG: Initial Description of Setting, History, and Ecology of a Site.

USEPA, March 1994 **
Publication 9345.0-05l. Vol. 2, No. 1. ECO Update: Using Toxicity Tests in Ecological Risk Assessment.

USEPA, September 1994 **
EPA 540-F-94-013. Vol. 2, No. 2. ECO Update: Catalogue of Standard Toxicity Tests for Ecological Risk Assessment.

USEPA, September 1994 **
EPA 540-F-94-014. 9345.0-52, Vol. 2, No. 3 ECO Update: Field Studies for Ecological Risk Assessment.

USEPA, September 1994 **
EPA 540-F-94-050. Vol. 2, No. 4. ECO Update: Selecting and Using Reference Information in Superfund Ecological Risk Assessments.

USEPA, January 1996 **
EPA/540/F-95/037. Vol. 3, No. 1. ECO Update: Ecological Significance and Selection of Candidate Assessment Endpoints.

USEPA, January 1996 **
EPA 540/F-95/038. Vol. 3, No. 2. ECO Update: Ecotox Thresholds. PB95-96334. Publication 9345.0-12FSI.

USEPA, June 2001 **
EPA 540/F-01/014. (Intermittent Bulletin) ECO Update: The Role of Screening-Level Risk Assessments and Refining Contaminants of Concern in Baseline Ecological Risk Assessments.

UESEPA, July 2008 **
EPA-540-R-06-072. ECO Update: Ground Water Forum Issue Paper.

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APPENDIX D

SCOPE OF WORK
FOR BASELINE ECOLOGICAL RISK ASSESSMENT

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)(USA BTAG, 2005), the ECSM, the list of Chemicals Of Potential Ecological Concern (COPECs), and the Scientific/Management Decision Point (SMDP) established at the end of the Site Inspection (SI). The ERA shall be conducted in accordance with steps 3 through 8 of ERAGS (USEPA, 1997b).

Additionally, the following guidance should be used as deemed appropriate:
EM 200-1-4, Volume II, Guidelines for Ecological Risk Assessment), (USEPA, 1998) 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, 1997b).

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:

(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 wildlife exposure parameters utilized (USEPA, 1993) and recalculate HQs for those pathways indicating a risk from the screening-level ERA. See TSERAWG 2008 for instructions. 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. (See. EM 200-1-12.) 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.

(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 (See TSERAWG, no date).

(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 (USEPA, 1997b). 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 (See TSERAWG, no date). 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 UFP-QAPP (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 UFP-QAPP 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 UFP-QAPP 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 UFP-QAPP 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 UFP-QAPP, 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 (USEPA, 1997b). The procedures for characterizing exposures and ecological effects were documented in the UFP-QAPP (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 (USEPA, 1997b).

(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 (USEPA, 1997b) and the Guidelines (USEPA, 1998) 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 UFP-QAPP. 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 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. Required publications.

Department of Defense (DoD), 2009
DoDI 4715.18. Emerging Contaminants (EC).

DoD, 2010
DoD Quality Systems Manual for Environmental Laboratories. Version 4.2.

DoD, 2012
DoDM Manual Number 4715.20. Defense Environmental Restoration Program (DERP) Management.

TSERAWG, September 2008
A Guide to Screening-Level Ecological Risk Assessment. TG-090801.

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Selection of Assessment and Measurement Endpoints for Ecological Risk Assessment. TG-090802.

USA BTAG, August 2005
Technical Document for Ecological Risk Assessment: Process for Developing Management Goals.

ER 200-1-7
Chemical Data Quality Management for Environmental Restoration Activities.

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.

EM 200-1-10
Guidance for Evaluating Performance-Based Chemical Data.

EM 200-1-12
Conceptual Site Models.

USEPA, December 1989
EPA/540/1-89/002. Risk Assessment Guidance for Superfund: Vol. 1 - Human Health Evaluation Manual (Part A). Office of Emergency and Remedial Response.

USEPA, December 1991a
EPA/540/R-92/003. Publication 9285.7-01B. Risk Assessment Guidance for Superfund: Volume I -- Human Health Evaluation Manual, Part B, Development of Risk-Based Preliminary Remediation Goals, Interim.

USEPA, December 1991b
EPA/540/R-92/004, Publication 9285.7-01C. Risk Assessment Guidance for Superfund, Volume I - Human Health Evaluation Manual, Part C, Risk Evaluation of Remedial Alternatives, Interim.

