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31 December 2010

ENVIRONMENTAL QUALITY

RISK ASSESSMENT HANDBOOK
VOLUME II: ENVIRONMENTAL EVALUATION

ENGINEER MANUAL

AVAILABILITY

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

EM 200-1-4

CEMP-RT

Manual
No. 200-1-4

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Environmental Quality
RISK ASSESSMENT HANDBOOK
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1. Purpose. The overall objective of this manual is to provide risk assessors with the recommended basic/minimum requirements for developing scopes of work, evaluating Architect-Engineer prepared ecological risk assessments, and documenting risk management options associated with Hazardous, Toxic, and Radioactive Waste (HTRW) and Military Munitions Response Program investigations, studies, and designs consistent with principles of good science in defining the quality of risk assessments. This EM is intended for use by U.S. Army Corps of Engineers (USACE) Project Managers, technical personnel, and contractor personnel.

2. Applicability. This EM applies to all HQUSACE elements and USACE commands responsible for HTRW projects and Military Munitions Response Program projects.

3. References. References are listed in Appendix A.

4. Distribution. Approved for public release, distribution is unlimited.

5. Discussion. This manual is intended to provide USACE risk assessors and contractor personnel with supplemental guidance for performance and evaluation of risk assessments 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. It is not intended to replace the accepted guidance by the USEPA (e.g., *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessment*), but should be used in conjunction with that document. Additional information provided by this manual concerns presentation of the risk assessment results for use in risk management and decision-making, concerns focusing on the decisions, and criteria needed for decisions. Both risk and non-risk factors are presented for consideration by the risk managers.

FOR THE COMMANDER:

2 Appendices
(See Table of Contents)

DIONYSIOS ANNINOS
Colonel, Corps of Engineers
Chief of Staff

This manual supersedes EM 200-1-4, Volume II, dated 30 June 1996.

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CHAPTER 1
Introduction

1.1. Purpose and Scope**.** This handbook provides technical guidance to USACE risk assessors and risk assessment support personnel for planning, evaluating, and conducting ecological risk assessments (ERAs) in a phased Hazardous, Toxic, and Radioactive[1] Waste (HTRW) response action and Military Munitions Response Program (MMRP) projects with munitions constituents (MC). This handbook, a compendium to the *Risk Assessment Handbook: Volume I - Human Health Evaluation* (EM 200-1-4, USACE 1999), encourages the use of "good science" within the framework of existing U.S. Environmental Protection Agency ERA guidance.

1.1.1. Risk characterization is a similar process for both human health and ecological risk assessments. The fundamental paradigm for human health risk characterization has four phases: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization. Similarly, the fundamental framework for ecological risk characterization includes four analogous phases: (1) problem formulation, (2) exposure characterization, (3) ecological effects characterization, and (4) risk characterization.

1.1.2. This handbook encourages the concurrent assessment of human and ecological risks so that data collection activities are coordinated and risk managers are provided risk characterization results in a timely manner. Risk characterization results for human and ecological receptors should be reasonable and communicated to the risk managers in a clear and unbiased manner to facilitate the making of balanced and informed risk management decisions.

1.1.3. For the purpose and intended use of this risk assessment handbook, the focus is on the Defense Environmental Restoration Program (DERP) and Base Realignment and Closure Program (BRAC) cleanup programs to address CERCLA- and RCRA-related issues. EM 200-1-4 (USACE 1999), Risk Assessment Handbook, Volume I: Human Health Evaluation, contains a complete discussion of the USACE HTRW program, which will not be repeated here. The reader is referred to that document for details.

1.2. Applicability. This manual applies to all HQUSACE elements and USACE commands responsible for HTRW and MMRP projects with MC.

1.3. Distribution Statement. Approved for public release, distribution is unlimited.

1.4. References**.** References are listed in Appendix A.

1.5. Introduction.

1.5.1. When this engineer manual was first published in June 1996, little detailed guidance existed for performance of ecological risk assessments. The U.S.

[1] Note that radioactive hazards, radioactive wastes, radiation generating devices and radioactively contaminated materials are not addressed in this handbook.

Environmental Protection Agency (USEPA) was in the process of drafting their guidance (USEPA 1997a), as was the Army (Wentsel, et al. 1994). As time has passed, USEPA's guidance, *Ecological Risk Assessment Guidance for Superfund* (ERAGS)*: Process for Designing and Conducting Ecological Risk Assessments* (USEPA 1997a), has become the industry standard, outlining the accepted ERA process. ERAGS is based on the ERA paradigm first put forth in the document *Framework for Ecological Risk Assessment* (USEPA, 1992a), which was expanded upon and replaced by the *Guidelines for Ecological Risk Assessment* (USEPA 1998a).

1.5.2. The tiered approach originally put forth in this EM has fiscal and scientific merit; however, it does not strictly follow the ERAGS process. This has caused district risk assessors to avoid its use within the programs it was designed to augment Installation Restoration Program (IRP), Base Realignment and Closure, and Formerly Used Defense Sites (FUDS). Conversely, we have received positive feedback from both within and outside the U.S. Army Corps of Engineers, citing the usefulness of information contained herein. Therefore, this revision will discontinue the four-tiered process and will not specify procedures conflicting with the ERAGS framework. It will, however, contain all of the concepts and assessment techniques from the previous issue, in a format that will facilitate application to ERAs conducted in accordance with ERAGS.

1.6. Intended Audience and Use**.** This document was prepared for use by USACE personnel responsible for scoping, preparing, directing, and reviewing ERAs at HTRW response action sites. The engineering manual entitled, *Technical Project Planning (TPP) Process* (USACE 1998) should be reviewed, particularly for understanding the process described in Chapter 2 of this handbook on how to determine data quality objectives (DQOs) to support an ERA.

1.6.1. The data collection, assessment, characterization of risk and uncertainty, and the risk management decision-making aspects presented in this handbook are intended to satisfy the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and Resource Conservation and Recovery Act (RCRA) regulatory requirements. The assessment of ecological risks under these two functionally equivalent programs is essentially the same.

1.6.2. Response actions implemented in accordance with CERCLA or RCRA are not legally subject to the National Environmental Protection Act (NEPA) and do not require separate NEPA analyses. Therefore, this EM does not address NEPA directly. However persons responsible for NEPA evaluations (i.e., environmental assessments, environmental impact statements) may find many of the procedures in this handbook useful in fulfilling NEPA requirements.

1.6.3. The concepts and assessment techniques presented in this handbook can be used to optimize data quality design across regulatory program requirements (if applicable) and justify or demonstrate that certain units or sites could be combined and assessed as a single entity according to the concept of establishing a Corrective Action Management Unit (CAMU) or temporary units (TU). If both regulatory programs are

applicable at a site or unit, the ecological assessment components should be closely coordinated to avoid duplication of effort. Where possible, the technical and risk management approaches should be incorporated as specific language in agreements with USEPA or states.

1.7. USACE Role in the HTRW Program**.** In the execution of USACE environmental missions, the HTRW program is organized and staffed to respond to assignments for the following five national environmental cleanup programs: (1.) USEPA Superfund Program (a.k.a., CERCLA); (2) Defense Environmental Restoration Program, consisting of IRP, FUDS, and Department of Defense and State Memorandum of Agreement/Cooperative Agreement Program (DSMOA/CA); (3) BRAC; (4) Environmental Compliance Assessment System (ECAS) (USACE 1992); and (5) HTRW environmental restoration support for Civil Works projects and other federal agencies (Department of Defense (DOD) and non-DOD).

1.8. Overview of the HTRW Response Process**.** HTRW response actions involve all phases of a site investigation, design, remediation, and site closeout. The HTRW response process is generally comprised of six executable phases or steps, once the HTRW response site has been identified. They are: (1) Preliminary Assessment (PA); (2) Site Inspection (SI), including the Screening-Level ERA (SLERA); (3) Remedial Investigation (RI), including the Baseline ERA (BERA); (4) Feasibility Study (FS); (5) Remedial Design/Remedial Action (RD/RA); and (6) Site Closeout.

1.9. Role of Ecological Risk Assessments in the HTRW Process**.** Performing an ERA is an iterative process. Risk assessment information is continuously being collected during the HTRW site response process, leading to the characterization of risks and uncertainties qualitatively and/or quantitatively. Risk assessment information is used in various stages of the HTRW site decision process as described below:

1.9.1. *PA/SI or Other Preliminary Site Investigation Activities.* In this phase of the site process, risk assessment information is used to determine whether a site may be eliminated from further concern, to identify emergency situations which may require immediate response actions/interim corrective measures, to assess whether further site investigations are required, to develop a data collection strategy, and to set site priorities, e.g., to rank sites.

1.9.1.1. The SLERA (Steps 1 and 2 of ERAGS) developed during this phase should be conducted using conservative scenarios as guided by the preliminary ecological conceptual site model (ECSM), to ensure that any closeout decision at this stage is protective of the environment. The SLERA is not to be confused with the Preliminary Natural Resource Survey, which is a simple screening study, conducted by natural resource trustees in conjunction with a natural resource damage assessment (NRDA). If release of hazardous substances appears to have resulted in natural resource injury (NRI), then Section 122(j) of CERCLA (as amended) requires federal natural resource trustees to be notified. Section 122(j)(1) encourages federal natural resource trustees to participate in response and remedy negotiations, so that data collected for an ERA can be used by the trustees in carrying out their responsibilities.

1.9.1.2. The Army has published guidance for coordination with the natural resource trustees during CERCLA investigations. For FUDS, see *FUDS Program Guidance to Implement Army Interim Policy for Integrating Natural Resource Injury Responsibilities and Environmental Response Activities* (USACE 2003b). For active installations, see *United States Army Interim Natural Resource Injury Policy Guidance* (USA 2005).

1.9.2. *RI or Other Additional Site Investigation Activities.* Data collected in this phase should comprise those media and pathways identified in the SLERA, including background data. If the data are useable and appropriate for the potential exposure pathways that are considered to be complete, a BERA can be developed. The BERA can help identify the potential for unacceptable ecological risks at the site.

1.9.2.1. *Data Collection for Potential Ecological Risks.* For assessing the potential for ecological risks, data should be collected in the boundary or study area of ecological concern and may need to be collected in reference areas as well. The study area may necessitate combining solid waste management units (SWMUs) or operable units (OUs) or developing a multi-site ERA if such combination is consistent with the ECSM for assessing contamination and remediation options. Combined OUs or SWMUs should be discussed with the regulators and identified in the agreements with agencies, the work plan, or other decision documents.

1.9.2.2. The Army biological technical assistance group (BTAG) has authored a position paper on how and when to combine sites for assessment of ecological risks. See *Integrating Multi-Site Ecological Risk Assessments for Wide-Ranging Receptors* (USA BTAG 2006).

1.9.3. *FS, RD/RA or Other Remedial Design and Implementation Activities.* The BERA completed in the RI serves to identify the need for response actions and the relative degree of response required. The potential environmental impacts posed during remediation (short-term and long-term) and the residual risks after remediation are evaluated during remedy selection.

1.9.4. *Use of Ecological Risk Assessment in Special Studies*. The following are examples of ERAs used in special studies:

a. Applicable or Relevant and Appropriate Requirement (ARAR) Waiver – If a site-specific remedial action objective (RAO), developed from the BERA is as protective as a particular ARAR, an ARAR waiver request may be submitted under CERCLA Section 121(d)(2). The same process may be used to waive state ARARs.

b. Emergency Response – The effectiveness of a proposed removal action, particularly for a time critical removal action, can be evaluated by the ERA in terms of the ability of the action to reduce exposure or risks.

c. Biological Assessment of Endangered Species – The Endangered Species Act (ESA) requires the preparation of a biological assessment if federally listed endangered or threatened species or their habitat could be impacted by the contaminants or clean-up actions (e.g., incinerator emissions) at hazardous waste sites. The ERA for the

endangered or threatened species, and optional assessment of the Category 2 and rare species, may satisfy the draft and final biological assessment requirements (Section 7 consultation) of U.S. Fish and Wildlife Service (USFWS) or other trustee agencies.

1.10. Ecological Risk Assessments as Decision Criteria in the HTRW Program**.**

1.10.1. The role of a risk assessment in the site decision-making process at CERCLA and RCRA sites has been well defined by USEPA either through rule making or program directive/guidance. Therefore, risk assessments have been used as decision criteria in the USACE's HTRW program involving CERCLA and RCRA sites. For BRAC, FUDS, or other HTRW work, which may not be on the national priorities list (NPL), risk assessments should be similarly applied. Activities at these sites require the evaluation of potential human health and environmental risks in order to return the property to conditions appropriate for the current and planned future land uses. Therefore, a site-specific BERA is an important decision tool to USACE customers. If cleanup is needed, the extent or level of cleanup required will be based on results of the BRA (including the ERA and the human health risk assessment(HHRA)), in addition to ARARs or other non-risk factors. Therefore, risk assessment is used as a decision tool at all HTRW response action sites.

1.10.2. DOD and other federal agencies recognize the need for early input from all stakeholders (broadly defined as the regulators, concerned citizens, environmental groups, and other appropriate public and private interested parties) in order to facilitate risk management decision-making. Establishing an early dialogue with stakeholders is particularly important for ERAs to develop assessment strategies and preliminary RAOs.

1.11. Concept of Risk Assessment and Good Science**.**

1.11.1. Risk assessment can be qualitative and/or quantitative. It includes an integration of hazard (chemical or non-chemical), exposure (scenario and pathways), exposure-response (relationship between the magnitude of exposure and the resulting ecological effects) and characterization of the risks and uncertainties. The risk assessment process relies on strong fundamental scientific principles and representative data. Despite this effort, there will be unavoidable data gaps and uncertainties where scientific and professional judgment is needed to predict or infer certain outcomes under certain scientific principles (Federal Focus Inc. 1994). The application of such judgment requires that the risk assessor provide the rationale or basis for the judgment. This view is reflected by the *Policy for Risk Characterization* (USEPA 1995a) and the National Academy of Science (NAS) *Science and Judgment in Risk Assessment* (1993). Both USEPA and NAS recognize the inherent uncertainties in the risk assessment methodologies, and the need for making risk assessments more transparent, clear, consistent, and reasonable.

1.11.2. The fundamental principles of "good science" entail the thorough understanding of: (1) site chemical data; (2) physical, chemical, and ecotoxicity information associated with site chemicals; (3) fate and transport modeling; (4) bioavailability and extent of uptake or bioconcentration; (5) the exposure-effects relationship of site chemicals and underlying uncertainties/conservatism; (6) uncertainties and limitations of the derived risk estimate; (7) the correct interpretation of previously collected data, considering confounding factors, and making objective inferences or test

hypotheses; and (8) unbiased presentation of findings and limitations or uncertainties associated with the findings.

CHAPTER 2

Planning and Scoping an Ecological Risk Assessment

2.1. Introduction. This chapter introduces the conceptual and technical objectives of an ERA. The foundation for the present ERA approach is contained in ERAGS (USEPA 1997a). ERAGS prescribes an 8-step process, the first two steps constituting the SLERA, and steps 3 through 8 making up the BERA.

2.1.1. The ERA is one component of overall site investigation and remedial activities. It should be developed with recognition of how it is supported by preceding and concurrent components of site activities, such as sampling and analysis and the HHRA effort, and how it supports and shapes the subsequent components, such as remedial design.

2.1.2. According to ERAGS, an ERA is defined as a process that evaluates the likelihood that adverse ecological effects are occurring or may occur as a result of exposure to one or more stressors. A stressor, as defined by USEPA, is any physical, chemical, or biological entity that can induce an adverse ecological response. In the Superfund program, an ERA entails the qualitative and/or quantitative appraisal of the actual or potential impacts of a hazardous waste site on plants and animals other than humans or domesticated species. Substances designated as hazardous under CERCLA (see 40 Code of Federal Regulations (CFR) 302.4) are the stressors of concern[1]. These definitions recognize that a risk does not exist unless: (1) the stressor has an inherent ability to cause adverse effects, and (2) it co-occurs with or contacts an ecological component long enough and at sufficient intensity to elicit the identified adverse effect(s).

2.1.3. The approach to ERAs as presented in ERAGS is conceptually similar to the approach used for human health, but is distinctive in its emphasis in three areas. First, the ERA should consider effects beyond those to individuals of a single species and should examine a population, community, or ecosystem (an exception is evaluation of threatened or endangered species, where protection of the individual is mandated). Second, no single set of ecological values to be protected can generally be applied to all sites. Rather, these values are selected from a number of possibilities based on both scientific and policy considerations. Finally, in addition to chemical induced toxic stresses, ERAs may consider nonchemical induced stresses (e.g., loss of habitat) qualitatively.

2.1.4. The fundamental framework for ecological risk characterization includes four phases: (1) problem formulation, (2) exposure characterization, (3) ecological effects characterization, and (4) risk characterization. Problem formulation is a planning and scoping process that establishes the goals, breadth, and focus of the ERA. Its end product is an ECSM that identifies the environmental values to be protected (i.e.,

[2] In very limited circumstances, the USACE may respond to substances that are not CERCLA hazardous when they present an imminent and substantial endangerment. The appropriate legal office should be consulted priot ro doing so.

assessment endpoints), the data needed, and the analyses to be used. The second phase develops profiles of environmental exposure and the third phase evaluates ecological effects of the contaminants of potential ecological concern (COPECs) on the receptors of concern. The exposure profile characterizes the ecosystem, in which the COPECs may occur, as well as the biota that may be exposed. The exposure profile also describes the magnitude and spatial and temporal patterns of exposure. The ecological effects profile summarizes data (or in some cases, bioassessment results) on the effects of the COPECs, on the receptors of concern, and relates them to the assessment and measurement endpoints (see Section 3.3.3). Risk characterization integrates the exposure and effects profiles. The potential for risks can be estimated using a variety of techniques including comparing individual exposure and effects values, comparing the distribution of exposure and effects, or using simulation models, and can be expressed as a qualitative or quantitative estimate, depending on the available data.

2.2. Purpose of the Ecological Risk Assessment.

2.2.1. The main purpose of the ERA is to provide the necessary information to assist risk managers in making informed site decisions. The ERA should provide an objective, technical evaluation of the potential ecological impacts posed by a site, with the risk characterization clearly presented and separate from any risk management considerations. Although risk assessment and risk management are separate activities, the risk assessor and risk manager need to work together at various stages throughout the process to define decision data needs.

2.2.2. The risk assessor does not make decisions on the acceptability of any risk level for protecting the environment or selecting procedures for reducing risk. The ERA is used by the risk manager, in conjunction with regulatory and policy considerations, to determine the appropriate response actions at the site. In the ERA, the risk assessor needs to present scientific information in a clear, concise, and unbiased manner without considering how the scientific analysis might influence the regulatory or site-specific decision. The risk assessor is charged with:

a. Generating a credible, objective, realistic, and scientifically balanced analysis;

b. Presenting information on the problem, exposure, effects, and risks; and

c. Explaining confidence in the assessment by clearly delineating strengths, uncertainties, and assumptions, along with impacts of these factors (USEPA 1995a).

2.3. Objectives of the Ecological Risk Assessment. The specific objectives of the ERA are: (1) to identify and characterize the current and potential future threats to the environment from a hazardous substance release; and (2) to establish remedial action objectives that will protect those ecological receptors potentially at risk, if appropriate. The ERA provides important risk management input at various project phases, identifying ecological species or resources to be protected, as well as limitations and uncertainty.

2.4. Planning Considerations. Planning and problem identification are critical to the success of the ERA and its usefulness with respect to remediation planning. To ensure

that the scope of the ERA is sufficient for making appropriate risk management decisions, the risk assessor must always be mindful of the question, "Do the data and ERA approach support risk management decision-making?" The technical requirements of the ERA should be considered early in the HTRW process to ensure that appropriate information is gathered. It is important that the ecological risk assessor be involved in the early planning stages of field investigations, including ECSM development, identification of site media to be sampled, sampling plan design, data validation, compilation, and interpretation. This will help ensure that the best possible and most relevant data are available for use in the ERA.

2.4.1. *Process Discussions*. Throughout the planning process, the risk assessor should strive to point out potential setbacks, problems, or difficulties that may be encountered in a "real world" situation (see ERAGS, Step 5). Biological sampling programs often entail scheduling constraints. For example, surveys for endangered species (e.g., an orchid) should be conducted in the appropriate season (e.g., June, not December). When special circumstances (e.g., lack of data, extremely complex situations, resource limitations, statutory deadlines) preclude a full assessment, such circumstances should be explained and their impact on the risk assessment discussed. The risk assessor should also explain the minimum data quality considered to be acceptable, how non-detects will be treated, and how medium-specific data will be evaluated or compiled to derive or model the exposure point concentration in the risk assessment.

2.4.2. *Coordinating ERA and HHRA Planning*. Planning for an ERA should be conducted concurrently with that for a HHRA in that these two efforts often have similar data needs, especially in the initial contamination characterization stages. Data needs for the ERA, however, eventually focus on protection of ecosystem components, while the HHRA focuses on protection of a single species, humans. The ERA format and process is designed to be flexible. This allows for coordination with the HHRA in the chemical sampling program, determination of the nature and extent of contamination, characterization of site risk, and the overall site management decision process.

2.4.2.1. Coordinated planning efforts for the ERA and HHRA, particularly where there is to be an expedited cleanup, should include consideration of the following:

a. Overlaps in information needs with regard to human and ecological food chain issues;

b. Benefits of the cleanup and the effectiveness of presumptive remedies;

c. Ecological impacts from removal or remedial activities designed to protect human health;

d. Identification of hot spots that may impact both human health and ecological receptors;

e. Identification of the key assumptions and criteria common to the human health and eco risk assessments that may drive cleanup decisions and focus the decision making process;

f. Early actions which may be taken at sites that could quickly and at a relative lower cost reduce both ecological and human health risk;

g. Identification of areas of greatest concern that may be addressed as discrete tasks, thereby allowing priority to be given to those actions (removal/remedial) that achieve the greatest protection of the environment and human health for the capital (dollars) spent; and

h. Activities common to both the ecological and human health risk efforts that support DoD responsibilities as a Natural Resource Trustee or help coordinate between multiple Natural Resource Trustees where jurisdictions or responsibilities overlap.

2.4.3. *Planning for an ERA*. The ERA should be developed, to some extent, with its end uses in mind. Early interaction with risk managers and remedial designers is needed to obtain information on the risk management options likely to be considered if remedial action is required. This is not to infer that the ERA should be tailored to specific remedial options, for that would compromise the objective nature of the assessment. However, if the risk manager or remedial designer needs to know certain factors (for example, how thick must the cap be to prevent on-site burrowing animals from being at risk), the risk assessor should provide the basis that will allow him or her to answer this question.

2.4.3.1. Before initiating the ERA, project planning is generally conducted to help set priorities and establish budget constraints. Early project planning establishes the focus and complexity of the ERA. Planning includes a review of the available background material and discussions to define the scope and critical aspects of the ERA. Spatial boundaries such as the size of the site, extent of contamination, potential threats to onsite and nearby ecosystems, and important ecosystem components (e.g., fisheries) greatly determine the potential scope and design of the ERA. Any remediation or restoration plans for the site should be considered in the planning stage. Data deficiencies should also be recognized at this stage to the extent possible. Recognizing these planning elements and articulating specific objectives early in the planning stage will drive the design and focus of the subsequent ERA efforts.

2.4.3.2. In the risk planning process, when NRI are possible, it is important for the project delivery team (PDT) to coordinate with natural resource trustees (e.g., DoD, the State, National Oceanic and Atmospheric Administration (NOAA), USFWS, U.S. Forest Service (USFS), and the Bureau of Land Management (BLM) at the earliest possible stage. In this way, the trustee can be assured that potential environmental concerns are addressed, and conclusion of action may be expedited. Coordination with natural resource trustee agencies such as NOAA, provides for the exchange of ideas and issues to ensure the technical adequacy of the RI/FS, and to ensure the protectiveness of the selected remedy for trust resources. Coordination also allows DoD access to the trustees' specific skills, information, and experience in ERAs. This interaction may occur

through a variety of informal and formal forums, including but not limited to: preliminary scoping and drafting of work plans, review of final work plans and subsequent data, technical review committees, meetings, and public information meetings. The Army has published guidance for coordination with the natural resource trustees, which should be consulted whenever the potential for NRI is discovered (USACE 2003b and USA 2005).

2.4.4. *HTRW Technical Project Planning Process.* USACE recognizes the need for cost-effective and efficient site investigation/response actions. To this end, EM 200-1-2 (USACE 1998), Technical Project Planning (TPP) Process, provides guidance on data collection programs and defines DQOs for HTRW sites. The HTRW TPP process is a four-phased process that begins with the development of a site strategy and ends with the selection of data collection options. Using this process, the risk assessor will be able to define minimum information requirements for risk evaluations in support of site decisions. The project planning process should produce an outline for a site-specific ERA that is credible, objective, realistic, and scientifically-balanced.

2.4.4.1. In identifying data needs for the ERA, the risk assessor must fully understand the customer goals, the regulatory programs driving the HTRW project execution, the study elements necessary for the relevant project phase, and the type of ERA needed, based on the study elements. The concept of TPP is fully explained in EM 200-1-2, which emphasizes the need for the data users (in this case, the risk assessor) to identify minimum data requirements for the tasks to be performed. The concept of "minimum requirements" for the ERA is important in that it identifies certain minimum requirements for data collection activities preceding the ERA to ensure that critical data gaps are addressed.

2.4.4.2. DQOs define the project's data needs, data use, number of samples required, the associated quality requirements (e.g., detection limits, blanks, split and duplicate samples, etc.), and level of confidence or acceptable data uncertainty for the requisite data. DQOs are generated at the final phase of the TPP process after the customer has selected the preferred data collection program. The process includes evaluation of previously collected data, and assessment of need for additional data to support the study elements for the current or subsequent phases of the project. This coordinated project planning effort is designed to satisfy the customer goals, applicable regulatory requirements, and minimum technical data requirements for performing a site-specific ERA.

2.4.4.3. Throughout the process, USACE HTRW personnel of various disciplines and responsibilities work closely together to identify data needs, develop data collection strategy, and propose data collection options. The TPP process implements the USEPA's DQO process (USEPA 2000b), which is an iterative process applicable to all phases of the project life cycle. The DQO development process is considered to be a total quality management tool (USEPA 1989c). Incorporating the TPP process is key to ensuring successful planning and performance of the ERA.

2.4.5. *Site-Specific Considerations*. Site-specific data should be collected and used, wherever practical, to determine whether or not a site release presents unacceptable risks and to develop quantitative cleanup levels that are protective. Site-specific data can include such things as plant and animal tissue residue data, bioavailability factors, and population- or community-level effects studies.

The Army BTAG has prepared a position paper specifically for planning an ERA (USA BTAG 2002a). This document applies the TPP process to ERA planning and will assist the risk assessor in establishing the data required for the ERA.

2.5. Establishing the Level of Effort. The preliminary level of effort and nature of the ERA are directly related to the study elements that need to be addressed. Boundaries need to be set early in the scoping process, since the amount of information that could be incorporated into an ERA is potentially limitless. Although often predetermined to a large extent by schedule and budget constraints, these boundaries should be tied to the objectives of the assessment and the site-specific nature of the potential risk.

2.5.1. *Approach and Level of Effort*. The approach and level of effort for an ERA are based on DQOs developed during the TPP process. DQOs address data quality and quantity requirements, as well as data use. DQOs are integral to the design and conduct of cost-effective and efficient ERAs under current and future land-use scenarios. While the overall framework for the conduct of the risk assessment should remain consistent with the ERAGS paradigm, the risk assessor may apply a variety of approaches and classification schemes in the conduct of the ERA. Two distinct approaches are generally seen in ERAs: the criteria-based approach and the ecological effects-based approach, which will be discussed in Chapter 3.

2.5.2 *SLERA (Steps 1 and 2 of ERAGS)*. The SLERA constitutes the first two steps in the ERAGS process and is intended to allow a rapid, inexpensive determination if the site poses no or negligible risk. A SLERA may be performed for a PA/SI, or as the initial step in the RI (if it was not done prior). The SLERA is generally a criteria- or chemical concentration-based approach. Chemical criteria, such as state and federal ambient water quality criteria (AWQC), sediment quality guidelines, or ecotoxicological risk-based screening concentrations, similar to human health risk-based concentrations, are routinely screened against in the SLERA. These chemical screening concentrations represent conservative values that are designed to be protective of specific receptors or ecosystems (aquatic, terrestrial, wetland), and should not be applied as cleanup levels at a site. Screening concentrations, however, are not available for all chemicals and all receptors.

2.5.2.1. In addition to conservative environmental criteria, exposure factors that are used should also be conservative. ERAGS lists the following factors and provides explanation relative to how these parameters are evaluated in the SLERA: area use factor – 100%; bioavailability – 100%; life stage of receptor – most sensitive; body weight and food ingestion rate – minimum body weight to maximum ingestion rate; dietary composition – 100% of diet consists of the most contaminated dietary component. The SLERA may help eliminate chemicals, pathways of exposure (e.g., soil ingestion),

foraging guilds (e.g. small mammalian herbivores), and even entire sites (yet in practice this is rare given the conservatively biased approach that is used). If the SLERA indicates the potential for risk, project planning should occur to review the screening results and define the scope and critical aspects of performing a BERA.

2.5.2.2. In certain circumstances, it may be worthwhile to refine some exposure parameters to evaluate less conservative exposures. This decision would be based on the likelihood that more realistic exposure parameters would bring the calculated hazard quotients (HQs) below one. This step (Step 3A) would occur prior to beginning problem formulation for the BERA (see Section 5-2). The decision to continue beyond the SLERA does not indicate that risk is unacceptable or that risk reduction is necessary, rather it indicates that a more focused evaluation and characterization of the potential for risk and accompanying uncertainty is needed.

2.5.3. *BERA (Steps 3 through 8 of ERAGS).*

2.5.3.1. The ecological effects-based approach is more commonly applied in the BERA. This approach is based on the detailed evaluation of site-specific conditions using toxicity tests or actual biological measurements. This approach is commonly applied to aquatic ecosystems, where standardized American Society for Testing and Materials (ASTM) test methods may be used. This causal evidence approach allows for the identification of biological or ecological impacts without specific accountability for the chemical causative factors and is not constrained by the limitations of chemical analytical techniques. Chemical concentration data are used primarily to establish general accordance. As proof of causality is not a requirement for the ERA, the evaluation of causal evidence is used to augment the risk assessment. Criteria for evaluating causal associations have been suggested by Hill (1965) and are provided in USEPA's Guidelines (1998a).

2.5.3.2. Unlike the SLERA, the focus of the BERA is to evaluate potential threats using site-specific information wherever possible. Only those receptors, pathways and COPECs remaining after the SLERA are evaluated, and exposure factors are adjusted to more realistic levels. The BERA should provide an objective, technical evaluation of the potential ecological impacts posed by a site. The process combines data from biotic and abiotic media along with exposure and toxicity information to provide a determination of environmental risk. The BERA should be clear about the approaches, assumptions, limitations and uncertainties in the evaluation, to enable the risk assessor and manager to interpret the results and conclusions appropriately. The BERA is used by the risk manager, in conjunction with regulatory and policy considerations, to determine the appropriate response actions at the site.

2.5.3.3. To evaluate the relationship between contamination and ecological effects, the BERA requires evaluation of strategy objectives and data needs, based upon the integration of three types of information:

a. Chemical: Chemical analyses of appropriate media to establish the presence, concentrations, and variability of specific toxic compounds.

b. Ecological: Ecological information to document potentially exposed ecosystems and populations (or threatened and endangered individuals); to characterize the condition of existing communities; and to observe whether any obvious adverse effects have occurred or are occurring.

c. Ecotoxicological: Ecotoxicological information or testing to establish the link between adverse ecological effects and known contamination.

d. Without these three types of data, other potential causes of the observed effects on ecosystems unrelated to the presence of contamination, such as natural variability and human-imposed habitat alterations, cannot be eliminated.

2.5.4. *Risk-Based Analysis of Remedial Alternatives.* Various types of ERAs may be applied to conduct a screening evaluation of remedial alternatives or a more detailed analysis of a selected alternative. Generally, the procedure used for the SLERA will be sufficient in providing the risk inputs for selection of potential remedial alternatives or corrective measures (including the no-further action alternative) or the need for procedural changes or engineering controls to minimize short-term risks or residual risks. The two prime objectives of this type of ERA are: 1) the development of remediation goals to be applied to site cleanup, and 2) development of comparative risk assessments between different remedial options. The first type is sometimes performed as a component of the RI, but is distinguished in this section because of its use in the development of remedial options. The second type of ERA is not as commonly performed, but it can be useful in distinguishing between potential remedial options. When evaluating ecological risks and the potential for response alternatives to achieve acceptable levels of protection, the risk manager should characterize risk in terms of (1) magnitude, (2) severity, (3) distribution, and (4) the potential for recovery of the affected receptors.

2.6. Scoping an Ecological Risk Assessment. For scoping purposes, it should be noted that most ERAs are highly site-specific and often require unique investigative plans and actions. The approaches and contents of the anticipated ERA should be explained or discussed in the project planning stage in unambiguous terms. An iterative, tiered approach to the risk assessment, beginning with the SLERA, is used to determine if a more comprehensive assessment is necessary. The nature of the risk assessment depends on available information, the regulatory application of the risk information, and the resources available to perform the ERA. Informed use of reliable scientific information from many different sources is the central feature of the ERA process (USEPA 1995a,c). Therefore, establishing a scope of work for an ERA requires familiarity with the site features/habitats, the COPECs, and the receptors of concern.

2.6.1 Engineer Pamphlet (EP) 200-1-15 (USACE 2001), Standard Scopes of Work for HTRW Risk Assessments, was written to provide the USACE risk assessor with the minimum information necessary to begin scoping an ERA, either screening-level or baseline. The Scopes of Work (SOWs) are provided in Word® format to allow the risk assessor to tailor the SOW to site-specific conditions.

2.6.2. As part of their ECO Update series, USEPA published Developing a Work Scope for Ecological Assessments (USEPA 1992k). Written to support Superfund, this document will help ensure that the ERA accomplishes its objectives within reasonable budget and schedule limitations.

2.7. Guidance. Principal guidance documents for conducting or managing ERAs within the USACE HTRW program are listed below. The risk assessor, as well as the project manager (PM), should be familiar with the procedures put forth in these documents.

2.7.1. *Department of Defense.*

2.7.1.1. The DoD Tri-Services Ecological Risk Assessment Work Group has produced ERA guidance generally following ERAGS protocols. The Tri-Service Procedural Guidelines for Ecological Risk Assessments (Wentsel et al. 1996) preceded ERAGS but advocated the same 8-step process, and provides information on more than 100 environmental models and test methods.

2.7.1.2. The Tri-Service Remedial Project Manager's Technical Handbook For Ecological Risk Assessment (Simini et al. 2000) provides the PM with information to ensure the ERA stays focused while being timely and cost-effective

2.7.2. *U.S. Army*. The Army BTAG has published several position papers applicable to ERAs. Designed to clarify and enhance the ERAGS process, these papers are written for either technical personnel, or the PM.

2.7.2.1. Technical Document for Ecological Risk Assessment: Planning for Data Collection, (USA BTAG 2002a). As noted above, this document applies the TPP Process to ERA planning.

2.7.2.2. Technical Document for Ecological Risk Assessment: Selection of Assessment and Measurement Endpoints for Ecological Risk Assessments, (USA BTAG 2002b). The purpose of this document is to provide general recommendations in regard to selecting appropriate assessment and measurement endpoints for ERAs at Army installations.

2.7.2.3. Technical Document for Ecological Risk Assessment: Screening-Level Ecological Risk Assessments for Army Sites, (USA BTAG 2005a). This document is designed to assist the risk manager in understanding the SLERA and how it applies to the overall site investigation process.

2.7.2.4. Technical Document for Ecological Risk Assessment: Process for Developing Management Goals (USA BTAG 2005b). This document directs how to establish management goals that lead to selection of assessment and measurement endpoints for ERAs.

2.7.2.5. Technical Document for Ecological Risk Assessment: Integrating Multi-Site Ecological Risk Assessments for Wide-Ranging Receptors (USA BTAG 2006). This

document is a technical guide addressing criteria for identifying when and why a multi-site ERA may be appropriate and how it may be conducted.

2.7.3. *USEPA (Superfund)*.

2.7.3.1. Ecological Risk Assessment Guidance for Superfund (ERAGS): Process for Designing and Conducting Ecological Risk Assessments, Interim Final (USEPA, 1997a). This document provides guidance to site managers and RPMs who are legally responsible for the management of a site on how to design and conduct technically defensible ecological risk assessments for the Superfund program. This document supersedes USEPA's 1989 Risk Assessment Guidance for Superfund, Volume 2, Environmental Evaluation Manual (USEPA 1989a) as guidance under Superfund. However, the Environmental Evaluation Manual contains useful information on the statutory and regulatory basis of ecological assessment, basic ecological concepts, and other background information that is not repeated in ERAGS.

2.7.3.2. Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference, Final (USEPA, 1989b). This document provides information for field and laboratory procedures for designing, implementing, and interpreting ERAs at hazardous waste sites.

2.7.3.3. The Role of Screening-Level Risk Assessment and Refining Contaminants of Concern in Baseline Ecological Risk Assessments. ECO Update, Intermittent Bulletin (USEPA 2001a). This supplemental guidance is intended to provide further clarification and direction regarding SLERAs, as described in ERAGS. It also provides an approach for incorporating additional components into the Problem Formulation phase of more detailed (i.e., “baseline”) ecological risk assessments, particularly in Step 3.2, which discusses refining COPECs.

2.7.3.4. Role of the Ecological Risk Assessment in the Baseline Risk Assessment. (USEPA 1994a) Memorandum from Elliott Laws, Assistant Administrator. August 12. USEPA Office of Solid Waste and Emergency Response (OSWER) Directive No. 9285.7-17. This document emphasizes USEPA’s interest in protection of the environment as well as human health.

2.7.4. *USEPA (Agency-wide)*. Guidelines for Ecological Risk Assessments, Final (USEPA, 1998a). This document provides a flexible process for organizing and analyzing data, information, assumptions, and uncertainties to evaluate the likelihood of adverse ecological effects. ERA provides a critical element for environmental decision-making by giving risk managers an approach for considering available scientific information along with the other factors (e.g. social, legal, political, or economic) in selecting a course of action. These guidelines will help improve the quality of ERAs at USEPA while increasing the consistency of assessments among the Agency’s program offices and regions. The Guidelines expand upon and replace the USEPA’s Framework for Ecological Risk Assessment (USEPA 1992a).

2.7.5. *USEPA (Regional)*. Some USEPA Regions have supplemented the national USEPA risk assessment guidance with their own guidance, policies and procedures for use in conducting an ERA. These guidance documents, in the form of memoranda, directives, or stand-alone documents, address a wide range of issues. Regional guidance should be consulted and evaluated for applicability for any work within the regional boundaries. Access to EPA Regions can be obtained through: http://www.epa.gov/epahome/locate2.htm

2.7.6. *State*. Some states have established guidance for performing hazardous waste risk assessments within the state. Some have also promulgated cleanup levels and/or procedures to supplement the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). It should be noted that CERCLA has clearly defined ARARs within the process, and such state guidance, policy or procedures may or may not qualify. Nonetheless, the risk assessor should evaluate the applicability of any state guidance/requirements when performing HTRW work within the state. Access to state hazardous waste programs can be obtained through: http://www.epa.gov/epaoswer/osw/stateweb.htm

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CHAPTER 3
Problem Formulation

3.1. Introduction. Planning and problem identification are critical to the success of an ERA and its usefulness with respect to decision-making. The interface among risk assessors, risk managers, and stakeholders at the beginning of the process, and the communication of risk at the end of the ERA, is critical to ensure that the results of the assessment can be used to support a management decision (USEPA 1998a).

3.1.1. The characteristics of an ERA are determined by agreements reached by risk assessors and risk managers during the planning process. These agreements include: (1) clearly established and articulated management goals (see Section 3.3.3.), (2) characterization of decisions to be made within the context of the management goals, and (3) agreement on the scope, complexity, and focus of the ERA, including the expected output and the technical and financial support available to complete it (USEPA 1998a).

3.1.2. The TPP Process delineated in EM 200-1-2 (USACE 1998) was developed to focus on data needs and to design quality data collection options. The TPP Process also encourages early refinements of potential data collection options as a means of identifying the most cost-effective options for selection. The Army BTAG has authored a position paper that applies the TPP process to determining data needs for an ERA. This paper, *Technical Document for Ecological Risk Assessment: Planning for Data Collection* (USA BTAG 2002a), should be consulted prior to initiating problem formulation for any ERA, either screening-level or baseline.

3.2. Problem Formulation – SLERA. Problem formulation for the SLERA begins with a compilation of readily available information on the environmental setting and potential contamination problem. USEPA suggests use of their environmental checklist (Appendix B of USEPA 1997a) in conjunction with a site visit by a qualified ecologist/biologist to help determine the level of effort needed to assess ecological risk at a particular site. Knowledge of the environmental setting and potential contaminant migration pathways allows for an early determination of the presence or absence of complete exposure routes and the potential for significant ecological impacts. State and federal laws (e.g., Clean Water Act (CWA), ESA) designate certain types of receptors (endangered species) and environments (critical habitats, wetlands) that require special consideration during the risk assessment process or protection at the remediation stage. Knowledge of pertinent state and federal laws pertaining to natural resources and sensitive environments at the site is a key element of the problem formulation step and the identification of endpoints. Ecological information on potentially impacted environments and components can be derived from an installation's Integrated Natural Resource Management Plan, installation natural resource personnel, state natural heritage reports, and federal agencies such as the USFWS.

3.2.1. *Reconnaissance.* During the reconnaissance, a checklist of biological species should be developed. From this list, receptors of special concern will be

identified. Depending on the contaminant sources and potential transport pathways, these receptors could include major elements of the given food chain from plants to higher trophic levels such as insects, reptiles, birds, and mammals. Aquatic ecosystems, for example, can include aquatic plants, bottom fauna (e.g., insects, mollusks), amphibians, turtles, piscivorous snakes, fish, wading birds or ducks, and predatory raptors.

3.2.2. *Receptors.* Receptors are the components of ecosystems that are or may be adversely affected by a chemical or stressor. In the SLERA, species, species groups, functional groups (e.g., producer, consumer, decomposer), food guilds (i.e., organisms with similar feeding habits), and critical habitats are the focus of receptor selection. Receptors can be any part of an ecological system, including species, populations, communities, and the ecosystem itself. Toxicity of chemicals to individual receptors can have consequences at the population, community, and ecosystem level. Population level effects may determine the nature of changes in community structure and function, such as reduction in species diversity, simplification of food webs, and shifts in competitive advantages among species sharing a limited resource. Ecosystem functions may also be affected by chemicals, which can cause changes in productivity, or disruption of key processes (alteration of litter degradation rate). Because it is difficult to assess potential impacts to all receptors, a smaller group of receptors of concern (key receptors) are used to assess potential harm to all components of the system. In the ERA, specific organisms or groups (e.g., small herbivores) are usually selected as key receptors, depending on whether the ERA is screening-level or baseline. The reader is directed to the Army BTAG position paper, *Technical Document for Ecological Risk Assessment: A Guide to Screening Level Ecological Risk Assessment* (USA BTAG 2005a) for additional information.

3.2.3. *Ecological Conceptual Site Model – SLERA***.** A preliminary ECSM should be developed during the problem formulation. The ECSM is a simplified, schematic, diagram of possible exposure pathways and the means by which contaminants are transported from the primary contaminant source(s) to ecological receptors. The exposure scenario(s) usually include consideration of sources, environmental transport, partitioning of the contaminants amongst various environmental media, potential chemical/biological transformation or speciation processes, and identification of potential routes of exposure (e.g., ingestion) for the ecological receptors. Because this is a screening effort and knowledge of site-specific ecological receptors may be lacking, the ECSM should be quite simplified, incorporating general categories (e.g., terrestrial or aquatic biota) in place of site-specific ecological receptors. Reference EM 1110-1-1200, *Conceptual Site Models for Ordnance and Explosives (OE) and Hazardous, Toxic, and Radioactive Waste (HTRW) Projects* (USACE 2003a)(currently under revision), for additional information on conceptual site models.

3.2.4. *Chemical Data Collection and Review – SLERA.* Appropriate data must be used for the SLERA to meet its objectives. Data available from PA/SI activities are

usually limited in number but should be broad in scope of chemical analysis and in the number/type of abiotic media sampled.

3.2.4.1. Sampling should have been conducted in areas of suspected contamination and background areas to distinguish site contamination from background levels and to provide information on the "worst case." If sampling was not conducted in areas of suspected contamination, the SLERA will not provide an adequately cautious assessment of potential risk. Similarly, if a broad chemical analysis was not performed, or if data are not available for all abiotic media of potential concern, the screening SLERA will be limited and cannot be used to eliminate the site from further consideration.

3.2.4.2. The following are examples of minimum requirements for data applied to a SLERA:

a. Chemical-specific analyses of appropriate abiotic media of potential concern (soil, sediments, surface water); and

b. Data of good quality according to the analytical methodology applied.

3.3. Problem Formulation – BERA. An initial step in problem formulation for the BERA may be the development of working hypotheses. Hypothesis development is essential when statistical comparisons are anticipated (e.g., comparisons of on-site to off-site biotic populations).

3.3.1. *Ecological Conceptual Site Model – BERA.* The ECSM, which should have been established in the PA/SI project phase, presents all potential exposure pathways (sources and release mechanisms, transport media, exposure points, exposure routes and receptors) and identifies those pathways which are complete (significant or insignificant) and incomplete. The ECSM helps the project team focus the data collection effort to evaluate significant pathways and address project requirements. At this time, data concerning potential existence and locations of sensitive environments, endangered species, or valued resources should already have been collected.

3.3.1.1. The ECSM establishes the complete exposure pathways that are to be evaluated in the ERA and the relationship between the measurement and assessment endpoints (see Section 3.3.3). The ECSM forms the basic decision tool for evaluating the appropriateness and usefulness of the selected measurement endpoints in evaluating the assessment endpoints (See 3.3.4.). The ECSM is also used as a tool for identifying sources of uncertainty in the exposure characterization (exposure point chemical concentrations).

3.3.1.2. Initial formulation of the ECSM in the SLERA is based upon existing information and assumptions regarding chemical presence and migration, which now should be verified and refined with data collected during the RI. The ECSM is refined in greater detail throughout the characterization of exposure portion of the BERA (see Chapter 4). The risk assessor and project team members should review site data and information collected in earlier project efforts (i.e., PA/SI) to establish or refine the

ECSM (based on more complete background information or non-chemical data) and assess potential early/immediate response actions, as appropriate. All existing data should be reviewed for quality, usability, and uncertainty before defining new data acquisition requirements. The information should be able to assist the risk assessor in developing a more definitive ECSM, or multiple ECSMs if there are multiple OUs, SWMUs, areas of concern (AOCs), or CAMUs/TUs (if appropriate). This information should include:

a. COPECs (information concerning the source characteristics, media contamination, and background chemicals, including those of anthropogenic origin, is needed to identify COPECs);

b. Potential target media (groundwater, surface water, soil/sediment, and air);

c. Media parameters and characteristics;

d. Potential receptors in the target media;

e. Major exposure routes or pathways of concern (e.g., direct contact resulting in soil or sediment ingestion or dermal absorption of contaminants in the media, consumption of food chain crops or prey species, surface water ingestion, and inhalation of contaminants in ambient air);

f. Migration and transport potential of site chemicals from the source, including the effect of existing institutional controls or interim corrective measures or removal actions (e.g., groundwater capture well systems to prevent migration to surface water);

g. Exposure areas or units with common COPECs, which also pose common exposure pathways and threats to ecological receptors;

h. Potential secondary, tertiary, and quaternary sources of contaminants, and their release/transport mechanisms;

i. Level of contamination when compared to available ARARs or benchmark values, and relevancy of sample location/matrix;

j. Removal actions or interim corrective measures taken; and

k. Data usability based on quality assurance characteristics, parameter analyzed, validation results, and the way the data were compiled that may severely restrict their use in the risk assessment.

3.3.2. *Management Goals.* Prior to conducting an ERA, social and political considerations are used with site information to develop management goals. These management goals are the cornerstone of subsequent phases of the risk assessment. The problem formulation phase of the BERA uses management goals to develop ecological endpoints.

3.3.2.1. Management goals are defined as a general statement about the desired condition of ecological values of concern (USEPA, 1998a). These goals may vary from

"no unreasonable effects on bird survival" to "minimize surface water impacts" to "reestablish a tall grass prairie". Since ERA management goals often come from interpretations of law by regulators or the desires of the property owner and/or the local community, it is critical to involve all stakeholders when planning an ERA to ensure management goals are appropriate for the site and ecosystem of concern.

3.3.2.2. The Army BTAG has authored a position paper on when and how to establish management goals for an ERA. See *Technical Document for Ecological Risk Assessment: Process for Developing Management Goals* (USA BTAG 2005b).

3.3.3. *Selection of Key Receptors*. Receptors are the components of ecosystems that are or may be adversely affected by a chemical or other stressor. Endpoints are characteristics of an ecological component that may be affected by an environmental stressor (e.g., chemical contaminant). Because it is difficult to assess potential impacts to all receptors for all endpoints, ecological assessment methods select particular types of receptors (key receptors) and endpoints to represent potential harm to all components of the system.