USEPA, December 1991c
EPA/540/R-92/003. OSWER Directive 9285.7-09A. Guidance for Data Useability in Risk Assessment (Part A). Final report.

USEPA, December 1993
EPA/600/R-93/187. Wildlife Exposure Factors Handbook, Volume I of II.

USEPA, 1997a
EPA 540-R-97-036. Health Effects Assessment Summary Tables (HEAST), 1997 Update.

USEPA, 1997b
EPA/540/R-97/006. Environmental Response Team. Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments.

USEPA, May 1998
EPA/630/R-95/002F. Guidelines for Ecological Risk Assessment.

USEPA, December 2001
Publication 9285.7-47. Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part D, Standardized Planning, Reporting and Review of Superfund Risk Assessments) Final.

USEPA, September 2002a
EPA 540-R-01-003. Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites. OSWER 9285.7-41

USEPA, November 2002b
EPA/240/R-02/004. Guidance on Environmental Data Verification and Data Validation.

USEPA, December 2002c
EPA/240/R-02/009. Guidance for Quality Assurance Project Plans.

USEPA, July 2004
EPA/540/R/99/005. OSWER 9285.7-02EP. Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment), Final.

USEPA, March 2005
EPA-505-B-04-900A. DoD: DTIC ADA 427785. Uniform Federal Policy for Quality Assurance Project Plans; Evaluating, Assessing, and Documenting Environmental. Data Collection and Use Programs. Part 1: UFP-QAPP Manual. Final Version. Intergovernmental Data Quality Task Force.

USEPA, January 2009
EPA-540-R-070-002. OSWER 9285.7-82. Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment), Final.

2011 Edition
EPA/600/P-09/052F
Exposure Factors Handbook 2011 Edition (Final)

USEPA
ProUCL Software. Latest version.

USEPA
On-Line Database: Integrated Risk Information System (IRIS).

USEPA
On-Line Database: Provisional Peer Reviewed Toxicity Values (PPRTVs).

b. Related publications.

40 CFR Part 300
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TSERAWG, October 2011
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U.S. Army, November 2009
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EM 200-1-15
Technical Guidance for Military Munitions Response Actions

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

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OSWER Directive No. 9285.7-17. Role of the Ecological Risk Assessment in the Baseline Risk Assessment.

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OSWER Directive No. 9355.7-04. Land Use in the CERCLA Remedy Selection Process.

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OSWER Directive 9340.1-02. Revised Policy on Performance of Risk Assessments during Remedial Investigation/Feasibility Studies (RI/FS) Conducted by Potentially Responsible Parties.

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

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

USEPA, December 2001
EPA 540-R-02-002. OSWER 9285.7-45. Risk Assessment Guidance for Superfund: Volume III - Part A, Process for Conducting Probabilistic Risk Assessment.

USEPA, April 2002
OSWER 9285.6-07P. Role of Background in the CERCLA Cleanup Program.

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OSWER 9285.6-10. Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites.

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OSWER Directive 9285.7-53. Human Health Toxicity Values in Superfund Risk Assessments.

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EPA/600/R-06/038. Assessing Risks to Populations at Superfund and RCRA Sites Characterizing Effects on Populations. ERASC-006.

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Publication 9345.0-05l. Vol. 2, No. 1. ECO Update: Using Toxicity Tests in Ecological Risk Assessment.

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EPA-540-R-06-072. ECO Update: Ground Water Forum Issue Paper.

APPENDIX E

PERFORMANCE WORK STATEMENT FOR SCREENING-LEVEL RISK ASSESSMENT

Screening-Level Risk Assessment

A section of the Site Inspection (SI) Report for the site will 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 if the site can be eliminated from further concern or if additional investigation is required due to [Hazardous, Toxic and Radioactive Waste (HTRW)] [Munitions Constituents (MC)] contamination. The screening-level risk assessment shall be in conformance with the following guidance documents:

EM 200-1-4
Risk Assessment Handbook, Volume I: Human Health Evaluation.

EM 200-1-4
Risk Assessment Handbook, Volume II: Environmental Evaluation.

USEPA, December 1989
EPA/540/1-89/002. Risk Assessment Guidance for Superfund: Vol. 1 - Human Health Evaluation Manual (Part A). Office of Emergency and Remedial Response.

USEPA, June 5 1997
EPA/540/R-97/006. Environmental Response Team. Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments.