3.3.3.1. *Objectives.* Grouping of species, organisms, habitats, or ecosystem components under the heading of key receptors helps focus the exposure characterization portion of the BERA on species or components that are the most likely to be affected and on those that, if affected, are most likely to produce greater effects in the onsite ecosystem. The focus of receptor selection process is on species, groups of species (e.g., birds, benthic invertebrates), or functional groups (feeding guilds), rather than higher organizational levels such as communities or ecosystems. Chemical-specific toxicological parameters are also generally limited to the more common organisms or species in the onsite environment and prey organisms that are likely to be used more heavily than others. Although grouping species together for the purposes of exposure and risk quantitation (model analysis) results in some uncertainty, this uncertainty might be offset by the use of conservative criteria to select key receptors with the greatest sensitivity (highest trophic level receptor or chemically sensitive) or greatest opportunity for exposure.

3.3.3.2. *General Considerations*. The selection of key receptors is in part a subjective decision based on species presence, dominance, judged importance in the food chain, and societal or scientific value. Key receptors and are not only species, but may include habitat or areas of special legal protection. Location-specific ARARs, identified as part of the RI effort, may concern locations of natural resources, sensitive ecological receptors or species protected under a number of resource protection statutes. Some of these statutes were developed several decades ago, and their requirements are very specific. Environmental statutes such as the ESA, Migratory Bird Treaty Act, Eagle Protection Act, and Wetlands Protection Act, are used in conjunction with other criteria to help identify (but not mandate) important receptors and select appropriate ecological endpoints (see Section 3.3.4). These laws may also be applied to risk management decision-making during the FS to evaluate the need for and extent

of remediation and the potential effects of various remedial alternatives, based on risk characterization performed in the ERA.

3.3.3.2.1. Primary criteria for key receptor selection generally include consideration of the following:

a. Likelihood of contacting chemicals,

b. Abundance in the study area.

c. A key component of ecosystem structure or function (e.g., importance in the food web, ecological relevance),

d. Listing as rare, threatened, or endangered by a governmental organization; or critical habitat for such,

e. Sensitivity to chemicals, and

f. Recreationally valued species (e.g., game animals).

3.3.3.2.2. Additional criteria used in key receptor selection include habitat preference, food preference, and other behavioral characteristics, which can determine population size and distribution in an area or significantly affect exposure potential. Key receptors may include mobile game species with large home ranges; or smaller non-migratory species; or organisms that are sedentary or have a more restricted movement. For chemicals that bioaccumulate, the effects are usually most severe for organisms at the top of the food chain (e.g., top predators) like bass in aquatic ecosystems or raptors in terrestrial ecosystems.

3.3.3.3. *Likelihood of Contacting Chemicals.* Information from the site reconnaissance, biota checklist (if available), and other available literature are used to compile a candidate list from which preliminary key receptors are selected. General field guides and publications on local and regional fauna, including environmental impact statements, provide good preliminary information. Regional natural resource agencies, such as state fish and wildlife departments, should be consulted for more detailed information. Site maps should be reviewed for information on general physiography, ecosystems, and habitat types.

3.3.3.3.1. Potential key receptors should be evaluated with respect to their likelihood for directly or indirectly contacting areas affected by chemical input. Key receptor selection analysis includes an evaluation of the receptor's relation to COPEC exposure through both direct contaminant accumulation from the abiotic environment and bioaccumulation through the food chain. Habitat destruction and loss or absence of the receptor from impacted habitats are additional considerations in selecting key receptors.

3.3.3.3.2. Where sites are large and numerous species are likely to be present, the preliminary receptors may be reduced into categories (e.g., small birds, small

mammals, wading birds, semiaquatic mammals) or into groups of species that are more toxicologically sensitive (i.e., demonstrate adverse effects to lower environmental concentrations of the COPECs). The list may also be reduced by grouping species into taxonomically related groups and/or feeding guilds, such as hawks or eagles that are often top predators in terrestrial food webs. From the reduced list, representative species can be determined on the basis of observations indicating which species are common onsite and potentially most sensitive to the COPECs.

3.3.3.4. *Sensitivity to Chemicals*. Species differ in the ways that they uptake, accumulate, metabolize, distribute, and excrete contaminants. Susceptibility of an organism also varies with the manner in which organisms are exposed to chemicals in their environment. When possible, key receptors and endpoints are selected by identifying those that are known to be susceptible to chemicals at the site based on published literature. This process ensures that a conservative approach is taken to evaluate receptors (at the individual/population, community, or ecosystem level) and endpoints likely to be adversely affected in combination with the potentially most hazardous chemicals found at the site.

3.3.3.5. *Threatened and Endangered Species*. By definition, threatened and endangered species are already at risk of extinction: the loss of only a few individuals from the population may have significant consequences for the continued existence of the species. While threatened and endangered species and/or habitats critical to their survival, may not necessarily be an important functional component of the ecosystem, they are generally selected as key receptors due to their significant social and scientific value.

3.3.3.5.1. If a species is rare, but not legally designated as either threatened or endangered, local ecologists or other experts should be consulted to determine the importance of the species in the context of the site. Migratory birds may also require special consideration.

3.3.3.5.2. Federal and state natural resource trustees or other specialists should be consulted to determine the location of such species and their potential for exposure to the COPECs. The major sources of information on rare, threatened, and endangered species are field offices of the USFWS and NOAA, officials of state fish and game departments and natural heritage programs, and local conservation officials and private organizations.

3.3.3.6. *Importance of the Food Web*. The purpose of determining the food web is to evaluate pathways from chemicals in soil, sediment, or water to the affected species. Food web analysis is most important where toxicological data indicate that the COPECs bioaccumulate or if the potential effects on organisms might alter population levels of one or more species. Food webs for many sites can be quite complex. Diagramming the complete food web, however, is rarely necessary. Based on the preliminary list of important species at the site, a preliminary simplified food web can be drawn.

3.3.3.7. *Food Web Construction.* Food web construction requires general knowledge on the food habits of species or species groups (e.g., waterfowl, grasshoppers, zooplankton) potentially occurring on the site. Available data on feeding relationships, such as the percent contribution of a prey species in the diet of a predator, can be included to indicate the strength of the feeding relationship.

3.3.3.7.1. Depending on the particular site conditions, one may construct either one or more simple food chains, a community food web, a sink food web, or a source food web (Fordham and Reagan 1991). A food chain would be used to illustrate the movement of chemicals through a series of organisms by progressive consumption.

a. A community food web includes the feeding relations of the entire community.

b. A source food web includes a designated food source (e.g., a particular plant species), all of the organisms that consume the source, and all the species that consume these organisms up to the highest trophic levels involved (Cohen 1978).

c. A sink food web is also a subset of the community food web and includes all the types of organisms eaten by a designated sink species (e.g., bald eagle), the food of these organisms (e.g., fish and small mammals), and so on to the lowest level of the food web (e.g., primary producers) (Cohen 1978). Sink food webs are especially important where threatened and endangered species are a designated key receptor and the pathways by which chemicals biomagnify through various trophic levels to this receptor are to be quantified.

3.3.3.8. *Keystone Species*. Species that may not appear to be important may nevertheless play significant roles in the stability of an ecosystem. Certain rodents (kangaroo rats, prairie dogs) in the arid southwest, for example, are considered keystone species due to their importance as prey, their practice of managing vegetation in such a way as to control species presence, and their importance in providing habitat for other species like burrowing owls. Certain insect groups (both aquatic and terrestrial) may also be regarded as keystone species because of their importance as prey for a wide variety of receptors, the profound effects they can have on vegetative communities, and their potential importance as vectors for contaminant transport. Because of the specialized knowledge required to recognize keystone species and other important receptors, ecologists play a central role throughout the design and conduct of the BERA.

3.3.3.9. *Reptiles and Amphibians.* Consideration of reptiles and amphibians has generally been avoided in BERAs due to limited knowledge about contaminant effects and issues associated with variations in bi-phasic life history strategies. Where scope is limited in a BERA, USEPA (1986b) suggests one means for evaluating reptiles and amphibians is to assume that when birds and mammals are protected via the risk criteria of the assessment, then reptiles and amphibians are also protected. While some protection is afforded reptiles and amphibians by these criteria, the level of protection is not known. As more toxicological information becomes available on such organisms, it should be considered more accurately in the BERA.

3.3.3.10. *Recreationally and Commercially Valued Species*. USEPA (1998a) suggests that potential adverse effects be noted on species that are of recreational and commercial importance (e.g., sport fish, game), although as key receptors they may not be ecologically relevant. Species that are food sources and directly support these important species, as well as habitats essential for their reproduction and survival, should also be considered in the planning and assessment process.

Information on which species are of recreational or commercial importance in an area can be gathered from state environmental or fish and wildlife agencies, federal agencies such as NOAA, USFWS, USFS, and local conservation and fish and game personnel. Commercial fishermen's and trappers' associations may also be valuable sources of data.

3.3.4. *Ecological Endpoints*. Ecological endpoints are identified within the ERA process to provide a basis for characterizing risks to the environment. Ecological endpoints are the particular types of actual or potential impacts a chemical or other environmental stressor has on an ecological component (typically a key receptor). These endpoints are of two types:

a. Assessment Endpoints. Explicit expressions of the actual environmental value that is to be protected, operationally defined by an ecological entity and its attributes. (USEPA 1998a).

b. Measurement endpoints. Measurable responses to a stressor that are related to the valued characteristics chosen as assessment endpoints (USEPA 1998a)[3].

3.3.4.1. ERAs typically address both assessment and measurement endpoints. Assessment endpoints are the ultimate focus in risk characterization and the link to the risk management process. Assessment endpoints most often describe the environmental effects that drive decision-making, such as reduction of key populations or disruption of biological community structure. Selected assessment endpoints should focus on identifiable harm that may come to exposed receptors. Such harm includes death or reproductive impairment. Appropriate measurement endpoints should also focus on determining which pathways may be complete for site COPECs and receptors. As in the PA/SI, measurement endpoints in the BERA are frequently based on toxicity values from the available literature. Sometimes, however, measurement endpoints are expressed as the statistical or arithmetic summaries of the actual field or laboratory observations or measurements.

3.3.4.2. A BERA may include descriptive sampling and measurement of ecological attributes such as tissue residue levels or biological diversity in the contaminated area compared to a nearby reference area. Ecological attributes that can be adversely

[3] The term “Measurement Endpoint” has been redefined to “Measures of Effect” in the Guidelines (USEPA 1998a), noting that the latter term is more specific and less confusing. However, since ERAGS (USEPA 1997a) uses the term Measurement Endpoint, this document will as well, in order to maintain consistency with that document.

affected by contaminants are numerous. Selection of which attributes to measure should be well documented and based on the TPP process (USACE 1998). Comparison of ecological attribute measurements made at the reference and contaminated sites can provide a qualitative measure of the ecological similarity between the two sites. Interpretation of the significance of differences in measurements between contaminated and reference sites is not always straightforward, especially where there are a large number of species present and the analyses become quite complex. The detection of differences between on-site and reference communities does not necessarily indicate that contaminants are exerting biological effects. When quantitative risk estimates are available and the results indicate the potential for risk, conclusions from biological field studies and bioassays can be used as confirmatory weight-of-evidence to support risk conclusions and interpretation. Some additional abiotic sampling and analysis may also be needed so that the biotic data collected can be related to the chemical and physical habitat currently affecting the biota.

3.3.4.3. When possible, receptors and endpoints are concurrently selected by identifying those that are known to be adversely affected by chemicals at the site based on published literature. COPECs for those receptors and endpoints are identified by drawing on the scientific literature to obtain information on potential toxic effects of site chemicals to site species. This process ensures that a conservative approach is taken to selecting endpoints and evaluating receptors that are likely to be adversely affected by the potentially most toxic chemicals at the site.

3.3.4.4. The Army BTAG has authored a position paper that provides general recommendations in regard to selecting appropriate assessment and measurement endpoints. See *Technical Document for Ecological Risk Assessment: Selection of Assessment and Measurement Endpoints for Ecological Risk Assessments* (USA BTAG 2002b).

3.3.4.5. *Population Versus Individual/Community/Ecosystem Endpoints*. The toxicity of contaminants to individual organisms (receptors) can have consequences at the population, community, and ecosystem level. Population level effects may determine the nature of changes in community structure and function, such as reduction in species diversity, simplification of food webs, and shifts in competitive advantages among species sharing a limited resource. Ecosystem functions may also be affected by contaminants, which can cause changes in productivity, or disruption of key processes (alteration of litter degradation rate). Potential endpoints for ERAs at the individual, population, community, and ecosystem level include the following (USEPA 1989b):

Level 1: Individual Endpoints:

Changes in behavior
Decreased growth
Death

Level 2: Population Endpoints:

Increased mortality rate
Decreased growth rate
Decreased fecundity
Undesirable change in age/size class structure

Level 3: Community Endpoints

Decreased species diversity
Decreased food web diversity
Decreased productivity
Change to less desirable community

Level 4: Ecosystem Endpoints

Decreased diversity of communities
Altered nutrient cycling
Decreased resilience
Altered productive capability

3.3.4.5.1. Population-level assessment endpoints are generally recognized in ERAs because: (1) responses at lower levels (i.e., organismal and suborganismal) may be perceived as having less social or biological significance (actions may be taken to protect individuals of endangered species but only because it is prudent in light of the precarious state of the population); (2) populations of many organisms have economic, recreational, aesthetic, and biological significance that is easily appreciated by the public; and (3) population responses are well-defined and more predictable with available data and methods than are community and ecosystem responses. Populations are biologically relevant because of their role in maintaining biological diversity, ecological integrity, and productivity in ecosystems; individuals are important only in maintaining populations. Because the environmental values to be protected are sustainability of species or characteristics at higher levels of ecological organization (e.g., biological diversity), the individual level is not appropriate for assessment endpoints evaluation, except where loss of one individual could impact the survival of a threatened or endangered population.

3.3.4.5.1.1. Ecosystem responses are characterized by many of the same measures as communities: species composition and diversity, nutrient and energy flows and rates of production, consumption, and decomposition. Unlike community measures, ecosystem structure and function include nonliving stores of materials and energy along with animals, plants, and microbes that make up the biotic portion of the environment.

3.3.4.5.1.2. There is a general consensus among ecologists that results of community and ecosystem studies are complex and highly variable, and therefore difficult to interpret. One reason for this difficulty is that contaminants exert their effects on communities both directly and indirectly. Direct and indirect toxicity can cause changes in community structure due to differences in sensitivity among species.

Indirect effects such as resultant shifts in diversity, productivity, or predator-prey interactions (as the outcome of competition) are extremely difficult to predict or measure.

3.3.4.5.1.3. Indirect effects of chemicals are often cited as justification for testing at higher level of organization. Implementation of such testing, however, tends to be expensive, time-consuming, present great uncertainty, and may have limited relevance to the risk management decisions. If ecological endpoints are not appropriate and compelling, they will not provide information relevant to site remediation decisions.

3.3.4.6. *Assessment Endpoints*. Most ecological assessment methods focus on population measures as endpoints, since population responses are more well defined and predictable than are community and ecosystem responses. The latter responses are often more difficult to measure and interpret, highly variable, and not diagnostic of actual exposure. Population measures can also be used to model changes at the community or ecosystem level. Where the population is protected and individuals are important to the overall sustained success of the population, then assessment endpoints focus on adverse effects at the individual level.

3.3.4.6.1. Assessment endpoints are identified by drawing on the scientific literature to obtain information on the potential adverse effects of site conditions to populations, communities, and ecosystem levels of ecological organization. Valued ecological resources such as trees, fish, birds, and mammal populations are typically selected as the focus of the assessment endpoints.

3.3.4.6.2. In ERAs, ecological entities that are valued (based on a combination of societal and ecological concerns) and to be protected are first identified and then investigated by directly measuring appropriate ecological parameters or responses (measurement endpoints) that are related to the assessment endpoints[4]. Unlike human health risk assessments which focus on risk to individuals, ecological risk assessments usually address risk at the population, community, or ecosystem level of organization. The exception to this is in the case of endangered or threatened species, where individuals must be protected in order to preserve the population.

3.3.4.7. *Measurement Endpoints*. When assessment endpoints cannot be measured directly, measurement endpoints are selected. Measurement endpoints are those used to approximate, represent, or lead to the assessment endpoint (USEPA 1989b). Measurement endpoints should be selected so as to provide insights related to the specific assessment endpoint. Toxicity reference values (TRVs)(e.g., median lethal

[4] For a site where there are storage yard drums leaking to a nearby stream in which there are fish upon which bald eagles (a federally protected species) are feeding, a likely assessment endpoint would be: impairment of reproductive success in the bald eagle. The corresponding measurement endpoint could be dose-response data for the COPEC in a related species (e.g., another member of the order Falconiformes or family Accipitridae). Exposure characterization could require fish and abiotic media sampling to confirm the contaminant transport pathway and modeling of fish tissue concentrations to bald eagle tissue concentrations. Comparison of dietary (fish) eagle concentrations and modeled eagle tissue concentrations to concentrations known to impair reproduction in the eagle generates the risk estimate.

dose (LD_{50}), lowest observed adverse effects level (LOAEL), no observed adverse effects level (NOAEL)) obtained from the scientific literature are used as toxicological endpoints (or surrogate measurement endpoints) for the purpose of risk characterization. Where estimated exposure concentrations far exceed the effects levels, and adverse effects are considered likely, additional confirmatory data may be needed in the decision-making process. For wildlife, confirmatory data may be obtained on a variety of measurement endpoints including chemical analyses of tissue samples from potentially exposed wildlife or their prey, or from observed incidence of disease, reproductive failure, or death. Several factors should be examined in the selection of measurement endpoints, including: the sensitivity of the receptor; size comparability; diet composition and quantity; home range size; abundance; resident versus migratory species; and whether toxicity data are available (Hull and Suter 1993). Use of field measurement endpoints may also require comparison to a reference area. Where biological data are to be collected, the DQO process and guidance provided in USA BTAG (2002a) should be followed.

3.3.5. *Chemical Data Collection and Review – BERA*. Planning, collection, and review of chemical data constitute the initial and often the most substantial level of effort in a BERA. Because of the importance for obtaining useable data to the end goal of an acceptable ERA, the following paragraphs describe the data collection and review process in detail.

3.3.5.1. *Planning and Providing Input to Data Collection*. The ecological risk assessor can effectively contribute to the data collection process when he/she is involved early on and has some information regarding the ecological setting and the contamination history of the site. To effectively contribute to the overall data collection and analysis process, the risk assessor should be knowledgeable and experienced with the overall DQO process.

3.3.5.1.1. Data needs for the ERA are likely to overlap with those for the human health risk assessment or other data users' needs in specific physical areas of a site. The potential for data need overlaps should be identified early on. Nearby surface water bodies that are potentially linked to the source through chemical fate and transport are typically sampled for human health purposes. Sediment samples may also be required by the human health risk assessor, but human exposure points may be different from ecological ones, so proposed sample locations should be reviewed. The ecological risk assessor may need water and sediment samples from specific locations such as where waterfowl are feeding or where effects on benthic communities are likely to occur. Similar data needs should be determined early on by the human health and ecological risk assessors for the elimination of unnecessary work or redundancies in sampling.

3.3.5.1.2. Historical data collected for purposes other than the ERA may be available from previous investigations, facility records, permit applications, or other sources. Often, use of historical data sets is limited by the lack of information on sample locations, analytical methods, detection limits, laboratory and quality

assurance/quality control procedures, or scope of analyses. Data from historical sources, therefore, may not be appropriate to use in the quantitative ERA; however, it often can be used in a supportive, qualitative role. When evaluating historical or purposely collected data, a number of factors need to be evaluated.

3.3.5.1.3. On the other hand, unique data needs may also be identified early on in the investigation that would require purposive (biased) sampling in order to collect abiotic samples from specific areas of contaminant or ecological concern. On-site animal activity should be initially observed to best evaluate obvious activity patterns relative to the contaminant source areas. For example, if receptors of special concern are observed on site, it may be advisable to collect chemical sample(s) from their specific habitat.

3.3.5.1.4. The need to detect contaminants at extremely low concentrations may also be a unique data need for the ERA. For example, some polycyclic aromatic hydrocarbons (PAHs) (naphthalene, benzo-a-pyrene, and phenanthrene) have reported effects levels in sediments below the normal reporting limits for these chemicals. Also, matrix interference in soil and sediment analyses often results in detection limits well above ecological effects levels. While it may be desirable, it is not always possible to have the reporting limits or detection limits lower than the effects levels. Such considerations, however, are important to the data collection planning process, the data interpretation, and resultant risk characterization.

3.3.5.1.5. The risk assessor's data needs for a site is the culmination of the assessor's effort to conceptualize and develop a strategy for conducting the BERA, based on available chemical and ecological information. Often, the ecological risk assessor is invited to merely comment or advise on a sampling program that has already been devised for other users, which is normally not an effective way to initiate site investigations. Other times, the ecological risk assessor may be largely responsible for design of the entire sampling program. The level of effort for this task may range from minimal to large and complex.

3.3.5.1.6. Appropriate sampling and analysis methods should be identified, and detailed work plans developed. If biological sampling is short-term, seasonality of the species, population, or community to be sampled should be carefully considered, so that representative biotic samples can be collected. For example, if an assessment endpoint concerns adverse effects in nesting birds, then bird surveys should be conducted in the summer; if, however, the assessment endpoint concerns migratory birds, more appropriate seasons for surveys are spring and fall. Also, locations of biological sampling should be chosen in view of any previous sampling of exposure point media and any anticipated abiotic sampling and chemical analysis.

3.3.5.2. *Evaluation of Existing Chemical Data*. Care should be taken where data collected during earlier site work (e.g., the PA/SI) are largely intended for use in the HHRA, as detection limit needs can be different for the two assessments. For example the drinking water criterion for copper is 1.3 mg/L, while the chronic aquatic life criterion for copper at 100 mg/L $CaCO_3$ hardness is much lower (12 µg/L).

3.3.5.2.1. Conversely, some of the listed carcinogenic organic compounds are relatively non-toxic to aquatic life, but have extremely low human consumption criteria limits. The PA/SI environmental media data should be evaluated to determine whether chemical concentrations exceed ARARs or guidance criteria. Where data gaps are identified (e.g., chemical data are not available for the location or media of ecological interest), then planning for additional data collection should be undertaken.

3.3.5.2.2. The need to conduct biological sampling could be indicated by exceedance of the toxicity benchmarks or other regulatory criteria or by the presence of organic chemicals that biomagnify. Organic chemicals with bioconcentration factors (BCFs) greater than 100 (on a 3% mean lipid content) or logarithm of the n-octanol water partition coefficient (log K_{ow}) values greater than 3.5 are of greatest concern (USEPA 1991b) due to their potential to biomagnify in ecological systems[5]. Organic chemicals with BCFs greater than 300 are considered to be of significant concern in aquatic ecosystems, while for terrestrial organisms, BCFs as little as 0.03 can be significant. Chemicals with water solubilities less than 50 mg/L and potential for significant partitioning into environmental media other than air and water would also be of concern. The presence of chemicals that can biomagnify generally results in a greater level of effort for characterizing risk or in the need to proceed to biological sampling.

3.3.5.3. *Review of Analytical Data*. The quality of an ERA depends directly on the quality of the chemical data applied. Regardless of how well other components of the ERA are performed, if data quality is poor or data do not accurately reflect site contamination or the types of exposures assessed, the ERA will not provide an adequate description of potential adverse ecological effects posed by the site. Therefore, it is imperative that data types used in the assessment be carefully evaluated and properly used.

3.3.5.3.1. Planning for appropriate data acquisition is an important step in obtaining the necessary, high quality data. During this planning stage, appropriate location, number and types of samples, detection limits and analytical methods can be specified as part of the DQO process. These and other minimum requirements for ERA data should be specified prior to data collection by having the risk assessor involved in early stages of site planning. Once available, a thorough review of the data is needed to ensure that DQOs and minimum requirements have been met. This further ensures that the most appropriate information is used in the ERA.

3.3.5.3.2. Numerous factors may potentially have to be considered when identifying minimum data collection requirements for an ERA, or when reviewing existing data to determine usability in an ERA. Relevant guidance on data usability in ERAs is published in the following documents:

[5] See discussion in Section 3.3.6.10 relative to the Great Lakes Water Quality Initiative (GLWQI; USEPA 1995b) as that reference considers a log K_{ow} of 3.0 as the demarcation between bioaccumulators and non-bioaccumulators.

a. *Guidance for Evaluating Performance-Based Chemical Data* (USACE 2005)

b. *Guidance for Data Useability in Risk Assessments* (Parts A and B) (USEPA 1992b,c)

c. *Laboratory Data Validation Functional Guidelines for Evaluating Inorganics Analysis* (USEPA 1994b)

d. *Laboratory Data Validation Functional Guidelines for Evaluating Organics Analysis* (USEPA 1994c)

3.3.5.3.3. An evaluation of data quality should examine the following five broad categories:

a. Data Collection Objectives (discussed above),

b. Documentation,

c. Analytical Methods/Quantitation Limits,

d. Data Quality Indicators, and

e. Data Review/Validation.

3.3.5.3.4. Each of these categories contains other factors that should be considered, as well. In some cases, portions of the evaluation are performed by disciplines other than the risk assessor (for example, data validation is most often performed by a qualified chemist); in other cases, the risk assessor must take the lead in acquiring and reviewing the information. In either case, the risk assessor must be aware of the important factors within each category to enable him or her to judge whether the data are appropriate for inclusion in an ERA.

3.3.5.4. *Data Presentation and Summary*. Data that have been identified as acceptable for use in the ERA should be summarized in a manner that presents the pertinent information to be applied in the ERA. Any deviations from the DQOs or minimum requirements should be identified, and the potential effect upon the ERA described in the assessment. Any data that have been rejected as a result of the data evaluation should be identified, along with a reason for their rejection.

3.3.5.4.1. At this point in the ERA, all appropriate site data identified as acceptable by the data evaluation process should be combined for each medium for the purposes of selecting preliminary COPECs for the site. However, this does not mean that all available data are to be combined. "Appropriateness" of data should take into consideration the area of exposure to be assessed.

3.3.6. *Selection of COPECs*. COPECs are those chemicals that can potentially induce an adverse response in ecological receptors. Because not all chemicals found at a site will have adverse effects on biota, the list of chemicals to be evaluated can be narrowed. Chemical, physical, ecological, and toxicological criteria are used in

evaluating preliminary COPECs. COPECs typically include: (1) chemicals that are not laboratory contaminants (i.e., chemicals whose detection has not been flagged as a result of laboratory contamination), (2) chemicals that occur at higher concentrations than found at background or reference sites, (3) chemicals that have the potential (qualitatively based on concentrations detected and toxicity) to cause acute or chronic toxicity following exposure, (4) chemicals which have the potential to bioaccumulate or biomagnify. Although the selection process for COPECs parallels that for the human health risk assessment, the lists may differ somewhat based on chemical fate and transport characteristics and species-specific toxicities.

3.3.6.1. *Objectives*.

3.3.6.1.1. The objective of selecting preliminary COPECs for the ERA is to identify a subset of chemicals detected at the site that have data of good quality, are not naturally occurring or a result of non-site sources, and are present at sufficient frequency, concentration, and location to pose a potential risk to ecological receptors. The selection of COPECs is a process that considers site-specific chemical data in conjunction with the preliminary ECSM that describes potential exposure pathways from chemical sources to ecological receptors. This selection process is needed for several reasons:

a. Not all chemicals detected at a site are necessarily related to site activities. Some may be naturally occurring, a result of anthropogenic activities, or a result of chemical use in off-site areas.

b. Some chemicals may be a result of inadvertent introduction during sampling or laboratory analysis.

c. Disparities as well as similarities exist in the selection process for COPECs and chemicals of potential concern for human health.

d. Not all chemicals detected at a site are present at high enough concentrations to pose a potential exposure or ecological threat. Additionally there may be trace elements present at nutritionally required or ecologically-protective concentrations.

3.3.6.1.2. The chemical selection process is performed by evaluating the data that have been identified as useable by the data evaluation process. Chemical selection involves evaluation of these data using criteria to identify those chemicals that are <u>not</u> appropriate to retain as COPECs. Through an exclusion process, the COPECs are selected from the list of chemicals analyzed in site media. The outcome of the selection process is a list or lists of chemicals in site media that will be assessed quantitatively in the ERA.

3.3.6.2. *General Considerations*. The following general factors should be considered before applying the chemical selection process. These factors allow the assessor to select the most appropriate data to include in the assessment.

What is the exposure area?

a. An exposure area can be defined as the area in which a receptor will be exposed to a medium through one or more exposure pathways. The boundaries of the exposure area depend on the available pathways for exposure, the home range of the receptor and the extent of contamination within the habitat. For example, an exposure area may be the entire site if chemical contamination is widely dispersed, or it may be a small sub-section of the site if chemical contamination is localized. The exposure area may be a downwind/downgradient area for air, soil, or surface water exposure. Because the exposure area is a function of receptor foraging range as well as areal extent of contamination, the exposure area may include portions of the site that have not been impacted by specific chemicals that are being assessed. For example, if a former tank area is being assessed within a larger site, soil samples from the general tank area should be considered as a discrete exposure area, and should not be combined with other site soils that are remote from the tank area. When unrelated areas of the site are combined with impacted areas, detection frequency and exposure point concentrations can be biased low. It would be appropriate, however, to include samples from within the defined tank area that are reported as non-detected with the contaminated samples from within the same area since these samples are within a defined exposure area. Under some circumstances, however, inclusion of unrelated areas may be acceptable where doing so provides a more realistic foraging-exposure area for a receptor population of concern.

b. Not all chemical data collected from site media represent those to which ecological receptors are necessarily exposed. When selecting COPECs, the potential receptors, exposure pathways, and exposure routes identified in the preliminary ECSM should be examined. The preliminary ECSM will identify how and where exposure is expected to occur (i.e., through soil, sediment, or water ingestion, by direct contact or indirect ingestion, etc.). This information is then used to help identify the media and locations where assessments will be directed and COPECs need to be identified.

c. A distributional analysis of the chemicals present at a site should be conducted. This examination would differentiate between impacted areas and non-impacted areas. The distributional analysis may be a statistical or a qualitative evaluation. The distributional analysis may identify the whole site as the exposure area or only sub-units of the site as the exposure area. It should be noted that some sites are simply too small to support adequate populations of animals to warrant evaluation of ecological risks. Some states do not require any evaluation of ecological threats unless the site is at least 2 acres in size.

d. Reference area locations should not be included with site samples when defining an exposure area. Reference locations are selected to represent off-site conditions and to help distinguish between chemicals and ecological conditions that are site-related and those that are not. Reference samples may or may not be "clean", depending on local background conditions, global atmospheric deposition, other

anthropogenic sources, or upgradient sites (i.e., other non site-related sources of chemicals may be present), but they should not be impacted by site conditions. Reference samples should be collected from locations un-impacted by anthropogenic inputs, to the greatest degree reasonably possible. Reference areas may be used to establish background chemical concentrations, if appropriate criteria are used to select the reference areas.

Are the chemical data appropriate?

Even with high quality, useable data, the form of the chemical or sampling technique should be examined for useability and relevance for exposure. Federal AWQC for metals are based on total recoverable metals; measurement of dissolved metals levels would therefore not be directly comparable (although dissolved metals measurements do have a place in ERAs)[6]. Filtered water samples are generally not relevant for most wildlife exposures. To apply federal AWQC, site-specific factors associated with metals availability (e.g., total organic carbon, pH) and toxicity to aquatic life need to be collected (USEPA 1993b).

Are the chemical data ecologically relevant?

Soil and sediment samples from below a predetermined biologically relevant depth are not typically included in the terrestrial assessment. The biologically relevant depth is based on the ecology of the site and the depth to which small mammals or other receptors of concern (birds or invertebrates) on the site burrow and may therefore be exposed. Feeding habits of animals also determine the type of exposure. Data composited from multiple locations over a large area are not relevant to exposures for animals with a small home range or specific habitat preferences.

3.3.6.3. *Selection Criteria/Methodology*. Criteria that can be applied to determine whether a chemical should be removed as a potential COPEC must be fitting to the selected or anticipated ecological endpoints and the overall adequacy of the sampling program. The process for selecting COPECs is not entirely standardized or mechanistic, but employs a considerable amount of professional judgment throughout the process. For example, the assessor should consider whether limited chemical distribution or limited presence is an artifact of sampling inappropriate media or locations. Could site-related COPECs potentially exert similar toxic action as background "contaminants" or exacerbate the toxicity of the background "contaminants"? [7] The decision to carry forward all detected compounds into the exposure and effects characterization portions of the or BERA is sometimes made depending on the number of chemicals detected and project scope. More often, risk assessors chose to sequentially eliminate chemicals through the progressive

[6] USEPA has published metals ratios so that comparisons can be made between dissolved and total metals concentrations (see *Water Quality Standards: States Compliance - Revision of Metals Criteria*, Interim Final Rule, 60 FR 22229 (USEPA 1995d)).

[7] Contaminants, in this case, refers to naturally-occurring metals or organics or chemicals present as a result of large, regional-scale contamination.

application of screening criteria. Through this elimination process, the risk assessor assures that all chemicals are addressed (not overlooked), but that only the relevant chemicals are carried forward into the quantitative risk analysis. Examples of screening criteria include the following:

a. Non-detection (use of appropriate detection limits);

b. Limited chemical distribution and limited presence in environmental media;

c. Comparability with screening criteria (AWQC, effects range – low (ER-L), lower effects level (LEL), etc.);

d. Comparability with background concentrations (consideration of site-relatedness);

e. Non-site-relatedness;

f. Role as an ecologically essential nutrient at site concentrations;

g. Low toxicity/bioconcentration screen; and

h. Low potential for bioaccumulation and biomagnification.

3.3.6.3.1. These criteria are typically applied sequentially to the available data. Once a chemical is eliminated based on a screening criterion, it is not considered in subsequent screenings or assessments. Each of the above criterion is discussed further in the following sections.

3.3.6.3.2. The ECSM will often identify two or more ecological receptors of concern, particularly where both terrestrial and aquatic ecosystems are present. In these cases, the COPEC selection process is branched: one branch focuses on aquatic receptors, the other branch focuses on terrestrial receptors. Within the terrestrial COPEC selection process, further branching may occur in those cases where the chemicals are known to bioaccumulate. Where there are migratory birds and higher trophic level predatory raptors present, for example, one branch would focus on the COPECs that may have acute or chronic effects on migratory birds, and the other branch would focus on chemicals that bioaccumulate and may affect the top trophic level receptors (e.g., raptors).

3.3.6.4. *Non-detection*. Chemicals analyzed for but not detected in any sample of a site medium should not be included as COPECs for that medium. To be selected, a chemical must be detected in at least one sample of the environmental medium of interest (i.e., the results are not all reported as non-detect and qualified with a "U"). Where samples have an associated duplicate analysis, the mean of the two samples (if both were detected) is usually presented ; if both the sample and the duplicate results were not detected (ND), then the lower of the two censoring limits should be used; if one result is detected and the other is ND, then the detected concentration is reported.

3.3.6.4.1. Care must be taken when evaluating non-detects with very high censoring limits as non-detects may mask the presence of a chemical if the risk-based decision limit that is less than the censoring limit. Although a quantitative estimate of the chemical's concentration value is unavailable in such a case, the chemical may need to be assessed qualitatively if it is present in other site media.

3.3.6.4.2. Detection levels also need to be evaluated with respect to ARARs and toxicity screening levels. For some PAHs and dioxins, quantitation limits below the estimated toxicity effects level for a particular receptor of concern may not be possible. For other chemicals, such as mercury, the detection limit (0.01 µg/L) is barely below the AWQC (0.012 µg/L).

3.3.6.5. *Chemical Distribution*. The physical distribution and frequency of detection of a chemical in a site medium or exposure area can be used to remove a chemical from consideration as a COPEC. The premise behind this criterion is that a chemical with limited presence in a medium or exposure area is unlikely to be contacted frequently and, therefore, does not pose as great a potential ecological risk as do more frequently detected chemicals.

3.3.6.5.1. The distribution of the chemicals present in a site or exposure area should be examined by identifying where the chemicals were and were not detected and their frequency of detection. If this evaluation indicates that the distribution of a chemical is low, i.e., it is detected in only one or a few locations, it may be reasonable to exclude it as a COPEC (assuming an appropriate sampling design was used), or to select the chemical as a COPEC for a smaller exposure area of the site. Within the smaller exposure areas, chemicals detected in five percent or fewer samples may also be considered for elimination.

3.3.6.5.2. The following factors should be considered when applying this criterion:

a. The number of samples available. In a small data set, a limited frequency of detection of a chemical may be more a statistical artifact of a limited sampling design rather that the infrequent presence of the chemical.

b. The quantitation limit and censoring limit. If the quantitation limit or censoring limit exceeds a risk-based limit, it is typically not possible to determine whether or not contamination is present above or below the risk-based threshold.

c. The sampling scheme. Biased sampling plans may over-represent the occurrence of chemicals).

3.3.6.6. *Comparability with Background Concentrations*. In conducting a risk assessment, it may be important to distinguish site contamination from anthropogenic or naturally occurring background in order to determine the presence or absence of contamination and to compare with background risk (USEPA 1992b,c). Some chemicals detected in site media may be naturally occurring or present as a result of ubiquitous or off-site chemical use. Therefore, it is appropriate to exclude them from

the risk assessment. Background samples are kept separate from the site data for the purposes of assessing exposures, and are used exclusively to identify non-site-related chemicals.

3.3.6.6.1. The most appropriate measure of background quality is obtained by the collection of background data from unaffected on-site areas or nearby, off-site areas, or reference areas. The risk assessor should be involved in the selection of background sample numbers, types, and locations as part of the ERA minimum data requirements, to ensure that adequate data are collected. When selecting COPECs, the background data collected should be reviewed to identify whether minimum requirements have been met, or in the case of historical data, whether background measurements are adequate. The following factors should be considered:

Are the locations of the background samples appropriate?

a. Appropriate background sampling locations vary with the media being examined, but should generally be offsite; hydrologically upgradient for surface water and sediments; upwind of the site at the time of measurement and under usual climate conditions for air; and in areas remote from surface water drainage for soil. Background samples should also be located away from other potential off-site sources of contamination that would not impact the site, such as other sites, roadways, etc.

b. If off-site areas have the potential to contribute chemicals to the site being assessed (for example, upgradient industrial facilities), part of the goal of identifying appropriate background sample locations should be to obtain sufficient background samples to identify potential chemical contributions from off-site sources.

Are the background samples comparable in type to the media being examined?

Background samples should be as similar as possible to the site samples being evaluated. Background sampling locations should have similar habitat and soil conditions to the onsite locations. Soil and sediment depths and stream characteristics should be comparable. The type of analyses performed on site and background samples (such as filtered versus unfiltered water, soluble versus total metals) should also be comparable.

Are the number of background measurements sufficient?

a. Erroneous conclusions may be drawn if the number of background samples collected is insufficient to adequately describe background. The number of background samples should be specified as a minimum requirement during the project planning stage. The development of statistically based data quality objectives (e.g., per USEPA 2000b) and sampling designs per USEPA QA/G-5S (USEPA 2002b) is typically the most effective approach to help ensure that the sample size will be adequate for background comparisons. The actual number of samples with data available should be examined to determine if the minimum requirements have been met. For historical

data, it is important to determine whether the nature (e.g., locations) and number of background samples is appropriate or if additional samples are needed.

b. Sampling data from Superfund sites have shown that data sets with fewer than 10 samples per exposure area provide poor estimates of the mean concentration, while data sets with 10 to 20 samples per exposure area provide somewhat better estimates of the mean, and data sets with 20 to 30 samples provide fairly consistent estimates of the mean. In general, the sample mean approaches the true (population) mean as more samples are included in the calculation.

3.3.6.6.2. Acquisition of site-specific background information is always preferable to regional or national values when examining site-relatedness and comparability to background concentrations. Literature values describing regional or national background ranges for chemicals in soil, groundwater, surface water, and sediments may be used, but only if site-specific background is unavailable. Regional or national ranges are relatively insensitive and can lead to the erroneous inclusion or exclusion of a chemical as a COPEC. If historical data include National Pollutant Discharge Elimination System data, they may be used in addition to any other regulatory-required data acquisition.

3.3.6.7. *Comparison to background*. Determination of comparability with background can be accomplished in several ways, depending on the amount of data available. Statistical and non-statistically based evaluations have been historically used to compare site and background concentrations. A statistical evaluation is best when there are sufficient site and background samples to do statistical comparisons (e.g., to test the null hypothesis that there is no difference between the site and background mean chemical concentration at a defined level of confidence). This approach requires quantitative data quality objectives (DQOs) to be established during project planning and needs to be supported by statistically based sampling design. Prior sampling data is also desirable to help estimate the number of sample size that will be required to do the comparisons.

3.3.6.7.1. Several statistical tests are available with which to determine whether the two data groups, background and site, are comparable. Texts on statistics, such as Zar (1984), Ludwig and Reynolds (1988), or Gilbert (1987), should be consulted for tests applicable for use in specific site conditions. Also refer to EM 1110-1-4014 (USACE 2008). Test selection depends upon data distribution (normal, non-normal), whether non-detected values are included, if appropriate proxy values are used, number of samples, and other factors. Statistical evaluations are often the most reliable method for comparing site and background data.

3.3.6.7.2. A geochemical approach can be very effective for distinguishing anthropogenic from naturally occurring metal concentrations, particularly when it supplements traditional quantitative statistical evaluations. Geochemical evaluations can identify naturally occurring metal concentrations that would be erroneously identified as site-related by traditional statistical evaluations. The geochemical approach can not only be used to determine whether a study area has been affected by

anthropogenic metal contamination but can also identify the individual sampling locations that are suspected to possess the elevated metal concentrations. However, it is important to recognize the limitations of this approach. Its primary disadvantage is that it is subjective, as it is predominately qualitative in nature. In particular, decision errors are not quantified and well-defined criteria for distinguishing native from anthropogenic metal concentrations are not specified. In addition, although the approach distinguishes anthropogenic metal contamination from naturally occurring concentrations, it does *not* distinguish site-related contamination from non-site-related anthropogenic metal contamination. In other words, elevated contamination relative to background identified by the geochemical approach may be consistent with anthropogenic background. Statistical comparisons using a background study area would typically be needed to distinguish site-related contamination from total background metal concentrations (from anthropogenic and non-anthropogenic sources). Lastly, an additional limitation of the approach is that it implicitly assumes that, at most, only a portion of the site has been impacted by anthropogenic metal releases. This assumption is typically reasonable but can be violated if the study area is too small (i.e., is predominately limited to a “hot spot”). (Refer to USACE 2008 for additional information on geochemical evaluations.)

3.3.6.7.3. Non-statistical numerical comparisons are often done when background data are limited or when minimum requirements for ERA data collection have not been met and less than optimal numbers of background sample results are available. However, when possible these types of comparisons should be avoided, as they are not as reliable as statistical and geochemical evaluations and can result in incorrect decisions (e.g., may produce high false positives or false negative rates). Examples of non-statistical numerical comparisons include the following:

a. Comparison of site and background arithmetic mean concentrations;

b. Comparison of range of detected concentrations in both data sets.

c. Comparisons of maximum detected values.

3.3.6.7.4. Sometimes some multiplicative factor of the mean is used to determine “comparability.” As an example of this approach, site samples could be defined as comparable if the mean concentration is less than or equal to two times the mean background concentration. However, it is emphasized the criterion for "comparability" is rather arbitrary for these types of comparisons, and may produce conclusions that are either incorrect or inconsistent with statistical evaluations.

3.3.6.8. *Determination of Site-Relatedness*. Background sampling is conducted to distinguish site-related contamination from naturally occurring or other non-site-related levels of chemicals (USEPA 1989d). In some instances, comparison with background is insufficient to identify chemicals that are derived from other sources, despite appropriate planning of background sample locations. If such chemicals are not site-related, however, they generally should not be included quantitatively in the ERA,

although this decision requires professional judgment for reasons noted earlier, as well as and policy and legal considerations.[8] If adequate and confirmable information is available that identifies a different site as the source of a chemical, even in the absence of background information, it may be appropriate to exclude that chemical as a COPEC. The supporting information must be conclusive and presented in the report.

3.3.6.9. *Trace Element and Essential Nutrient Status*. Some chemicals are essential trace elements or nutrients in the diet of plants or animals, and may be present in site media at nutritionally required concentrations or ecologically-protective levels. The following chemicals can be evaluated with regard to essential trace element or nutrient status:

Calcium	Iron
Copper	Potassium
Chromium (trivalent)	Selenium
Magnesium	Sodium
Manganese	Zinc

3.3.6.9.1. Elements that serve as nutrients and are within the recommended allowable dietary range for some receptors may be toxic to other ecological receptors at the same concentration (McDowell 1992). For example, metals such as copper may not be toxic to animals which drink the water, but may be toxic to aquatic organisms. The toxicity of such chemicals should be evaluated in light of the potential site-specific receptors. As a general screening tool, the nutritional requirements of domestic animals (mammals and birds) can be used to assess whether site concentrations of these elements are within acceptable ranges or are likely to pose a hazard to on-site receptors. Nutritional requirements and limits for livestock and experimental laboratory animals (e.g., small mammals, birds, fish) are well-established.

3.3.6.9.2. The evaluation of chemicals as trace elements or dietary requirements may be made on a qualitative or quantitative basis. Elements such as calcium, iron, magnesium, potassium, and sodium are rarely retained as COPECs, for example. It should be noted in any case, however, whether the elements could be present at a site as a result of site activities. If it is known that a particular element's occurrence is a result of site activities, it may not be appropriate to remove it from the list of COPECs.

3.3.6.10. *Preliminary Toxicity Screen*. A toxicity screen to determine which chemical concentrations exceed toxicity benchmarks may be performed for the selection of COPECs. Various TRVs for water and sediment developed by USEPA (1986a, 1993a, 1994d, 1995b,d, 1996) can be used. Oak Ridge National Laboratory (ORNL)(1998) has also developed screening benchmark preliminary values for aquatic

[8] Recent court cases, plus policies adopted by some states, suggest that "non-site-relatedness" is not an appropriate criterion; mere presence of a potential COPEC may require a response, while the assessment or assignment of liability for that response must be determined separately and is not to interfere with the response assessment.

and terrestrial ecosystems. Guidance values from NOAA (Long and Morgan 1991), Washington State Department of Ecology (1991), Florida Dept. of Environmental Protection (MacDonald 1994), and Canada (Long et al. 1995, Persaud et al. 1992, CCME 1995) for marine and freshwater sediment threshold environmental effects levels can be used directly in screening for COPECs in aquatic ecosystems with few or no modifications. Additional toxicity benchmarks for aquatic ecosystems may be developed using information provided in USEPA databases such as ECOTOX and ASTER, available at http://www.epa.gov/med/prods_pubs.htm

3.3.6.10.1. Standardized values to perform a toxicity screen of chemicals in terrestrial ecosystems are generally not available, although ORNL (1998) has published toxicity benchmarks for a variety of species that can be used in a terrestrial toxicity screen. Standardized values for screening terrestrial wildlife, the ecological soil screening values (EcoSSLs) are currently under development by USEPA, and many values have already been published (http://www.epa.gov/ecotox/ecossl/). Four water quality criteria (mercury, p,p'-dichlorodiphenyl-trichloroethane (DDT), 2,3,7,8-tetrachlordibenzo-p-dioxin (TCDD), and polychlorinated biphenyls (PCBs)) for the protection of wildlife (birds and mammals) which feed on aquatic organisms are published in the GLWQI Final Rule (USEPA 1995b). In a few cases, chronic federal AWQC for chemicals that bioaccumulate are based on final residue values and the protection of sensitive mammals (PCBs and mink) or birds (DDT and brown pelican). Where such exposure pathways are appropriate, the GLWQI criteria and federal and state AWQC should be used in screening water concentrations for COPEC selection. A cautious approach should be used in COPEC screening as toxicity can differ among similar receptor species due to differences in either physiology or exposure.

3.3.6.10.2. In terrestrial ecosystems, chemicals may be very limited in distribution, but still present potential for acute toxicity for ecological receptors. For those chemicals that are found at limited locations or in five percent or fewer samples and tend not to bioaccumulate, the median lethal concentration (LC_{50}) values (for plants or soil-dwelling organisms) may be compiled from available ecotoxicological literature and compared to the concentration in soil. The concentration term for each chemical in soil is the lower of (1) the maximum detected concentration or (2) the 95% UCL of the mean.

3.3.6.10.3. Chemicals that have the potential to bioaccumulate or biomagnify through the food web should be retained for consideration as COPECs, even where distribution is limited or they might be eliminated based on the preliminary toxicity screen. Chemicals that bioaccumulate include those that are taken up by an organism either directly from exposure to a contaminated medium or by consumption of food containing the chemicals (Rand and Petrocelli 1985). Chemicals that biomagnify are those that are found in increasingly higher tissues concentrations in higher trophic levels (i.e., concentrations increase across at least two trophic levels) (USEPA 1995b). By definition, chemicals that tend to biomagnify also bioaccumulate. Chemicals with a log K_{ow} of less than 3.0 or an organic carbon partition coefficient (K_{oc}) of less than 500 (i.e., logarithm of the organic carbon partition coefficient (log Koc) less than 2.7) are not expected to bioaccumulate or biomagnify. A lengthy list of bioaccumulative(biomagnify)

and nonbioaccumulative chemicals that are of potential concern is presented in the GLWQI (USEPA 1995b)[9].