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APPENDIX F

PERFORMANCE WORK STATEMENT FOR BASELINE RISK ASSESSMENT

Baseline Risk Assessment

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 BRA is used to evaluate risks/hazards from exposure to [Hazardous, Toxic and Radioactive Waste (HTRW)] [Munitions Constituents (MC)] contamination under baseline (no action) conditions. The Contractor shall use all available site information to prepare the BRA addressing both current and reasonably anticipated future land uses. The risk assessment shall be in conformance with the following guidance documents (note the Contractor will consider USEPA regional or state requirements for utilizing:

EM 200-1-4
Risk Assessment Handbook, Volume I: Human Health Evaluation.

EM 200-1-4
Risk Assessment Handbook, Volume II: Environmental Evaluation.

USEPA, December 1989
EPA/540/1-89/002. Risk Assessment Guidance for Superfund: Vol. 1: Human Health Evaluation Manual (Part A). Office of Emergency and Remedial Response.

USEPA, December 1991
EPA/540/R-92/003. Publication 9285.7-01B. Risk Assessment Guidance for Superfund, Human Health Evaluation Manual, Part B, Development of Risk-Based Preliminary Remediation Goals, Interim.

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USEPA, June 1997
EPA/540/R-97/006. Environmental Response Team. Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments.

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Publication 9285.7-47. Risk Assessment Guidance for Superfund, Human Health Evaluation Manual, Part D, Volume I - Human Health Evaluation Manual (Part D, Standardized Planning, Reporting and Review of Superfund Risk Assessments) Final.

USEPA, July 2004
EPA/540/R/99/005. OSWER 9285.7-02EP. Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment), Final.

USEPA, January 2009
EPA-540-R-070-002. OSWER 9285.7-82. Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment), Final.

GLOSSARY

Abbreviations and Acronyms

BRA	Baseline Risk Assessment
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act.
COPEC	Chemicals of Potential Ecological Concern
COPC	Chemicals of Potential Concern
CSM	Conceptual Site Model
CTE	Central Tendency Exposure
DERP	Defense Environmental Restoration Program
DoD	Department of Defense
DQOs	Data Quality Objectives
ECSM	Ecological Conceptual Site Model
ECO	Ecological
EM CX	Environmental and Munitions Center of Expertise
EP	Engineer Pamphlet
EPA	Environmental Protection Agency
ERA	Ecological Risk Assessment
ERAGS	Ecological Risk Assessment Guidance for Superfund
ERASC	Ecological Risk Assessment Support Center
FS	Feasibility Study
FUDS	Formerly Used Defense Sites
HEA	Health and Environmental Assessment
HEAST	Health Effects Assessment Summary Table
HHRA	Human Health Risk Assessment
HI	Hazard Index
HQ	Hazard Quotient
HSWA	Hazardous and Solid Waste Amendments
HTRW	Hazardous, Toxic, and Radioactive Waste
IEUBK	Integrated Exposure Uptake Biokinetic
IRIS	Integrated Risk Information System
MC	Munitions Constituents
MMRP	Military Munitions Response Program
ORNL	Oak Ridge National Laboratory

OSWER	Office of Solid Waste and Emergency Response
OTSG	Office of the Surgeon General
POC	Point of Contact
PPRTVs	Provisional Peer Reviewed Toxicity Values
PA	Preliminary Assessment
PWS	Performance Work Statement
QA	Quality Assurance
QC	Quality Control
RAGS	Risk Assessment Guidance for Superfund
RCRA	Resource Conservations and Recovery Act
RFA	RCRA Facility Assessment
RFI	RCRA Facility Investigation
RI	Remedial Investigation
RME	Reasonable Maximum Exposure
RSL	Regional Screening Level
SARA	Superfund Amendments and Reauthorization Act
SI	Site Inspection
SLERA	Screening-Level Ecological Risk Assessment
SMDP	Scientific Management Decision Point
SOW	Scope of Work
SSMOs	Site Specific Management Objectives
RTVs	Reference Toxicity Values
TPP	Technical Project Planning Process
TRV	Toxic Reference Value
TSERAWG	Tri-Service Environmental Risk Assessment Working Group
UCL	Upper Confidence Limit
UFP-QAPP	Uniform Federal Policy for Quality Assurance Project Plans
USA BTAG	U.S. Army Biological Technical Assistance Group
USACE	U.S. Army Corps of Engineers
USACHPPM	U.S. Army Center for Health Promotion and Preventive Medicine
USAIPH	U.S. Army Institute of Public Health
USEPA	United States Environmental Protection Agency