3.3.6.10.4. The chlorinated pesticides are the most well known of the chemical groups that tend to bioaccumulate and biomagnify. PCBs and dioxins/furans are also strong bioaccumulators and biomagnifiers. Volatile organic compounds (VOCs) such as tetrachloroethene, toluene, trichloroethene, 1,1,1-trichloroethane, and xylenes are unlikely to bioaccumulate and biomagnify (Van Leeuwen et al. 1992; USEPA 1982). Semivolatiles, including PAHs, tend not to bioaccumulate and show little tendency to biomagnify because they are readily metabolized (Eisler 1987b, Beyer and Stafford 1993).

3.3.6.11. *Presentation of COPECs*. The chemical selection process results in a select list of preliminary COPECs that will be quantitatively assessed in the BERA. Tables should be developed identifying the COPECs selected for each medium and/or exposure area. All chemicals that were removed from consideration should be identified, with an explanation of the reason for the removal. A flow diagram illustrating the COPEC selection process should be included to clearly illustrate the decision process used.

3.3.7. *Level of Effort*. The BERA may include laboratory or field bioassays and/or more detailed, sophisticated computer models or probabilistic methods. Quantitative biological samples, as well as abiotic samples, as needed, may be collected to document exposure, to assess bioaccumulation potential, or to determine dose-response of the tested species or the selected receptors when exposed to site media. Limited field investigations may be conducted to determine presence of specific receptors or to estimate biodiversity. It also may include short-term toxicity tests or bioassays, standard rapid biological field assessment protocols, or focused tissue residue analyses of key receptors or their prey. As needed, semi-quantitative sampling of the contaminated area and a reference site may be conducted to describe the identity and populations of biota in both areas. If limited fate/transport modeling (e.g., one-dimensional analytical model) is used, site-specific input values for key parameters of the model may be needed. This data, when integrated with chemical data, should generally be adequate to provide information on the significance of potential or observed ecological effects, the need for remediation/removal actions, and the development of preliminary cleanup goals based on ecological concerns and remedial action objectives.

[9] The GLWQI table is based on chemicals that bioaccumulate and are of initial concern in the Great Lakes because of their strong tendency to biomagnify. Chemicals listed in this table as "not of concern" are still of considerable concern due to their bioaccumulation potential. Chemicals that bioaccumulate in lower level organisms may still present a significant contaminant pathway and dietary hazard to higher trophic level receptors, even if they don't biomagnify in the latter. For example, copper is bioaccumulated to very high level by oysters, but does not biomagnify through food webs. PAHs are accumulated in invertebrates which lack metabolic pathways for their excretion, yet are not accumulated in most vertebrates which have such enzyme systems.

3.3.7.1. A variety of ecological evaluation tools, techniques, or approaches may be used to evaluate and estimate the magnitude and importance of the potential risk. Such techniques vary in level of effort, sophistication, and cost, but the most sophisticated or time-consuming techniques are not necessarily the most appropriate to a given site. Assessment of chemical effects on key receptors is directly dependent on the use of evaluation techniques appropriate for the assessment and measurement endpoints. Decisions as to which techniques to use should be well documented during problem formulation.

3.3.7.1.1. Each of the evaluation techniques has its own unique advantages and disadvantages in terms of the data and information provided. Some of these tools are useful to measure effects at the individual operable unit and species level; e.g., field sampling of tissue residues. Tools, such as Habitat Evaluation Procedures (USFWS 1987) and Index of Biological Integrity (IBI) (Karr et al. 1986), can be used to quantify adverse effects to biological resources at the community/ecosystem level by measuring reductions in habitat quality. Others such as toxicity tests are used to characterize cumulative hazards from multiple chemicals with no attempt to apportion chemical contribution from the individual COPECs or to discern mechanisms of chemical interactions. Tools such as probabilistic pathways analysis are most appropriate when there is an endangered species at risk from chemicals that bioaccumulate. To measure critical ecosystem functions such as nutrient cycling, tools other than those listed may be needed.

3.3.7.1.2. Each technique has its own peculiarities in terms of the interpretation of results, and many of these tools cannot account for such phenomena as biological resistance and avoidance. Also, some of these tools are restricted as far as their applicability (e.g., Wetland Evaluation Technique (WET) may only be used in wetlands). No single species test, indicator parameter analysis, statistical procedure, or field inspection review can address the complex nature and extent of contamination or risk in biological systems. Impacts at one hierarchal level do not always translate easily into effects at other levels, and emergent system-level properties cannot be studied at lower levels of organization (Kimball and Levin 1985). Chains of influence are common features of ecosystems, and indirect effects, which can be more important than direct effects, often predominate in ecosystems (Kimball and Levin 1985, Johnson et al. 1991). To thoroughly evaluate ecosystem risk, multimedia (i.e., air, water, soil, sediment, and biota) as well as different trophic and hierarchal (organism, community, population, ecosystem) levels may all need to be addressed or measured.

3.3.7.1.3. The following paragraphs are intended to guide the risk assessor in determining, on a site-specific basis, the level-of-effort necessary to address data gaps and complete the BERA with an acceptable level of uncertainty.

3.3.7.2. Examples of some ecological evaluation techniques and tools (and references where descriptions of the approach may be found) include:

a. HQs,

b. Sediment-Water Equilibrium Partitioning (USEPA 2005a, Chapman 1997) or Water Quality Approach (Long and Morgan 1991),

c. Screening Level Concentration Approach (Long and Morgan 1991)

d. Apparent Effects Threshold (AET) or Species Approach (Long and Morgan 1991),

e. Bioeffects/Contaminant Co-Occurrence Analyses Approach (Long and Morgan 1991),

f. Sediment Quality Triad Approach (Chapman 1989, Porebski et al. 1999),

g. Rapid Bioassessment Protocols (Barbour et al. 1999, USEPA 1989g),

h. Sediment Quality Criteria Approach (Chapman 1989),

i. Bioassay Approach (Toxicity Tests) (USEPA 1989b, USEPA 1994f, USEPA 1994g, ASTM 2005),

j. Diversity Indices (Pielou 1975),

k. Species Richness/Relative Abundance Indices,

l. Wetland Evaluation Technique (USACE 1987, Clairain and Smith 1988),

m. Index of Biological Integrity (Karr et al. 1986),

n. Habitat Evaluation Procedures (USFWS 1987),

o. Exposure Pathway Analysis (Fordham and Reagan 1991),

p. Probabilistic/Sensitivity/Uncertainty Analysis (MacIntosh et al. 1994, USEPA 2001b),

q. Linear Structural Modeling (Johnson et al. 1991), and

r. Linked Deterministic and Simulation Models.

3.3.7.2.1. Standardized protocol and detailed descriptions of some of the numerous ecotoxicological investigative methods available are provided in various agency (USEPA, ASTM, the U.S. Food and Drug Administration (FDA), the U.S. Army Edgewood Chemical Biological Center (USAECBC), NOAA, the Water Environment Research Foundation (WERF)) publications.

3.3.7.2.2. *Biological-Based Assessments.* Bioassays or measurements of biological integrity, rather than chemical analyses, may be preferred, or even required under some federal regulations (40 CFR, Part 227.13, *Federal Regulations on Ocean Dumping of Dredged Sediments,* USEPA 1991c, USEPA 1998c) to determine whether a particular

abiotic medium (sediment, soil, surface water) is toxic to biota or contains chemicals at concentrations of ecological concern. Decisions as to which method to use depend on project objectives, data needs, desired certainty level, and the suitability of each method to meet these needs.

3.3.7.2.2.1. In addition to methods described in the field studies and laboratory studies sections below, the following descriptions mention only a few of the numerous field and laboratory methods that may be employed to better characterize risk or provide a basis for remediation decision-making. The need for measuring additional ecotoxicological endpoints should be carefully evaluated. The risk assessor should consider the following specific criteria:

a. The biological response is a well-defined, easily identifiable, and documented response to the designated COPECs (i.e., methodology and measurement endpoint are appropriate to the exposure pathway);

b. Exposure to the COPEC is known to cause the biological response in laboratory experiments or experiments with free-ranging organisms;

c. The methodology is capable of demonstrating a measurable biological response distinguishable from other environmental factors such as weather or physical site disturbance;

d. The biological response can be measured using a published standardized laboratory or field testing methodology; and

e. The biological response measurement is practical to perform and produces scientifically valid results (e.g., sample size is large enough to have useful statistical power and small Type II error).

Significant Ecological Threats:

a. The questions the risk assessor must keep in mind are "Do any ecological threats exist?" and "Are these ecological threats related to chemical contamination?" Using the information discussed above, the risk assessor can begin to identify the habitats potentially affected by contaminants at the site. Decisions can be partly based on absence of biota where expected, especially if plant or animal life is absent along likely contaminant exposure pathways. For example, if areas within the project exposure pathways(s) are devoid of plant life or are obviously stressed, a significant ecological threat probably exists. If there is a groundwater or surface water discharge zone to a stream that is affected by site chemicals and depleted of biota, that would be an obvious significant ecological threat. If effects are less obvious, then it may be necessary to use a more sophisticated approach to determine any impacts, such as a comparison of site biota diversity and relative numbers to an unaffected reference site within or adjacent to the watershed. For specific models and methods that may be employed, publications from USEPA (1989b), Wentzel, et al. (1996), WERF (1994), and NOAA (1992) can be consulted.

b. A relatively new alternative approach to ERA poses the essential question "Are ecological receptors at the contaminated site displaying signs of stress or impact as a result of having been chemically exposed?" With small rodents having been exposed for tens (and in some instances, hundreds) of generations by the time ERA efforts commence (owing to their relatively short life spans, and contaminant-release events having occurred decades ago), every opportunity for toxicological effects to have been elicited in on-site receptors has been afforded. For close to a decade the Army has employed the patent-pending Rodent Sperm Analysis (RSA) method (Tannenbaum et al. 2003; Tannenbaum et al. 2007) at terrestrial sites, noting that small rodents are for all intents and purposes the maximally-exposed receptors (given their miniscule home ranges and their non-migratory nature). The RSA method interprets an exceedance of just one of its sperm parameter thresholds to mean that larger, wider-ranging, and higher-trophic level site mammals (i.e., species for which a site cleanup could realistically proceed) as also being reproductively compromised. Conversely, if maximally-exposed small rodents are not found to be reproductively compromised, there is no reason to suspect that the other mammals are experiencing reproductive stress or impact. One key advantage of the RSA method over desktop approaches to ERA is that the potentially exhaustive suite of site stressors is evaluated for its ability to have compromised reproduction, and thereby overall health.

3.3.7.3. *Short-Term Assessments*. The following biological sampling methods are simple, short-term and reasonably inexpensive. The resultant information can be used to provide further quantification of ecological risk assessment and to improve risk interpretation through additional weight-of-evidence and should reduce the uncertainties of the BERA.

3.3.7.3.1. *Field Studies*.

a. Quantitative (semi-quantitative) descriptive sampling in contaminated and reference areas to confirm the identity and quantity of potentially exposed biota or to measure other ecological attributes such as biological diversity (Noss 1990, Debinski and Brussard 1972). For example, data on vegetation community composition, structure anddiversity can be collected using semi-quantitative methods such as relevé analysis and Braun-Blanquet rating methods (Mueller-Dombois and Ellenberg 1974).

b. Tissue sampling of key receptor species or their dietary or prey items to document exposure. Tissue residue studies are used to provide site-specific estimates of exposure to higher trophic level organisms and to relate tissue residue levels to concentrations in abiotic environmental media. Knowledge of the physiology and biochemistry of the species to be sampled for residue analysis is important. Species vary in their ability to metabolize various contaminants (e.g., fish can metabolize PAHs).

c. Rodent Sperm Analysis (RSA). Adult male rodents of one or more species that occur at both the contaminated site and a nearby, habitat-matched non-contaminated reference location are live-trapped. Sperm parameter (count, motility, morphology) population means are compared, and the absolute differences (i.e., reduction in count,

reduction in motility, increase in morphology) are compared to established thresholds for reproductive effect in site rodents. Corroborative RSA population metrics include total animal captures, number of species, sex ratios, and age distributions. Additional somatic corroborative metrics include organ-to-body weight ratios and tissue histology.

d. One-time collection of exposure point media (e.g., surface water, sediment) for use in short-term (acute) laboratory bioassays.

e. In situ acute bioassays, possibly using exposure point surface water and upstream water for dilution, to determine the LC_{50} contaminant concentration.

f. One-time confirmation surveys of federal or state-protected species to confirm their presence or document their potential presence (or presence of suitable habitat) and potential exposure to suspected COPECs. This is in keeping with the NCP directive to "assess threats to sensitive habitats and critical habitats of species protected under the ESA" (USEPA 1990a)

g. If needed, one-time collection of exposure point abiotic media (e.g., soils, sediment, surface water) for additional chemical analysis to supplement existing chemical data.

h. If needed, one-time collection of physical media from reference areas.

3.3.7.3.2. *Laboratory Studies*.

a. Laboratory analysis of biological samples (e.g., periphyton, benthic invertebrates, plants), as needed for taxonomy.

b. Chemical analysis of collected tissue samples for COPECs that are known or suspected of bioaccumulating or biomagnifying.

c. Acute bioassays using on-site exposure media to determine an LC_{50} or LD_{50}.

d. Additional chemical analysis of exposure point media for specific species of COPECs (e.g., chromium [+6] instead of total chromium) or selected COPECs at detection levels lower than TRVs for the selected ecological receptors.

e. If needed, chemical analysis of physical media collected from reference areas.

3.3.7.4. *Longer-Term Assessments*. There may be a need for longer-term field or laboratory studies (1 year or more), and employment of more extensive (and more expensive) tests to resolve issues presented by larger sites having complex ecosystems and food webs. Depending on site conditions and complexity, these may be the most appropriate type of additional investigation. The biological sampling may involve long-term (chronic) bioassays or tissue analysis of additional organisms or for additional analytes, and/or additional quantitative biological (i.e., population) sampling development. Data from quantitative surveys of populations and comparisons with reference location

population characteristics may also be obtained.[10] Chemical analyses of abiotic exposure media also may be appropriate in order to ensure areal and temporal correlation with biological data. Ecosystem function or other field data may be collected, including nutrient loss (amount of undecomposed litter), biomarkers, histopathological examinations, or mesocosm studies (in-situ biomonitoring). Site-specific input values for key parameters of the model are also needed, if more sophisticated fate and transport modeling is planned. Biological modeling may include single species modeling to evaluate exposure-response when that species is co-located with multiple contaminants, or multiple-species pathway analysis to simulate bioconcentration or bioaccumulation within the community food web.

a. Results of these field and laboratory investigations can fill the data gaps previously identified, and may supplement the results from studies conducted previously. The combined results are used to present risk estimates with less uncertainty, and provide a rationale for multiple year assessments (see Section 3.3.7.5), if needed.

b.. Population studies may be required in the event that there is an apparent decline in a key receptor's population size that is deemed important in the presence of a low HQ, or no apparent effect on population size in the presence of a high HQ. Population studies are typically more long-term and complex, although simple, short-term population studies may be performed. Population studies involve taking a census of the number of individuals in each life stage at several points over the course of one to several life cycles or seasons. These studies can be expanded by including observations of the health or intoxication of individuals at different life stages for each time interval. The temporal aspects of the study design are likely to provide insight into age-related or life-stage-specific sensitivities of the organisms in question.

c. This may also include sampling for model development or pattern description. Data may be collected to support single-species exposure models that employ Monte Carlo analysis techniques or integrated fate, accumulation and effects models, such as the pathways analysis model for estimating water and sediment criteria (Fordham and Reagan 1991). More intensive sampling to describe spatial patterns in biota and the extent of contaminant distribution in relation to these biological patterns may also be conducted.

3.3.7.4.1. *Field Studies*.

a. Quantitative biota (population/community) sampling extending over multiple seasons within one year to document seasonal variability of potentially exposed biota.

b. Quantitative biota sampling in reference areas employing the same methodology

[10] These characteristics include abundance, age structure, reproductive potential and fecundity proportion, productivity, standing crop or standing stock (total biomass), food web or trophic diversity, species diversity and dominance, presence of pollution tolerant/absence of pollution intolerant species, etc.

used at the exposure points to provide sufficient data for statistical comparisons to the data collected at exposure points.

c. Additional tissue sampling of the key receptor species or their diets or prey.

d. Collection of exposure point media (e.g., surface water, sediment) for use in additional acute or chronic (long-term) laboratory bioassays.

e. In-situ acute or chronic bioassays to determine LC_{50}, LOAEL, or NOAEL contaminant concentrations.

f. Additional surveys of federal or state-protected species suspected of being exposed to COPECs.

g. Additional sampling of abiotic exposure point media (e.g., soils, sediment, surface water) to supplement existing chemical data and correlate with the biological samples.

h. Additional collection of abiotic media from reference areas for chemical analyses.

3.3.7.4.2. *Modeling Studies*.

a. Single-species modeling, which is a toxicity model based on a well documented exposure-response relationship between a mixture of chemicals and a single species, can be run using Monte Carlo simulations to produce a cumulative distribution of projected ecological risk and can be run using various exposure scenarios representative of different remediation alternatives.

b. Multiple-species pathways analysis modeling, which simulates contaminant trophic transfer potential through community food webs.

3.3.7.4.3. *Laboratory Studies*.

a. Laboratory analysis of biological community samples (e.g., periphyton, benthic invertebrates, plants), as needed for taxonomy.

b. Chemical analysis of collected tissue samples for COPECs that are known or suspected of bioaccumulating or biomagnifying.

c. Acute or chronic bioassays using on-site exposure media in order to determine LC_{50}s, LOAELs, or NOAELs.

d. Acute or chronic bioassays using doses of COPECs suspected of presenting a risk in order to determine LD_{50}s, LOAEL, or NOAEL doses.

e. Chemical analysis of exposure point abiotic media for the COPECs, specific species of COPECs, or selected COPECs at detection levels lower than TRVs for the selected ecological receptors.

f. Chemical analysis of physical media collected from reference areas.

3.3.7.5. *Multiple Year Assessments*. Some studies are reserved for the largest and

most complex sites requiring multiple year sampling or modeling programs and is only appropriate where data and an BERA with the highest degree of certainty is required for the FS/RD-RA. Complex sites are those with complex chemical interactions among numerous COPECs and exposure matrices, wide-spread contamination or numerous contamination sources, and sites requiring the examination of potential risk reduction over time (e.g., Rocky Mountain Arsenal (USEPA 1993e)). This includes biological studies of long duration and great expense (e.g., multi-year population and community level studies) or complex exposure modeling.

The effort may require additional abiotic sampling and/or tissue residue sampling to establish correlation of cause-effect and or verification of a model.[11] To execute these models, a detailed understanding of the life history and population dynamics of species studied is required. Complex, mathematical ecosystem models, which describe the mechanisms of action to address exposure processes and pathways and toxic effects, are applied. Methods for linking laboratory-derived toxicity data to fish population models may be applied (Barnthouse et al. 1990). Other models, which address ecosystem functions (energy and nutrient cycling), may also be developed.

3.3.7.5.1. *Field Studies*.

a. Quantitative biota (population/community) sampling extending over multiple seasons and years to document long-term variability or trends of potentially exposed biota.

b. Quantitative biota sampling in reference areas during selected seasons to provide sufficient data for statistical comparisons to the data collected at exposure points.

c. Additional surveys of federal or state-protected species suspected of being exposed to COPECs.

d. If needed, collection of exposure point media for additional chemical analysis to support the biological sampling and modeling results.

e. If needed, collection of abiotic media samples from reference areas.

3.3.7.5.2. *Ecosystem Modeling Studies*. Complex, mathematical ecosystem models addressing such attributes as energy flow, material cycling, and food web assembly (Hull and Suter 1993).

3.3.7.5.3. *Laboratory Analysis*.

a. Laboratory analysis of biological samples (e.g., periphyton, benthic invertebrates, plants), as needed for taxonomy.

[11] All these models are likely to require high costs and biological monitoring/field validation efforts involving multi-year and multi-seasonal studies. These population and community models are often data intensive.

b. If needed, chemical analysis of exposure point media for the COPECs or specific species of COPECs.

c. If needed, chemical analysis of reference area physical media for the COPECs.

CHAPTER 4
Analysis Phase

4.1. Introduction. This chapter will address the two parts of the Analysis phase of the ecological risk assessment framework contained in ERAGS (USEPA 1997a). These two parts are characterization of exposure and characterization of ecological effects. Additionally, each part will be further divided to address procedures for screening-level and baseline ERAs.

4.2. Characterization of Exposure – SLERA. The two primary objectives of the characterization of exposure for the SLERA are 1) identification of the ecological receptor group(s) and 2) selection of appropriate exposure pathways and exposure point estimates. Because it is impossible to account for all species in the ecosystems potentially impacted, a few representative receptor groups are typically chosen for evaluation in the SLERA. Ecological receptor groups (feeding guilds) with the highest potential for exposure and/or high sensitivity to the COPECs should be identified. Development of a preliminary ECSM (see Chapter 3) in conjunction with the preliminary ecological site characterization can be used to identify these groups.

4.2.1. Evaluation of potential exposure pathways is one of the primary tasks of the characterization of exposure for the SLERA. Most ecotoxicological information is currently directed toward the quantification of exposure levels for terrestrial flora (uptake) and fauna (ingestion) and for direct contact with water by aquatic organisms. While other routes may be important (e.g., inhalation and dermal absorption by mammals), they are typically not addressed in a SLERA. The SLERA focuses on those pathways with maximum expected exposure potential based on professional judgment.

4.2.1.1. In the absence of sound site-specific information, preliminary exposure estimates are usually based on conservative assumptions such as:

a. Area use factor – 100%;

b. Bioavailability – 100%;

c. Life stage of receptor – most sensitive;

d. Body weight and food ingestion rate – minimum body weight to maximum ingestion rate; and

e. Dietary composition – 100% of diet consists of the most contaminated dietary component.

4.2.1.2. The screening assessment should specify which contaminants are of particular concern from an ecological perspective. This is generally done by comparing the highest detected chemical concentrations to the screening criteria, or by comparing estimated intake to a health-based TRV. If enough data are available, the 95% UCL on the mean may be used (see Chapter 3). The range of chemical concentrations detected,

as well as the number of samples collected, should be reviewed to evaluate which approach is most appropriate.

4.2.1.3. Additional information on exposure assessment for the SLERA can be found in the Army BTAG position paper, *Technical Document for Ecological Risk Assessment: A Guide to Screening Level Ecological Risk Assessment* (USA BTAG 2005a).

4.3. Characterization of Exposure – BERA. This section discusses the development of the characterization of exposure portion of a BERA. The purpose of the characterization of exposure is to estimate the nature, extent, and magnitude of potential exposure of receptors to COPECs that are present at or migrating from a site, considering both current and plausible future use of the site. Several components of the characterization of exposure have previously been evaluated during the SI and SLERA for the purposes of developing the ECSM and focusing investigative activities. These components include identification of COPECs, key receptors and food webs, exposure media, and preliminary exposure pathways and areas (see Chapter 3). These preliminary characterizations were based upon early and often incomplete information that now must be clarified in light of the information obtained during the RI field effort.

4.3.1. *Exposure Setting*. The objective of describing the exposure setting is to identify the site physical features that may influence exposure for both current and future scenarios. Most of this information should have been collected earlier (see Chapter 3), however, the description of the site setting in the characterization of exposure for the BERA should involve obtaining more specific, in-depth information than was obtained previously. While each site will differ in the factors that require consideration, some of the more common factors are listed below and discussed briefly. Examples of how the factors may influence exposure also are provided. The description should be supplemented by data collected during site investigations.

a. Geology. The land type and forms may influence exposure in various ways. For example, the topography of the area can influence the direction and rate of movement of chemicals to offsite areas.

b. Hydrology. The possible connection of surface water bodies with groundwater should be evaluated where there are surface waters or wetlands. The potential presence of groundwater seeps should also be evaluated. The presence and character of surface water bodies or wetlands may affect potential exposures in aquatic ecosystems.

c. Climate. The temperature and precipitation profiles of the area limit the types of receptors present, feeding habits, frequency of exposure (e.g., frozen surface water bodies) as well as influence the extent of chemical migration (e.g., surface water runoff and erosion, infiltration).

d. Meteorology. Wind speed and direction influence the entrainment of soil particles and the extent of transport and dilution of air contaminants.

e. Vegetation. The nature and extent of vegetation influence the fauna that are present and their potential for direct exposure and exposure through the food chain.

f. Soil type. The type of soil (e.g., grain size, organic carbon, clay content) influence soil entrainment, the degree of chemical binding, leaching potential, bioavailability, and the potential for unique vegetation types to be present. Soil characteristics also influence erosion and the resultant vegetative communities.

g. Land Use. The types of receptors likely to have contact with site media and COPECs depends, in part, on current and planned future land use. The appropriate current and reasonable future land uses should be identified.

4.3.2. *Exposure Analysis.* Exposure analysis combines the spatial and temporal distributions of the ecological receptors with those of the COPECs to evaluate exposure. The exposure analyses focus on the chemical amounts that are bioavailable and the means by which the ecological receptors are exposed. The focus of the analyses depends on the ecological receptors being evaluated and the assessment and measurement endpoints. A brief discussion on pertinent factors for generic exposure routes is presented below. When performing the characterization of exposure, these potential exposure routes should each be examined and a decision made regarding the exposure route and pathway completeness. Consideration of exposure routes and pathways for aquatic versus terrestrial receptors requires somewhat different perspectives. Methods for quantifying exposure for these receptors are also quite different. The approaches for assessing exposure in aquatic and terrestrial receptors are thus presented separately in the following text.

4.3.2.1. *Exposure Pathways Identification.* Exposure pathways should be identified for both current land use and reasonable future land use, which may or may not be the same. The following factors should be considered when identifying exposure pathways for current and future scenarios:

a. <u>What is the current and future land use?</u> Land use at and surrounding the site is used to identify the way in which the site is used and the types of exposure pathways that may be present and complete. Besides the current land use, the reasonably expected future land use should also be assessed and pathways of exposure identified.

b. <u>What is the exposure area?</u> If relevant, specific portions of the site or off-site areas that may be contacted by potential receptors should be identified. These may be source areas or secondary and tertiary media impacted by the source areas. The plausibility of the entire site being contacted or posing a potential exposure hazard should be examined. It should be noted that some sites are simply too small to support adequate populations of animals to warrant evaluation of ecological risks. Some states, such as Massachusetts, do not require any evaluation of ecological threats unless the site is at least 2 acres in size.

c. <u>In which media are COPECs presently contained?</u> If COPECs are not present in a medium sampled during the site investigation, and are not anticipated to be in that

medium during the plausible exposure period for current or future receptors, exposure to the medium does not need to be assessed.

d. For what period of time are the COPECs expected to remain in the medium?

By examining the chemical's likely fate, it should be determined whether depletion or reduction of the chemical concentration needs to be considered, and whether the exposure pathway is self-limiting.

e. Into which media are the COPECs anticipated to enter within the exposure period? For example, accumulation of chemicals into animal and plant species over time. Is predictive modeling needed?

f. What types of contact with the impacted media are possible? This determination is based upon uses of the medium and types of contact made with the medium. In general, direct contact (aquatic systems), direct uptake (plants), ingestion (animals), inhalation (animals), and dermal contact (animals) are the possible types of exposure/intake pathways assessed. Inhalation and dermal contact, however, are typically not assessed in terrestrial ERAs as these routes are not well studied for wildlife. Most wildlife also have protective features such as fur or feathers which typically result in dermal contact being a negligible exposure pathway.

4.3.2.2. *Exposure Routes for Aquatic Receptors*. A complete exposure pathway typically consists of four elements -- a source and release of COPECs, a transport medium, an exposure point with receptors, and an exposure (uptake) route. In the aquatic habitat (fresh water, estuarine, or marine), organisms exposed to COPECs are principally the aquatic organisms (e.g., algae, plants, invertebrates, fish, marine mammals) or their terrestrial consumers and predators (e.g., shore birds, waterfowl, piscivores). Exposure of terrestrial receptors is discussed in Paragraph 4.3.2.8.

4.3.2.2.1. The aquatic ECSM serves a very useful purpose -- it enables the risk assessor to visualize where and how COPECs may be moving from the source to the ultimate receptors of concern, through the various release mechanisms, secondary sources, uptake mechanisms, and primary receptors. The aquatic ECSM shows which pathways may be significant and what measurement endpoints should be considered.

4.3.2.2.2. From the primary source of COPECs, chemicals move toward the exposure points via the actions of direct discharge, leaching, infiltration, and erosion. Leaching and infiltration to groundwater is the most common contaminant route to aquatic receptors since many chemical releases are from tanks, pipelines, or other spills to site soils and from there to groundwater. Groundwater itself is only rarely an exposure medium for aquatic receptors, but it may be a primary pathway to surface water, where chemical concentrations are rapidly diluted, and to sediment. Volatilization of organic COPECs and dust generation from the primary source can occasionally be release mechanisms through the air to water and sediment, but the air pathway is rarely quantifiable except in cases of emissions from stacks or cooling towers.

4.3.2.2.3. Once in surface waters, chemicals are affected by a wide variety of physical and chemical processes that can change their chemical configuration, physical location, bioavailability, and toxicity within the aquatic environment. Chemicals can be lost from the water through volatilization. Chemicals in water can move into the bottom or suspended sediments via sorption or complexation with sediments or through precipitation and settling, which can be caused by an increase in the pH of the water. As indicated in the aquatic ECSM, chemicals move between water and sediment, with the sediments often serving as a source of chemicals that have been sequestered from past releases. Sediments are critical factors in aquatic ERAs because many COPECs accumulate to elevated concentrations in sediments, and therefore act as sources of chemicals to the interstitial (i.e., pore) water and overlying surface waters.

4.3.2.2.4. Aquatic receptors are, by definition, in continuous contact with the water. They are also in contact with sediments, either bed sediments covering the bottoms of the lakes, streams, and estuaries or suspended sediments that are in the water column. Aquatic receptors can be exposed to sediments through incidental ingestion while feeding or through contact of sediment with permeable membranes. The extent of exposure to chemicals in sediment varies with several factors, including bioavailability of COPECs, sediment type, sediment and water movements, organism life stage and location in the water column, migratory movements, and feeding strategies.

4.3.2.2.5. Aquatic receptors can also be exposed to COPECs by ingesting prey organisms that have bioaccumulated chemicals, typically organic compounds such as pesticides or PCBs. Evaluation of the potential for risk through exposure of aquatic receptors to COPECs is increasingly complex for the three exposure media -- water, sediment, and prey. Because of this increasing level of complexity in assessing the potential for exposure and risk, water is the exposure medium often evaluated first, by screening against established water quality criteria and standards or laboratory bioassay results. Contaminant concentrations in sediment can be compared to sediment standards, guidelines, or COPEC sediment levels that are back-calculated from water criteria using chemical-specific K_{oc} values in an equilibrium partitioning approach. Finally, potential risk from ingesting contaminated prey can be evaluated by using food ingestion models that consider all three pathways.

4.3.2.3. *Exposure Route Modifying Factors for Aquatic Receptors*. Numerous factors modify the extent of exposure in the aquatic environment. Although factors generally fit into physical, chemical, and biological categories, the factors act in combination with each other to affect the exposure of aquatic receptors to COPECs, bioavailability of the COPECs, and the toxicity of the COPECs.

4.3.2.3.1. *Physical Factors*. Physical factors affect the release mechanisms that move COPECs from the source along a transport medium to the exposure point; physical factors also can influence the movements of receptors and their presence at the exposure point. These physical factors include discharge, leaching, infiltration, erosion, dilution, settling, and resuspension on the physical media.

4.3.2.3.1.1. An example can serve to illustrate the physical factors that influence the presence and concentration of COPECs at the exposure point. COPECs in contaminated soils can move into groundwater through leaching from contaminated soils. Groundwater then moves toward surface waters at a given rate that when multiplied by a COPEC concentration in ground-water, results in a loading rate to the surface water. Groundwater typically moves through the interstices of the sediment where the COPECs can accumulate in the sediment or can be diluted when mixed with the surface water. Grain size and shape of the sediment particles affect the tendency of COPECs to adsorb onto the sediment, thereby reducing their mobility in the aquatic environment. Throughout, chemical factors such as pH, oxidation-reduction potential (Eh), and presence of other chemicals interact with the physical factors described and affect the presence, concentration, and form of the COPECs at the exposure points (sediment and surface water).

4.3.2.3.1.2. Physical factors can also influence the movement and location of aquatic receptors, thus affecting their exposure to COPECs. In an interactive scenario analogous to that described above for physical and chemical factors, physical factors interact with biological factors that also affect exposure of the receptors. Physical factors such as current velocities, water temperature, and water salinity can influence seasonal migratory movements and rates of growth that, in turn, can influence the location of the receptors relative to COPEC concentrations.

4.3.2.4. *Chemical Factors.* Chemical factors can affect the chemical and physical form of the COPEC, the bioavailability, and ultimately, the toxicity to receptors. In fresh water, pH, Eh, hardness, and the presence of dissolved and particulate organics affect the form and availability of many metals. The overall effect of these confounding natural factors on toxicity of metals is reflected in the water effect ratio (WER), which is based on the relative toxicities of a COPEC when tested in a dilution series using laboratory water versus the same COPEC tested using upstream natural water for dilution.

4.3.2.4.1. Some of the same chemical factors influencing exposure of receptors to COPECs in water also affect exposure to COPECs in sediments. Two other chemical factors, total organic carbon, and acid volatile sulfide (AVS) strongly affect exposure of receptors to COPECs in sediments. Increased levels of organic carbon in sediments tends to bind non-polar organics to the sediment. This effect is reflected in the chemical-specific K_{oc}.

4.3.2.4.2. AVS affects the binding of metals to sediments by providing additional binding locations for metals. The metals primarily affected include cadmium, copper, lead, nickel, and zinc. These metals replace iron in iron sulfide complexes. If the concentration of AVS exceeds the combined concentration of these five metals as determined through a procedure referred to as simultaneously extracted metals (SEM)(i.e., SEM/AVS ratio is greater than 1.0), the mobility of the metals is decreased due to the abundance of binding locations. If the AVS level is lower than the SEM level (i.e., SEM/AVS < 1.0), there may be a lack of binding locations, and the five SEM

metals are more available (and potentially toxic) to receptors. The results of the AVS and SEM analyses should be interpreted on a weight-of-evidence basis because of the confounding influence of other chemical and physical factors.

4.3.2.5. *Biological Factors*. Several biological factors affect exposure of aquatic receptors to COPECs in the water and sediment. Similar factors also affect the exposure of prey organisms to COPECs that can bioaccumulate in the prey tissues, thus contributing to the overall exposure of receptors to bioaccumulative COPECs. Some of the more important biological factors affecting exposure to COPECs are life stage, feeding strategy, and migratory movements of the receptors.

4.3.2.5.1. In a typical exposure scenario, COPECs are found in sediments and water but are at higher concentrations in the sediments. Several benthic invertebrate species (e.g., oysters), have larval stages that are planktonic (floating) and adult life stages that are sessile (attached to a substrate). If that substrate or the surrounding sediment has elevated COPEC concentrations, the adult is likely to be exposed to COPECs, whereas the larval stage is less likely to be exposed since it is not directly associated with the sediment.

4.3.2.5.2. Feeding strategy can also directly influence exposure to COPECs. Receptors that feed in or along the sediment are apt to be exposed to COPECs through ingestion of prey organisms that have accumulated COPECs as well as incidental ingestion of sediment. If a receptor feeds higher in the water column, it is likely to be exposed to lower levels of COPECs, as incidental ingestion of sediments would not be a valid pathway. If a receptor is an upper-level predator (e.g., black drum), it is only apt to be exposed to bioaccumulative COPECs through ingestion of prey that have elevated levels of COPECs in their tissues.

4.3.2.5.3. Migratory movements of receptors can directly affect exposure to COPECs. The effect of migratory movements is readily illustrated through a comparison of a fish that follows anadromous migratory patterns (i.e., moves from the ocean through an estuary into fresh water to spawn and then returns to the ocean) to a resident species of the estuary. If the estuary and its sediments have elevated levels of COPECs, the resident species is exposed throughout its life, while the anadromous species is only briefly exposed. In the case of the migratory species, although its year-round exposure cannot be confirmed, it often is assumed that the species is exposed to the COPECs only while it is in the vicinity of the contaminated sediment or other exposure medium.

4.3.2.5.4. The manner in which several of these biological factors may affect the exposure characteristics of receptors to COPECs provides an emphasis for going beyond mere listing of species present, which are formulated during the initial site description and/or reconnaissance. A functional evaluation of how the species present actually use the habitat is necessary. Uses such as spawning grounds, nursery grounds, or adult food foraging should be distinguished so that significant biological factors influencing exposure may be integrated in any evaluation of exposure routes.

4.3.2.6. *Exposure Routes for Terrestrial Receptors.* Similar to the aquatic ECSM, the terrestrial ECSM enables the risk assessor to visualize where and how COPECs may be moving from the source to the ultimate receptors of concern, through the various release mechanisms, secondary sources, uptake mechanisms, and primary receptors. The three principal potential exposure routes for terrestrial (animal) receptors are: dermal absorption, inhalation, and ingestion. Exposure route for plants include both root uptake and foliar absorption.

4.3.2.6.1. *Dermal Contact with Soil, Sediment, Water, and Air.* Dermal contact with soil, sediment, or water is a potentially significant exposure route for soil-dependent terrestrial animals (e.g., invertebrates and microbes) or animals, which spend considerable time submerged in surface water (e.g., muskrat, beaver). Wildlife may receive indirect dermal exposure by brushing against surface-contaminated vegetation. However, dermal absorption is generally an insignificant intake route for terrestrial wildlife, as such, receptors are largely protected by their fur, feathers, or scales. Soils that are covered by pavement are unlikely or impossible to contact, and the assessment should account for this accordingly. Further discussion of the assessment of dermal exposure is presented in Paragraph 4.5.5.3.

4.3.2.6.2. *Inhalation Exposure to Air.* Inhalation exposure by terrestrial receptors could occur to both vapor phase chemicals and particle phase chemicals. Quantitative methodologies for evaluating this exposure route in terrestrial fauna are not well established, but have been developed in order to evaluate wildlife exposure to herbicide sprays (USDOI 1991). Consideration should be given to the chemical form applied, degree of chemical absorption, methods for estimating exposure point concentrations, and toxicity values where there is the potential for this to be a significant pathway. Further discussion of the assessment of inhalation exposure is presented in Section 4.5.5.2.

4.3.2.6.3. *Ingestion of Water.* Ingestion of water by terrestrial wildlife should be examined where there is a significant water source. Analysis of unfiltered surface water samples best represents chemical concentrations to which a terrestrial receptor may be exposed. Potential exposure of biota to chemicals in small, temporal, surface water puddles is typically not evaluated (unless concentrations are extremely toxic) as the exposure is likely to be insignificant compared to exposure from other pathways.

4.3.2.6.4. *Ingestion of Soil or Sediments.* Ingestion of soil or sediment should be considered for all exposure scenarios that provide direct access to soil. Many wildlife species ingest soil while feeding, but ingestion rates are known for only a few species. Soil ingestion rates have been measured for certain livestock in order to estimate pathways for human exposure (USEPA 2005b). Similar estimates of soil ingestion rates for grazing wildlife may also be used.

4.3.2.6.4.1. Except for earthworms and some other soil invertebrates, most terrestrial animals do not "eat" dirt, but ingest only a limited amount of soil incidental to feeding (typically less than 10 percent of food intake). Deliberate ingestion of soil may occur under some circumstances, such as for sodium (salt licks) or calcium content, or

for grit. Soil intake may also be a result of incidental (direct) ingestion from soil adhered to the surface of food/prey items or from grazing, preening/cleaning or burrowing activities. Under certain site conditions, the soil in the gut of earthworms may be an important exposure medium for animals that eat these organisms (Beyer et al. 1993).

4.3.2.6.4.2. The sandpiper group is generally thought to have the highest rate of soil/sediment ingestion (7 to 30 percent) due to their diet of mud-dwelling organisms. Relatively high rates are also reported for wood ducks (11 percent), raccoon (9.4 percent) and woodcock (10.4 percent), which feeds extensively on earthworms, and Canada goose (8.2 percent) (Beyer et al. 1994). Soil ingestion rates for small rodents are reported at less than 2 percent (Beyer et al. 1994).

4.3.2.6.5. *Ingestion from Diet*. Bioaccumulative COPECs tend to increase in concentration within some organisms relative to their concentration in environmental media and dietary sources due to sequestration in certain body tissues. It should be noted that bioaccumulative COPECs can be present at a concentration in environmental media that is protective for direct exposure, but that can pose indirect risk to higher trophic level receptors (TNRCC 2001). Bioaccumulation can occur in an organism any time a chemical is taken up and stored faster than it is eliminated, and it represents the combined accumulation from diet and direct uptake from abiotic media.

4.3.2.6.5.1. Biomagnification is a special case of bioaccumulation whereby the concentration of a chemical increases at each successive level in the food chain. Predator species at the top of the food web are the most vulnerable to chemicals that biomagnify. In general, long-lived and larger species (that accumulate fat) have a greater opportunity to accumulate these compounds as well. Also, higher trophic level species, particularly bird species, may be more sensitive to the COPECs than the animals on which the birds prey. Persistent chemicals (i.e., half-life greater than 30 days), chemicals with a BCF of greater than 1000, or those chemicals with a log K_{ow} value greater than 4.2 tend to bioaccumulate (USEPA 2000a).

4.3.2.6.5.2. The Texas Natural Resources Conservation Commission (TNRCC) has identified COPECs that are able to pose substantial risk due to bioaccumulation, utilizing information from the USEPA, Environment Canada, the United Nations Economic Commission for Europe and the North American Commission for Environmental Cooperation. The table of bioaccumulative COPECs, below, is taken from TNRCC (2001).

CASRN	COPEC	Applicable Media
	Metals	
7440-43-9	Cadmium	Sediment, Soil
7440-47-3	Chromium	Soil
7440-50-8	Copper	Sediment, Soil
7439-92-1	Lead	Soil
7439-97-6	Mercury	Water, Sediment, Soil
744-02-0	Nickel	Sediment, Soil
7782-49-2	Selenium	Water, Sediment, Soil
7440-28-0	Thallium	Water
688-73-3	Tributyltin	Sediment
7440-66-6	Zinc	Sediment, Soil
	Organochlorine Pesticides	
309-00-2	Aldrin	Sediment, Soil
57-74-9	Chlordane	Sediment, Soil
72-54-8	DDD	Water, Sediment, Soil
72-55-9	DDE	Water, Sediment, Soil
50-29-3	DDT	Water, Sediment, Soil
60-57-1	Dieldrin	Sediment, Soil
72-20-8	Endrin	Sediment, Soil
76-44-8	Heptachlor	Sediment, Soil
1024-57-3	Heptachlor epoxide	Sediment, Soil
8001-35-2	Toxaphene	Sediment, Soil
	Other Pesticides and PCBs	
2385-85-5	Mirex	Sediment, Soil
3980-114-4	Photomirex	Sediment, Soil
1336-36-3	PCBs	Water, Sediment, Soil
	Other Semi-Volatiles	
None	Dioxins	Water, Sediment, Soil
None	Furans	Water, Sediment, Soil
118-74-1	Hexachlorobenzene	Water, Sediment, Soil
608-73-1	Hexachlorocyclohexane	Sediment, Soil
29082-74-4	Octachlorostyrene	Water, Sediment, Soil

4.3.2.7. *Plant Uptake*. The soil-plant system is an open system subject to inputs, contaminants and fertilizers, and to losses, through plant consumption, leaching, erosion and volatilization. Factors affecting the contaminant amounts absorbed by a plant are those controlling (Alloway 1990):

a. concentration and speciation of the contaminant in the soil solution;

b. movement of the contaminant from the bulk soil to the root surface;

c. transport of the contaminant from the root surface into the root; and

d. translocation from the root to the shoot.

4.3.2.7.1. Plant uptake is dependent on both the total quantity of the contaminant in soil as well as the root mass present. Terrestrial plant uptake of contaminated water can be a potentially significant pathway if the plant is a wetland species or a phreatophyte (plants that depend on groundwater for their moisture). The uptake route for water is generally insignificant for xerophytic (plants structurally adapted for life and growth with a limited water supply) and mesophytic (plants that grow under medium conditions of moisture) plants which have more shallow root systems and depend on surface water from rainfall.

4.3.2.7.2. In addition to the root absorption, plants can absorb contaminants through their foliage. Foliar absorption of contaminants (in the form of solutes) depends on the plant species, its nutritional status, the thickness of its cuticle, the age of the leaf, the presence of stomata guard cells, the humidity at the leaf surface, and the nature of the solutes (Alloway 1990). The uptake route from air to terrestrial plants can be a potentially significant pathway for vapor phase and particulate phase COPECs. While chemical concentrations found in the air pathway generally pose only a minimal risk to animal species, lichens, in particular, and trees can be especially sensitive to airborne contamination. In ERAs conducted near forested areas, air may be an important environmental transport medium for certain plant groups.

4.3.2.8. *Exposure Route Modifying Factors for Terrestrial Receptors.* Numerous factors influence the spatial distribution and abundance of a population of animals relative to the spatial extent of contamination. Exposure modifying factors such as home range, mobility, and life-cycle attributes (breeding seasons, longevity) should be evaluated in the characterization of exposure. Normalizing factors (e.g., body weight, growth rate) for the various receptors are also to be considered during exposure quantitation.

4.3.2.8.1. *Area Use.* Home ranges and feeding territories should be considered as they may greatly influence potential exposure. The size and spatial attributes of a home range often are determined by foraging activities, but also might depend on the location of specific resources such as dens or nest sites. Home ranges depend on habitat quality (e.g., carrying capacity), with home range sizes generally increasing as habitat quality decreases to a condition beyond which the habitat does not sustain even sparse populations. Home ranges can also vary by sex, season, and life stage. Population density (the number of organisms per unit area) also influences potential exposure.

4.3.2.8.1.1. The mobility of a receptor is usually expressed in terms of the average foraging range of the key receptor (or similar species) under consideration. Mobile receptors typically include the larger vertebrates and grazing species (deer, elk, antelope), predators (fox, coyote), migratory birds (robin) and predatory birds (hawk, eagle, falcon). The foraging areas of these transitory species are likely to be several square miles. Smaller mammals and birds constitute a category of mobile receptors whose foraging areas range from a fraction of an acre to several acres. Plants, soil

organisms, and most flightless invertebrates can be considered to be stationary due to the small area within which they live their lives.

4.3.2.8.1.2. In each case, to quantify chemical intake for the key receptor, an area use factor should be applied to account for the foraging range of the key receptor, as compared to the areal extent of the contaminated area. The area use factor is defined as the ratio of the area of contamination (or the site area under investigation) to the home range of the receptor (or feeding/foraging range).

4.3.2.8.2. *Exposure Frequency.* Exposure frequency is another type of modifying factor that can be used to adjust exposure and chemical intake for a key receptor. Resident species, rather than migratory species, should be evaluated first (when they are present), due to the longer exposure duration potential of the resident species. Migratory species should be evaluated where there is the potential for acute toxic effects from infrequent exposure or where exposure pathways present a greater exposure potential. Magnitude and frequency of exposure should be taken into consideration where the assessment endpoint and toxic effect are based on chronic exposure duration in the test organism.

4.3.2.8.3. *Seasonal Activity Patterns.* Many seasonal or life-cycle attributes affect an animal's activity and foraging patterns in time and space and their exposure potential. For example, many species of mammals, reptiles, and amphibians hibernate or spend a dormant period in a burrow or den during the winter months. Longevity and mortality rates also influence exposure potential and are important in determining potential for chronic exposures.

4.3.2.8.3.1. Seasonal variability may also affect the interpretation of ecological data and should be considered in the design of any sampling plan. Data obtained during any short period could be accurate, but only for that period. For example, pinyon mice apparently suffer substantial winter mortality (Morrison 1988). Trapping only in fall or spring would falsely indicate a relatively high or low population size, respectively. A full year of sampling is generally required to adequately characterize an ecological population.

4.3.2.8.3.2. Some vertebrate population cycles, however, can take much longer; e.g., a 23-fold difference between peaks and low numbers in snowshoe hares was described in one 15-year study (Keith 1983), and it took 12 years for a relationship between conifer seed crop and red squirrel abundance to be repeated (Halvorson 1984).

4.3.2.8.4. *Dietary Composition.* Dietary composition varies seasonally and by age, size, reproductive status, and habitat. Dietary composition is an important consideration for higher trophic level organisms indirectly exposed to chemicals that bioaccumulate or biomagnify.

4.3.2.8.5. *Habitat Preferences*. Many wildlife species have habitat preferences that may increase or decrease their potential exposure to contaminants. Woodcocks, for

example, will remain longer feeding in fields with tall cover than in those with short vegetation (Hull and Suter 1993). Robins, on the other hand, prefer fields or lawns maintained by regular mowing.

4.3.2.8.6. *Foraging Style*. Animals with different foraging styles may also have different morphologies and activity patterns that ultimately influence exposure to contaminants. Piscivorous avian species, for example, can be classified into three general types of foraging styles: raptorial predators (bald eagle), diving and swimming predators (common merganser), and wading predators (great-blue heron).

4.3.3. *Exposure Profiles*. Using information obtained from the exposure analysis, the exposure profile quantifies the magnitude and spatial and temporal patterns of exposure. The exposure profiles developed for the ecological receptors and COPECs serve as input to the risk characterization.

4.3.3.1. *Quantitation of Exposure*. For wildlife, chemical intakes are estimated for exposures occurring from complete exposure pathways for each receptor group. The exposures are quantified with respect to the magnitude, frequency and duration of exposure, to derive an estimate of chemical intake. Chemical intake by wildlife is estimated by combining two general components: the chemical concentration component and the intake/exposure factors component. In the following subsections the estimation of the exposure point concentrations, discussion of the selection of intake and exposure factors, and the specific methods of combining them mathematically are presented.

4.3.3.2. *Determining Exposure Concentrations (Aquatic and Terrestrial Scenarios)*. Exposure concentrations represent the chemical concentrations in environmental media that the receptor will contact. Exposure concentrations may be derived from either data obtained from sampling or from a combination of sample data and fate and transport modeling, both of which are described below.

4.3.3.2.1. For current (and perhaps some future) exposure scenarios where current site data are anticipated to be reasonably reflective of exposure concentrations over the exposure period, the exposure point concentration can be directly derived from site data. For future (and perhaps some current) exposure scenarios, where current site conditions are not anticipated to be reasonably reflective of exposure concentrations over the exposure period, some form of fate and transport modeling or degradation calculations can be applied. However, these too will be based upon current site conditions as a starting point. The available data need to be examined critically to select the most appropriate data in each medium to describe potential exposure. These data sets can vary depending on the receptor-specific exposure factors. For example, soil data for soil-dependent organisms (earthworms) and burrowing mammals would include samples from greater depths (up to 5’ below ground surface) than direct soil exposure for large herbivores (surface soils).

4.3.3.2.2. Since the exposure point concentration used in the assessment is a value that represents the most likely concentration to which receptors may be exposed, a value that reflects the central tendency of the data is appropriate to use. In order to account for uncertainties in the ability of the measured data to reflect actual site conditions, the concentration relating to the 95% UCL of the arithmetic mean is usually used as the exposure point concentration (USEPA 2002a). In cases where the 95% UCL concentration exceeds the maximum detected value (which can occur in small data sets or data sets with a large variance), the maximum value has been historically used[12]. However, the exceedance of the UCL by the maximum value is frequently indicative of an inadequate sampling design or a problem with the calculation of the UCL. The maximum value is not a representative estimate of the mean (it tends to over estimate the mean for large data sets and can under estimate the mean for small data sets). Prior to using the maximum detected value, the nature of the data should be re-examined; additional sampling may be required.

4.3.3.2.3. EPA has worked with its contractor, Lockheed Martin to develop a software package, ProUCL, to perform many of the calculations. The most recent version of this software, the ProUCL Version 4.0 Technical Guide and the ProUCL Version 4.0 User Guide are available at: http://www.epa.gov/esd/tsc/TSC_form.htm. The software uses a number of different statistical methods to calculate a set of UCLs and subsequently recommends the "best" (i.e., most representative) UCL. The guides contain in-depth discussions and recommendations for UCL calculations that are beyond the scope of this guidance. However, several salient issues are discussed.

4.3.3.2.4. Often in data sets, a number of data points for a given chemical in a given medium will be reported as non-detect or "less than values". These results are often referred to as "censored data." The numerical limit to which a non-detect is reported is some times called the "censoring limit." Common errors in reporting and handling these data can occur and include: (1) omission of the censoring limit, (2) failure to define the censoring limit, or (3) use of an inappropriate high or low censoring limit. For example, chemical results are often censored to the method detection limit (as defined in 40 CFR Part 136), a value that is typically too low to minimize false negatives. The appropriateness of the censoring limit should be reviewed by a qualified chemist as the censoring limits are part of the data set that will be used for UCL calculations. The most recent version of ProUCL requires separate entries for the detected results and the censoring limits for the non-detects.

4.3.3.2.5. It should be noted that, historically, some multiple of the censoring limit (usually one half) was substituted for each non-detect. This method is commonly referred to as the "substitution method." However, the substitution method can distort data sets (e.g., producing false positives or false negatives) and is now considered obsolete; as stated in the ProUCL User Guide, "…for data sets with NDs, the DL/2

[12] Reasons for the 95% UCL value exceeding the maximum values are numerous. Such a circumstance may be indicative of incomplete site characterization. This circumstance may also reflect high variance due to biased, purposive sampling rather than random sampling.

[one half the censoring limit] substitution method has been incorporated in ProUCL 4.0 only for historical reasons…It is well known that the DL/2 method…does not perform well…"

4.3.3.2.6. In certain situations, an unusually high or elevated censoring limit may be assigned to a non-detected result because of matrix interferences, high concentrations of target chemicals in the sample (e.g., requiring the samples to be diluted), presence of blank contamination or other factors. These results should be evaluated to determine whether or not they are appropriate for inclusion in the data set for the UCL calculation (e.g., it may be desirable to calculate the UCLs with and without these results to make this determination). However, the most recent version of ProUCL uses methods to treat non-detects that are relatively robust relative to the substitution method (which produces UCLs that are strongly dependent on the censoring limits).

4.3.3.2.7. Sample size influences the magnitude of the statistical confidence of the mean, as demonstrated by high 95% UCL concentrations for small sample sets. The reliability coefficients (the "H" or "t" value used in calculating the UCL concentration, obtained from statistical tables) are a function of the number of samples, and increase with a decreasing number of samples. The overall effect, then, of a small sample size upon statistical confidence is to increase the UCL concentration. In data sets in which minimum requirements have been set prior to sampling, the risk assessor should ensure that an adequate number of samples have been collected to minimize this problem. UCLs should be calculated using at least 10 – 15 samples (though a sample size of at least 20 – 30 would be preferable for the statistical calculations and is recommended). [13]

4.3.3.2.8. Exposure point concentrations are also sometimes derived from a combination of measured data and the application of environmental fate and transport modeling. For the most part, measured data points are preferred over modeled data; where data are modeled, some level of validation and ground-truthing is required (exceptions include ERAs for proposed incinerator emissions/deposition). Common instances in which modeling may be used to predict exposure point concentrations include:

a. When the potential exposure point is at a location other than those for which monitoring data are available (e.g., in off-site areas or locations in-between those which have been described);

b. When the potential exposure is anticipated to occur in the future (e.g., proposed incinerator emissions);

c. When the chemical concentrations are anticipated to change with time;

d. When the potential exposure is in a medium other than those sampled (e.g., exposure to air impacted by contaminated soil, when only soil was analyzed);

[13] Additional references appropriate for evaluation of exposure point concentrations are Shultz and Griffin (1999) and Singh et al (1997).

e. When the potential exposure point concentration is anticipated to increase with time (as with bioaccumulation into animal or plant species); and

f. When the bioavailable portion of the chemical concentrations are anticipated to change with time (e.g., seasonal AVS fluctuations, fluctuations between fresh and saline water either with migration downstream or tidal influence).

4.3.3.2.9. Many fate and transport models are available with which to predict exposure point concentrations from existing site data. These models are presented in other references and on various web sites, including the following:

a. The Adaptive Risk Assessment Modeling System (ARAMS™). ARAMS is not a model *per se*, but is a computer-based, modeling- and database-driven analysis system for estimating human and ecological health impacts and risks associated with military relevant compounds and other potential contaminants of concern. ARAMS is based on a widely accepted risk paradigm that integrates exposure and effects assessments to characterize risk. http://el.erdc.usace.army.mil/arams/

b. *Guidelines for Exposure Assessment* (USEPA 1992l)

c. Exposure Assessment Tools and Models Web Site, www.epa.gov/oppt/exposure/index.htm

d. The Center for Exposure Assessment Modeling Web Site, www.epa.gov/ceampubl/

e. The Center for Subsurface Modeling Support Web Site, www.epa.gov/ada/csmos.html

f. The USACE Groundwater[14] Modeling System Web Site, http://chl.erdc.usace.army.mil/chl.aspx?p=s&a=Articles;585

g. The USACE Surface Water Modeling System Web Site, http://chl.erdc.usace.army.mil/CHL.aspx?p=s&a=Software;4

h. The AFCEE Subsurface Models Web Site, http://www.afcee.brooks.af.mil/products/techtrans/models.asp (This includes a link to a model selection chart, as well as links to specific models).

i. *Superfund Exposure Assessment Manual* (USEPA 1988a),

j. *Air/Superfund National Technical Guidance Study Series* (Volumes I - V) (USEPA 1989e,f; 1992f, 1993c; 1995e),

k. *A Workbook of Screening Techniques for Assessing Impacts of Toxic Air Pollutants* (USEPA 1988b),

[14] Although groundwater modeling is typically not required for ecological receptors, there are times when groundwater discharges to the surface and modeling may be required or deemed beneficial.

l. *Selection Criteria for Mathematical Models Used in Exposure Assessments: Groundwater Models* (USEPA 1988c),

m. *Selection Criteria for Mathematical Models Used in Exposure Assessments: Surface Water Models* (USEPA 1987),

n. *Rapid Assessment of Exposure to Particulate Emissions from Surface Contamination Sites* (USEPA 1985),

o. Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions (USEPA 1998b), and

p. *Assessment and Control of Bioconcentratable Contaminants in Surface Water* (USEPA 1991b).

4.3.3.2.10. The type of model and level of effort to be expended in estimating exposure point concentrations with models should be commensurate with the type, amount, and quality of data available. In general, it is best to begin with a model that employs simplified assumptions (i.e., a "screening level" approach) and determine whether unacceptable ecological risks are posed by the exposure point concentration estimated by this approach. If so, a more complex model that applies less conservative assumptions can be used.

The validity of the estimation provided by the model will strongly depend on the variables that are input to the models. Efforts should be taken to ensure the use of input variables that best reflect site conditions and that are not overly conservative.

4.3.3.2.11. Initial abiotic sampling designs are often not established with sampling for the selected key ecological receptors in mind. Often, biased sampling designs are selected in order to best characterize potential hot-spot conditions and the nature and extent of contamination. Calculation of a 95% UCL or averaging of these point concentrations tends to result in an overestimation of the exposure concentration (and risk) for larger mobile animals (deer, antelope) that do not forage onsite or at any particular spot for extended periods of time. Where the receptor's home range is greater than the contaminated area, area use and exposure frequency factors can be used to modify the area-wide intake concentration. Where the receptor's home range lies within the contaminated area, alternate methods of removing the bias from the area-wide exposure concentration (e.g., weighted average, Theissen polygons) data set can be used, but may result in an over or underestimate of exposure.

4.3.3.2.12. Probabilistic methods can also be used for developing more appropriate exposure concentrations, where factors such as area use need to be considered (USEPA 1997b). For mobile receptors such as fish, large herbivores, and predators, determination of dietary exposure concentrations should be "area" (i.e., feeding range) based rather than "point" (i.e., fixed location) based. Using probabilistic uncertainty analyses methods to create models that simulate random walks, probable exposure conditions for mobile receptors can be estimated under different time scenarios (daily,

weekly, monthly, yearly). Two such models, developed for USACHPPM, are Terrestrial Wildlife Exposure Model (TWEM) and Spatially Explicit Exposure Module (SEEM), discussed below.

4.3.3.2.13. TWEM is a software tool that allows scientists to estimate exposure of terrestrial wildlife receptors to organic and inorganic chemicals in soil, water, and biota. These exposure estimates may then be used in screening-level ecological risk evaluations. SEEM is a tool by which to complete a wildlife exposure assessment guided by wildlife habitat preferences and foraging behaviors. SEEM incorporates habitat suitability indices and two foraging strategies to capture exposures that are more realistic than assuming uniform exposure across a heterogeneous site (i.e. site-wide averages). The modeling approach and level of complexity are user defined. As a result, SEEM can be employed to assess a variety of wildlife exposure problems. These models can be downloaded from the USACHPPM web site at: http://chppm-www.apgea.army.mil/tox/HERP.aspx

4.3.3.3. *Calculating Intake for Terrestrial Wildlife*. The following discussion of terrestrial wildlife intake focuses on the oral ingestion route only. Oral intake (ingestion) of three environmental media (food, water, soils/sediment) are the principal routes evaluated in a terrestrial ERA, as they typically represent the most significant exposure pathways. Quantitative data and methodologies by which to calculate inhalation and dermal contact rates for various terrestrial wildlife are generally lacking; limited guidance on these intake routes are provided by USEPA (1998b, 1993d), and USDOI (1991). For each receptor, the following four exposure factors are considered in the calculation:

a. Food Intake (FI) - These rates can vary by age, size and sex and by seasonal changes (ambient temperature, activity levels, reproductive activities, and the type of diet consumed). Food ingestion rates are available in the published literature for a limited number of wildlife species. Methods for estimating food ingestion rates are provided below. Food ingestion rates are typically expressed on a wet-weight basis. Where results from wildlife laboratory studies are expressed on a dry weight basis, this difference may be ignored as the moisture content of most laboratory studies is typically less than 10 percent water (Beyer and Stafford 1993).

b. Dietary composition (DC) - Dietary composition varies seasonally and by age, size, reproductive status, and habitat. Dietary composition is typically expressed as percentage of total intake on a wet-weight basis.

c. Water Intake (WI) - Water consumption rates depend on body weight, physiological adaptations, diet, temperature, and activity levels. Some species (e.g., deer mouse) can meet most of their daily water requirement with only the water contained in their diet. Water ingestion rates can be estimated using allometric equations below.

d. Soil/Sediment Intake - Soil or sediment intake is usually expressed as a percent of dietary intake. Data quantifying soil/sediment intake are limited; values for selected

wildlife species are presented in the *Wildlife Exposure Factors Handbook* (USEPA 1993d). As noted earlier, soil/sediment intake rates of up to 30 percent of diet are reported for some wildlife.

4.3.3.3.1. *Intake Equations*. Exposure or chemical intake by terrestrial wildlife is reported as "average daily dose" on a body weight basis, i.e., milligrams chemical per kilogram body weight per day (mg/kg-bw/d). It is fundamental that exposure, chemical intake, and toxicity benchmark determinations be adjusted to account for body weight and dietary intake of the organism, to account for the differences in food intake relative to body weight of the various organisms being compared. Exposure evaluations (and toxicity benchmark selection) based on a comparison of dietary chemical concentrations (i.e., milligrams chemical per kilogram food, mg/kg) amongst wildlife receptors (e.g., deer and rabbits) are sometimes mistakenly attempted in an ERA as a means to "simplify" the quantitation process.

4.3.3.3.1.1. The following equations for chemical intake were taken from the *Wildlife Exposure Factors Handbook* (USEPA 1993d). Additional equations for pathways (e.g., inhalation) and receptors (e.g., amphibians) not addressed here can also be obtained there.

$$\text{Daily Intake (mg/kg-bw/d)} = \frac{[(C \times FI) + (C \times WI)] \times EMF}{BW}$$

where:

C = Chemical concentration in food or water (i.e., mg/kg, mg/L, ppm)
FI = Food Intake rate (kg-food/day)
WI = Water Intake rate (L-water/day)
BW = Body weight of receptor (kg)
EMF= Exposure modifying factors (default value is 1.0) (unitless)

Birds For birds, Nagy (1987) developed the following equations for calculating food ingestion (FI) rates (in grams dry matter per day):

$FI\ (g/day) = 0.648\ Wt^{0.651}$ (g), or	all birds
$FI\ (kg/day) = 0.0582\ Wt^{0.651}$ (kg)	all birds
$FI\ (g/day) = 0.398\ Wt^{0.850}$ (g)	passerines
$FI\ (g/day) = 0.301\ Wt^{0.751}$ (g)	non-passerines
$FI\ (g/day) = 0.495\ Wt^{0.704}$ (g)	seabirds

where Wt is the body weight (wet) of the animal in grams (g) or kilograms (kg) as indicated.

Mammals For placental mammals, Nagy (1987) developed the following equations for calculating FI rates (in grams dry matter per day):

FI (g/day) = 0.235 $Wt^{0.822}$ (g), or — all mammals
FI (g/day) = 0.0687 $Wt^{0.822}$ (kg) — all mammals
FI (g/day) = 0.621 $Wt^{0.564}$ (g) — rodents
FI (g/day) = 0.577 $Wt^{0.727}$ (g) — herbivores

EPA (1988d) also provides the following equations for this calculation:
FI (kg/day) = 0.056 $(Wt)^{0.6611}$ (kg) — laboratory mammals
FI (kg/day) = 0.054 $(Wt)^{0.9451}$ (kg) — moist diet
FI (kg/day) = 0.049 $(Wt)^{0.6087}$ (kg) — dry diet

WATER INTAKE RATES

Birds Calder and Braun (1983) developed the following allometric equation for drinking water ingestion (WI) for birds:
WI (L/day) = 0.059 $Wt^{0.67}$ (kg) — all birds

To estimate daily drinking water intake as a proportion of an animal's body weight (e.g., as g/g-day), the WI rate estimated above is divided by the animal's body weight in kg:
WI (g/g-day) = WI (kg/kg-day), or
= WI (L/day)/Wt (kg)

Mammals Calder and Braun (1983) developed the following allometric equation for drinking water ingestion (WI) for mammals:
WI (L/day) = 0.099 $Wt^{0.90}$ (kg) — all mammals

where Wt is the average body weight in kilograms (kg). Additional sources of water not accounted for in this equation (i.e., metabolic water and water contained in food) help to balance the animal's daily water losses.

EPA (1988d) also provides the following equations for this calculation:

WI (L/day) = 0.10 $(Wt)^{0.7377}$ (kg) — laboratory mammals
WI (L/day) = 0.009 $(Wt)^{1.2044}$ (kg) — mammals, moist diet
WI (L/day) = 0.093 $(Wt)^{0.7584}$ (kg) — mammals, dry diet

To normalize drinking water intake to body weight (e.g., as g/g-day), the WI rate estimated above is divided by the animal's body weight in kg:
NWI (g/g-day) = WI (kg/kg-day), or
= WI (L/day)/Wt (kg)

4.3.3.3.1.2. Selection of appropriate intake and exposure modifying factors is a critical component of the assessment, for these values largely determine the overall risk estimates. The Wildlife Exposure Factors Handbook (USEPA 1993d) presents exposure profiles for selected species of birds, mammals, and reptiles and amphibians. Each species profile provides a series of tables presenting values for normalizing (body

weight) and contact (intake) rate factors, exposure modifying factors (home range), dietary composition, population dynamics, and seasonal activity patterns. Additional information on wildlife exposure factors can be found in the published literature including ORNL's (1998) screening benchmark reports, the USACHPPM life history database (USACHPPM 2004) and food requirements of wild animals: predictive equations for free-living mammals, reptiles, and birds (Nagy 2001). In an ERA, all exposure and intake factors applied to the assessment should be identified in tabular form, with the source of the value identified and a rationale for the use of the value presented.

4.3.3.3.1.3. If C and FI vary over time, they may be averaged over the exposure duration. However, it is not always appropriate to average intake over the entire exposure duration: For example, a given quantity of a chemical might acutely poison an animal if ingested in a single event, but if that amount is averaged over a longer period, effects might not be expected at all. Similarly, developmental effects occur only during specific period of gestation or development. C, FI, and BW should be selected so as to be comparable to the specific TRV that is used.

4.3.3.3.1.4. Wildlife can be exposed to contaminants in one or more components of their diet and different components can be contaminated at different levels. For example, the diet of the deer mouse, an omnivorous key receptor commonly assessed in ERAs, primarily consists of invertebrates and terrestrial plants. The daily intake for the deer mouse is thus expressed as [(chemical concentration in invertebrates x % ingested) + (chemical concentrations in terrestrial plants x % ingested) x daily food intake] / deer mouse body weight.

4.3.3.3.1.5. In order to describe a range of potential exposures presented by a site, the ERA may assess more than one potential exposure scenario. Use of a single expression of potential ecological risk does not provide information on the possible range of ecological risks, and may not allow the risk manager to evaluate the "reasonableness" of the estimate. Current risk assessment guidance for human health suggests the strategy for determining the exposure point concentration for soils should depend on spatial contaminant distribution. If a contaminant is widely distributed throughout the site, the exposure point concentration should be based on the 95% UCL of the arithmetic average for all site samples, including non-detects. However, if the contamination is unevenly distributed, i.e., "hotspot" areas exist, these areas should be evaluated by determining exposure concentrations in these areas. A percentage of time that the receptor spends on the site in these "hotspot" areas should be factored into the intake equation. Presentation of these and other scenarios (e.g., central tendency) provide information about the range of potential risks to the ecological receptors.

4.3.3.3.2. *Intake Variables.* To develop a "high end" assessment, USEPA recommends identifying the most sensitive parameters and using maximum or near maximum values for one or a few of these variables, leaving other variables at their mean values. Adopting maximum values for all intake and exposure parameters will

virtually always result in a risk estimate that is above that experienced by the most exposed receptor and is, therefore, inappropriate. According to USEPA (1992e) human health guidance, the chemical concentration relating to the 95% upper confidence limit of the mean is applied as the exposure point concentration term for both the average and the reasonable maximum exposure (RME) scenarios. Although an upper bound value, this concentration is descriptive of the mean, and accounts for the uncertainty associated with measurements of the "true" mean.

4.3.3.3.2.1. The average or central tendency exposure (CTE) is derived by applying average values for all intake and exposure (e.g., area use) parameters. Although description of an average exposure is not particularly useful when exposure varies greatly across all potentially exposed populations, it can provide information on the extent of impact of the exposure parameters that were maximized in the high end exposure. Use of a median value for exposure parameters, such as a geometric mean rather than arithmetic mean, is more meaningful since it represents a midpoint value (i.e., half the population above and half below).

4.3.3.3.2.2. Contaminants may enter terrestrial food chains directly from soil/sediment, water, or air or indirectly through the consumption of plants (producers) or animal prey (consumers). The following sections discuss means for determining chemical concentrations in plants and prey.

4.3.3.3.3. *Estimating Chemical Concentrations in Plants.* The three principal mechanisms by which contaminants can bioaccumulate in plants include: uptake by roots, direct deposition on exposed plant tissues, and air-to-plant transfer of vapor-phase contaminants. The relative importance of each pathway to the wildlife consumer depends on the specific plant, the contaminant, site-specific physicochemical conditions, and the preference of the wildlife receptor for the particular plant.

4.3.3.3.3.1. The plant-soil bioaccumulation factor (BAF_{plant}) or transfer coefficient is a measure of a contaminant's ability to accumulate in plant tissue and is defined as the chemical concentration in the plant (dry weight) divided by the chemical concentration in soil (dry weight). Bioaccumulation factors may be derived differently for inorganic and organic chemicals, but they are generally dependent on the bioavailability of the chemical in the soil or soil solution. Information and data on chemical transfer from soils, particularly sludge-amended soils, to a variety of crop species are available in the published literature (USEPA 1983, USDA 1983, USDOE 1984).

4.3.3.3.3.2. A number of models are also available for determining plant uptake of contaminants from soil (Kabata-Pendias and Pendias 1984, Briggs et al. 1982, Topp et al. 1986, and attachment 4-1 to the Eco-SSLs at: http://www.epa.gov/ecotox/ecossl/SOPs.htm). Root uptake of numerous contaminants, however, is inefficient and much of the contaminant concentrations found in plants results from volatilization and leaf uptake (Suter 1993). Some methods for calculating chemical concentrations in plant tissue due to root uptake and air to plant transfer are published by USEPA (1998b). Other methods are available in the published literature. Quantitative structure activity relationship (QSAR) models for determining combined

root and leaf uptake of organic chemicals in soils are presented by Topp et al. (1986) and Travis and Arms (1988).

4.3.3.3.4. *Estimating Chemical Concentrations in Animal Prey*. The animal prey that higher trophic level predators usually consume as food, take up contaminants from the food chain by ingesting soil-dependent organisms (plants, soil invertebrates), lower trophic level consumers, or soil and water directly. Methods for determining BAFs or biotransfer factors to livestock tissue are available for a variety of chemicals in plants such as grain (corn, oats, wheat, etc.), forage (pasture grass, hay) and silage (USEPA 1998b). Similar methods for wildlife tissue are generally not available and thus the livestock factors are sometimes used.

4.3.3.3.4.1. Models for determining the uptake and transfer of chemicals through various food chains are becoming more numerous in the literature (Winter and Streit 1992, Fordham and Reagan 1991). BAFs can oftentimes be estimated for a receptor of interest based on food chain data presented in the published literature or in studies conducted at Superfund sites where tissue sampling was performed.

4.3.3.3.4.2. Studies on the accumulation of elements by earthworms, as well as direct toxic threshold levels, are becoming more abundant due to the close association between soil contamination and earthworms and the wide variety of earthworm predators (Beyer 1990, Beyer and Stafford 1993). Several authors have published models for determining the uptake of organic chemicals by earthworms (Wheatly and Hardman 1968, Van Gestel and Ma 1988, Connell 1989).

4.3.3.3.5. *Bioavailability.* The intake equations used in ERAs typically do not contain a factor to account for bioavailability or bioassimilation and therefore may predict an intake higher than one that would occur in actual circumstances. By not including a factor to consider bioavailability, it is assumed that 100% of the chemical detected in the medium is bioavailable (when combined with toxicity values, the risk associated with the absorption of the chemical in the animal study is derived). Modifications may sometimes be made to these intake equations to account for this factor, if the appropriate information is available.

4.3.3.3.5.1. Bioavailability refers to the ability of a chemical to be "available" in the body to interact and have an effect. There are many aspects to bioavailability; however, the type most of concern to ERAs is the ability of the chemical to be absorbed into the body. Although the medium on which the chemical is contained may be contacted, the chemical may not be absorbed for a number of reasons, including the chemical form, competition with other factors (e.g., food in the stomach), damage of the organ (e.g., stomach, lung), effect of the medium in which the chemical is contained, and others. While many of these cannot be reliably addressed in an ERA, chemical form and effect of the medium can be addressed.

4.3.3.3.5.2. The form of the chemical can affect the degree of absorption into a body. This factor is most important for chemicals that form compounds (such as metals and cyanide) and chemicals that can exist in different valence states (again, some

metals). For example, soluble compounds of metals (e.g., barium sulfate) are readily absorbed through the stomach whereas insoluble forms (e.g., barium carbonate) are minimally absorbed. Usually, when environmental media are analyzed, chemicals are reported as an isolated entity (e.g., barium), and no information is provided on the form that existed in the medium. However, if the form of the chemical used at the site is known, and information on the absorption of that chemical form is available, the intake equation can be modified to account for a lesser absorption. Defensible information should be available to make this modification.

4.3.3.3.5.3. The medium in which the chemical is contained also can affect the degree of bioavailability. This is most pronounced in media that demonstrate an ability to bind chemicals (such as soil and sediments). When ingested by wildlife, a competition occurs between retention of the chemical on the medium and absorption of the chemical into the body. Therefore, some of the chemical may be excreted from the body without having been absorbed and some may have been absorbed and available to exert an effect. Many factors can influence the degree to which the medium will bind the chemical, most of which cannot be reliably predicted (for example, nature of the medium [organic carbon or clay content, particle size], other chemicals being absorbed, pH, organ condition, etc.). In some instances, information may be available on the degree to which a particular medium affects specific absorption routes. If the information justifies modifying the intake equations, such a modification may be made (Drexler et al 2003, Henningsen 2003, NAVFAC 2000, Ruby 2003).

4.3.3.3.5.4. In most assessments, it is generally assumed that environmental conditions are reasonably static and chemical concentrations remain constant over time, often for as long as 30 years. Such assumptions may be unreasonable. Chemical concentrations are usually reduced over time by degradation, migration, dilution, volatilization, or other removal processes. If these processes are known and can be quantified, a concentration that decreases over time can be derived for assessing intakes. If no allowances are made to decrease concentrations over time, risks will most likely be overestimated.

4.3.3.4. *Exposure Characterization Summary*. At the conclusion of the characterization of exposure, the estimated chemical intakes for each exposed receptor group under each exposure pathway and scenario should be presented in tabular form. This presentation should include an identification of all pertinent factors (basis of exposure point concentration, use of models, if applicable, assumptions made regarding exposures, etc.). These intake estimates are combined with the COPEC toxicity values, discussed in the following section, to derive estimates and characterize potential ecological risk.

4.3.3.4.1. Uncertainties associated with the estimation of chemical intake should be summarized at the conclusion of the characterization of exposure. The basis for each uncertainty should be identified (e.g., use of a default parameter, propagation of error through multiple layers of exposure modeling), the degree of the uncertainty qualitatively (low, medium or high) or quantitatively estimated, and the impact of the uncertainty qualitatively (overestimate and/or underestimate) or quantitatively stated.

Description and presentation of uncertainties are discussed further in Chapter 5 (Risk Characterization) and Chapter 6 (Uncertainty in ERAs).

4.4. Ecological Effects Characterization – SLERA. Screening level risk assessments may be largely qualitative, using simple comparisons of abiotic media concentrations to readily available screening "effects" criteria for these media, or they may employ a more quantitative investigative approach that incorporates a threshold level or dose-response assessment. In the more quantitative approach, screening level ecotoxicity values (reference diet, dose, tissue, threshold levels) are developed for the principal receptors of concern based on the complete exposure routes. For these complete exposure routes, the lowest exposure level (e.g., concentration in abiotic media, or in diet [ingested dose]) shown to produce no adverse effects (e.g., reduced growth, impaired reproduction, increased mortality) in the receptor of concern is identified. Where NOAELs are not available, the LOAELs or other available toxicity values should be used and this procedure should be discussed in the uncertainty discussion. The mode of toxicity represented by the screening criterion should match the mechanism of toxicity for the contaminant in question. For example, dioxins do not exhibit acute lethality as much as they inhibit successful reproduction. Therefore the criterion for dioxins should be a reproductive measure.

4.4.1. *Published Literature, Available Criteria and Information.* Sources for obtaining ecotoxicity benchmarks in a screening assessment are generally limited to published literature and readily available criteria and information such as the following. It should be noted that selection of appropriate benchmarks should be done during the TPP session prior to field work. This upfront agreement insures that problems are not encountered during review of the ERA.

a. Federal AWQC. EPA's compilation of national recommended water quality criteria is presented as a summary table containing recommended water quality criteria for the protection of aquatic life and human health in surface water for approximately 150 pollutants. These criteria are published pursuant to Section 304(a) of the CWA and provide guidance for states and tribes to use in adopting water quality standards.

b. State AWQC.

c. USEPA (USEPA 1996, NOAA (Long and Morgan 1991, Long et al. 1995), and Ontario (Persaud, et al. 1992) sediment criteria,

d. SQuiRTs. NOAA has developed a set of Screening Quick Reference Tables, or SQuiRTs, that present screening concentrations for inorganic and organic contaminants in various environmental media. The SQuiRTs also include guidelines for preserving samples and analytical technique options. The SQuiRTs were designed as a set of double-sided, color cards, organized into the following sections: Inorganics in Solids (freshwater and marine sediment, plus soil); Inorganics in Water (groundwater and surface water); Organics in Water and Solids; Analytical Methods for Inorganics; Analytical Methods for Organics; and Guidelines for Sample Collection & Storage.

e. USEPA EcoSSLs. EPA's Superfund program has issued ecological soil screening levels (Eco-SSLs) for twelve metals (aluminum, antimony, arsenic, barium, beryllium, cadmium, chromium, cobalt, copper, iron, lead, manganese, nickel, silver and vanadium), DDT, pentachlorophenol, and total PAHs, frequently found in soil at Superfund sites. Eco-SSLs for additional contaminants, including values for selenium, zinc, and dieldrin, are pending as of this writing.

f. USEPA ECOTOX Database. The ECOTOX database provides single chemical toxicity information for aquatic and terrestrial life. ECOTOX is a useful tool for examining impacts of chemicals on the environment. Peer-reviewed literature is the primary source of information encoded in the database. Pertinent information on the species, chemical, test methods, and results presented by the author(s) are abstracted and entered into the database. Another source of test results is independently compiled data files provided by various United States and International government agencies.

g. ORNL ecological benchmarks. Screening ecological benchmarks are used to identify chemical concentrations in environmental media that are at or below thresholds for effects to ecological receptors. The Environmental Sciences Division of ORNL developed and compiled a comprehensive set of ecotoxicological screening benchmarks for surface water, sediment, and surface soil applicable to a range of aquatic organisms, soil invertebrates, and terrestrial plants. Links to supporting technical reports from which the benchmarks were obtained are also provided.

h. USACHPPM Wildlife Toxicity Assessments (WTAs) The WTAs address a primary wildlife and habitat risk evaluation component--subsequent and related toxicity associated with exposures to a specific chemical--through rigorous investigation and evaluation of toxicity data, and logical derivation of terrestrial wildlife Toxicity Reference Values.

i. USACHPPM Terrestrial Toxicity Database (TTD) An assemblage of chemical-specific soil screening levels (SSLs) and TRVs that assist in plant, invertebrate and wildlife risk identification.

4.5. Characterization of Ecological Effects – BERA. The ecological effects characterization (toxicity assessment) includes a summary of the types of adverse effects on biota associated with exposure to site-related chemicals, relationships between magnitude of exposures and adverse effects, and related uncertainties for chemical toxicity, particularly with respect to site biota. Ecological receptor health effects are characterized using critical toxicity values, when available, in addition to selected literature pertaining to site- and receptor-specific parameters.

4.5.1. *Preliminary Toxicity Evaluation*. The preliminary toxicity evaluation provides toxicological profiles centered on health effects information on site biota. The profiles cover the major health effects information available for each COPEC. Data pertaining to site-specific species are emphasized, and information on domestic or laboratory

animals are used when site-specific biota data are unavailable. Adequacy of the existing database should also be evaluated as part of this task.

4.5.2. *Bioassessment Tools and Techniques*. Typically, the ecological effects characterization is based on a desk-top HQ approach. Numerous bioassessment tools,[15] however, are available to the risk assessor to employ for directly measuring or investigating toxicity, or even risk. Bioassessment techniques offer several advantages over the HQ or model approaches to toxicity estimation including:

a. Demonstrate whether the COPECs are bioavailable,

b. Evaluate cumulative impacts due to exposure to multiple COPECs,

c. Evaluate toxicity of COPECs for which no TRVs can be found,

d. Characterize the nature of the toxicity,

e. Integrate media variations and spatially characterize toxicity,

f. Monitor impacts before and after remediation,

g. Develop remedial levels in terms of toxicity and then monitor effectiveness and success of remedial actions.

4.5.3. *Objectives.* The characterization of effects in the BERA fulfills two specific objectives. First, available toxicological literature is reviewed to identify appropriate literature benchmark values to use, forming the basis for developing summaries of the potential toxicity of the COPECs for inclusion in the risk assessment. Second, appropriate TRVs are developed using literature benchmark values to estimate potential ecological risks associated with key receptor chemical exposure. This is accomplished by reviewing the available information on COPEC toxicity and summarizing the factors pertinent to the exposures being assessed. At this time, it is only rarely necessary to search the literature for toxicity information. The toxicity of most contaminants has been evaluated and TRVs have been calculated for use in ERAs. The information that follows is intended to assist when it is necessary to make the calculations. Reference USACHPPM (2000) for recommended procedures.

4.5.4. *Sources of Literature Benchmark Values.* The sources that should be consulted for literature benchmark values will vary with the type of organisms being used as ecological receptors (e.g., aquatic, terrestrial) and the level of effort. If the level of effort (time and money) is limited, then documents that summarize available ecotoxicological information will suffice. If a higher level of certainty in the data is an objective in the compilation of literature benchmark values, then the primary toxicological literature should be sought so that details of the toxicity test conditions can be reviewed, validity of the test results confirmed, and applicability to site conditions determined.

[15] An in-depth discussion of topics related to the use of bioassessment approaches in ERAs is available in the September 1994, Volume 2 series of *Eco Updates* (USEPA 1994f, 1994g, 1994h, 1994i)

4.5.4.1. Toxicologic information on chemicals in aquatic ecosystems is fairly plentiful, while that for terrestrial ecosystems is somewhat more limited. Most of the available toxicological information for soil-based exposures has been generated using soil-dependent biota. ORNL (1998), however, has published benchmark values for plants, sediment associated biota, and terrestrial wildlife. Compilations of toxicological data for soil-dependent organisms (plants, invertebrates, and microbes) are available in the open literature (Hulzebros et al. 1993, Kabata-Pendias and Pendias 1984, USFWS 1990, Overcash and Pal 1979, Gough et al. 1979, Callahan et al. 1994).

4.5.4.2. Toxicity data and information for developing wildlife TRVs also may be obtained from many of the same sources used for human health toxicity information, particularly where data on small mammals (rats and mice) are needed. Regional USEPA BTAGs (for NPL sites) and the Tri-Service Environmental Risk Assessment Working Group (TSERAWG) persons can also be contacted for assistance. Other sources for aquatic and terrestrial laboratory data are presented below:

a. USEPA Criteria Documents. Includes ambient water criteria documents, proposed sediment quality criteria documents, drinking water criteria documents, air qual effects assessment documents.

b. USFWS Contaminant Hazard Reviews. (Eisler 1985-1999). This is a series of reports reviewing the hazards of over 25 metals and organic compounds to fish, wildlife, and invertebrates. All are available in portable document format (PDF) files on-line.

c. Oak Ridge National Laboratory (ORNL 1998). Toxicological screening benchmarks for ERAs. This series of reports includes benchmarks for terrestrial wildlife, terrestrial plants, sediment-associated biota, and aquatic biota, and soil and litter invertebrates and heterotrophic processes.

d. Toxicological Profiles developed by the Agency for Toxic Substances and Disease Registry (ATSDR).

e. Aquatic and terrestrial toxicological data (and in some cases, literature citations). Available in public or on-line databases such as TOXNET (contains ChemIDplus, HSDB, Toxline, CCRIS, DART, GENETOX, IRIS, ITER, Multi-Database, Tri, Haz-Map, TOXMAP), BIOSIS, ECOTOX (contains AQUIRE, TERRETOX and PHYTOTOX), ASTER, Toxicity/Residue Database, Ecological Abstracts, Biological Abstracts, Current Contents, Duck data (USFWS). ity criteria documents, and health

f. National Academies of Sciences publications such as *Mineral Tolerance of Domestic Animals* (1980).

4.5.5. *Selection of Literature Benchmark Values.* Laboratory animals (rat and mouse) studies are generally classified by the U.S. Dept. of Health and Human Services (USDHHS) according to exposure duration: chronic ($\geq$365 days), intermediate or subchronic (15 - 364 days), and acute ($\leq$14 days). In aquatic bioassay tests, test durations for acute toxicity tests are typically 48 hours for invertebrates and 6 hours for fish. Definitions of the terms chronic, subchronic, and acute, however, are often

inconsistent, and depend on the organism being tested. Suter (1993) and USEPA (1995b) arbitrarily consider chronic to be 10 percent of the organism's lifespan. According to USEPA's health effects testing guidelines, chronic toxicity tests should involve dosing over a period of at least 12 months. The organisms studied and study duration should be reported when compiling literature benchmark values.

4.5.5.1. In selecting data to be used in the derivation of the TRV, the nature of the observed endpoints is the primary selection criterion. Literature benchmark values which best reflect potential impacts to wildlife populations through resultant changes in mortality and/or fecundity rates should be used. Toxic responses such as elevated enzyme levels (e.g., elevated blood aminolevulinic acid dehydrase from exposure to lead) or increased tissue concentrations, while they may serve as good biomarkers indicative of an organisms' exposure, are not useful endpoints insofar as being relevant and indicative of adverse impacts to key receptor populations. Relevant intermediate and chronic endpoints are those which affect organismal growth or viability, or reproductive or developmental success or any other endpoint which is, or is directly related to, parameters that influence population dynamics. The toxic effect manifested at the lowest exposure level is (generally) selected as the critical effect. For some ERAs, however, the lowest acute level also is selected for use in determining an acute TRV. Where the toxicity database is large enough, a dose-response curve may be generated and used as the basis to select a literature benchmark value or determine the TRV.

4.5.5.2. The following factors should be considered when selecting literature benchmark values and developing TRVs for use in the risk assessment:

a. Literature benchmark values should be obtained from bioassays having test conditions as similar as possible to on-site conditions. For example, water hardness, which affects the toxicity of many metals, should be the same in order to have the bioassay results applicable to site conditions.

b. The literature benchmark values and TRV should correspond with the exposure route being assessed; in ERAs, this is most typically the oral exposure route (dermal exposure may be assessed using modified oral toxicity values).

c. The TRV should be appropriate for the key receptor and toxicity endpoint being assessed, e.g., assessment of reproductive and developmental effects in mammals and birds would require at least two, but possibly four, TRVs. TRVs for different toxicity endpoints in different receptors or receptors groups may need to be developed.

d. The literature benchmark value and TRV should correspond to the appropriate exposure duration period: subchronic (two weeks to 1 year) or chronic (greater than one year).

e. The literature benchmark value and TRV should correspond to the chemical form being assessed (only applicable to some chemicals, but especially metals such as chromium [trivalent or hexavalent] and mercury).

4.5.5.3. The process for selecting benchmark toxicity values is flexible so that site-specific considerations can be incorporated. Careful consideration should be given to the development of benchmark toxicity values, as they may provide the preliminary information used to set the target cleanup levels at sites where remedial action is anticipated. In the HQ approach, the TRV is essentially the measurement endpoint and the hazard ratios calculated are inherently no more protective than the nature of the toxic mechanism described by the TRV. Caution should be taken in the assessment and selection of the TRV. For example, if the TRV were based on "acute" lethality, it would not be protective of chronic exposure conditions.[16]

4.5.6. *Development of Toxicity Reference Values.* Determination of TRVs for terrestrial and aquatic organisms is dependent on both life style and life stage. Literature benchmark values and TRVs for organisms in aquatic ecosystems (e.g., benthic macroinvertebrates and fish) are generally concentration-based, but can be dosed-based for amphibians and higher trophic level receptors (waterfowl and aquatic mammals). Amphibian exposure is perhaps the most difficult to quantify, as they have both concentration-based aquatic life stages and dose-based terrestrial life stages. Terrestrial TRVs can also be either concentration-based (e.g., flora and soil invertebrates) or dose-based (e.g., vertebrate fauna).

4.5.6.1. Federal AWQC are frequently used as the equivalent of a TRV for aquatic organisms. On some sites, AWQC may be judged to be overly cautious TRVs for the specific key receptors, if the organisms on which the AWQC are based are far more sensitive than any on-site receptors. In these cases, toxicity information used to develop the original AWQC may be used in conjunction with other toxicity data and literature benchmark values to develop a more site- and receptor-specific TRV, or it may be decided to do site-specific bioassays or toxicity testing.

4.5.6.2. In terrestrial ecosystems, two types of TRVs are needed: concentration-based TRVs for soil-dependent organisms and dose-based TRVs for wildlife. TRVs for soil-dependent organisms (e.g., plants, earthworms) are similar to AWQC in that they are concentration based. TRVs for wildlife are similar to the critical toxicity values (reference doses) used in human health risk assessments. In order to appropriately select and use TRVs and to identify assumptions and uncertainties associated with TRVs, an understanding of the general practice currently followed in selecting TRVs is needed. Site-specific TRVs for aquatic and terrestrial ERAs should be developed in consultation with local wildlife and regulatory agencies.

4.5.6.3. *Development of Aquatic TRVs*. As stated above, aquatic TRVs can be based on state or federal AWQC. However, especially in the case of metals, toxicity can be significantly affected by site-specific factors. Factors that can affect site-specific

[16] As assessment endpoints are typically phrased in terms of protecting populations, the TRVs focus on measures of growth, survival and reproduction. Under some circumstances, it may be appropriate to protect lower levels of biological order and employ biomarkers as benchmark values. Additionally, certain biomarkers are indicative of conditions which have direct implications to assessment endpoints of growth, survival, or reproduction and are not merely exposure markers.

values include: ambient water chemistry, different patterns of toxicity for different metals, metals fate and transport, use of standardized protocol for clean and ultraclean metals analysis. Also, applicability of the chronic criterion or acute criterion to the species of concern should be confirmed. Because AWQC have been calculated to protect populations of the most sensitive aquatic species, these criteria may be over (or under) protective of the aquatic ecological receptor(s) selected for the risk assessment. Methods used to calculate AWQC are described in Appendix A of the "Gold Book" (USEPA 1986a) and more recently in the USEPA's *Water Quality Standards Handbook* (USEPA 1993f) and *Interim Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria* (USEPA 1992g, 1993b, 1995d). To determine the basis for a particular chemical, the AWQC document for that metal or compound should be consulted. In the case of metals, the basis (total, total recoverable, or dissolved concentration) for the TRV or criterion and the chemical concentrations to which it is compared should be verified and consistent.

4.5.6.4. *Development of Terrestrial TRVs for Soil-Dependent Organisms*. Screening ecological benchmarks are used to identify chemical concentrations in environmental media that are at or below thresholds for effects to ecological receptors. The Environmental Sciences Division of ORNL developed and compiled a comprehensive set of ecotoxicological screening benchmarks for surface water, sediment, and surface soil applicable to a range of aquatic organisms, soil invertebrates, and terrestrial plants. These benchmarks, or updates performed in collaboration with the Center for Information Studies at the University of Tennessee and the Bechtel Jacobs Corp., are provided as a searchable database. Links to supporting technical reports from which the benchmarks were obtained are also provided.

4.5.6.4.1. The USEPA Eco-SSLs provide screening values for soil invertebrates and plants. It is emphasized that the Eco-SSLs are soil screening numbers, and as such are not appropriate for use as cleanup levels. Screening ecotoxicity values are derived to avoid underestimating risk. Requiring a cleanup based solely on Eco-SSL values would not be technically defensible.

4.5.6.4.2. Countries outside the U.S. (Canada, Netherlands) have developed various cleanup criteria for soils. Most of these criteria are with respect to groundwater protection although some countries (e.g., Canada) have developed a limited number of soil criteria based on phytotoxicity and animal health (ASTM 1995).

4.5.6.5. *Development of Terrestrial TRVs for Wildlife*. In general, TRVs are needed to represent levels of exposure that are associated with low risk for entire taxonomic classes (e.g., mammals) or for selected foraging guilds (e.g., carnivorous mammals). USACHPPM's Technical Guide 254 (USACHPPM 2000) focuses upon the development of chemical-specific TRVs for these receptor groups.

4.5.6.5.1. The methodology for generating defensible wildlife TRVs and for preparing acceptable documentation to support such TRVs consists of two phases. The three steps for Phase 1, Toxicity Profile, are performance of data collection and literature search, identify relevant studies, and prepare a toxicity profile. The three

steps for Phase 2, TRV Report, are derive TRVs and document selection rationale, assign confidence levels to the TRV, and prepare the TRV report.

4.5.6.6. *Use of an Acute to Chronic Conversion Ratio*. In some cases, chronic toxicity data are not available and an acute/chronic ratio must be applied to acute toxicity data (typically mortality) to estimate chronic effects levels. Because wildlife toxicity databases are fairly limited, use of a factor for extrapolating from acute data to chronic data will likely be large and result in an overly conservative TRV.

4.5.6.7. *Short Term Critical Toxicity Values.* Certain exposures, such as during construction or remediation activities, may occur only for a brief time. Likewise, exposure of mobile wildlife to site contamination may be brief and intermittent. These exposures require the use of short term, or acute toxicity values. In most cases, risk assessments are concerned with longer exposures that are appropriately addressed by subchronic or chronic TRVs. Applying these values, however, to very short term exposures (less than two weeks) may not be valid. Results of primary toxicology studies should be used in evaluating potential effects of short-term chemical exposures. Direct comparisons should be made cautiously, however, because of the limitations of single study results. The uncertainties and assumptions involved in the use of acute TRVs should be clearly stated in the assessment.

4.5.6.8. *Feeding and Drinking Rates.* When drinking and feeding rates and body weight are needed to express the NOAEL or LOAEL in mg/kg-bw/d, they should be obtained from the literature benchmark study from which the NOAEL or LOAEL was derived. As noted earlier, dietary chemical concentrations in mg/kg must be normalized for body weight and food intake of the test organism and receptor of concern before they can be used as a screening benchmark.

4.5.6.8.1. Depending on the organism and study, dry weight chemical concentrations may also need to be converted on a wet-weight basis. Use of wet weight versus dry weight in estimating dietary exposures can be problematic, particularly where the moisture content of the diet is highly variable (e.g., in plants). Dietary concentrations in most toxicological studies are reported on a wet-weight basis. However, moisture content of laboratory diets is also typically less than 10 percent, so this difference is sometimes ignored (Beyer and Stafford 1993). The risk assessor should, at a minimum, strive to be consistent (or conservative) in reporting between wet weight when comparing the TRV to the exposure intake value in the risk calculation. The basic equation for converting tissue analyte concentration between dry and wet weight samples is:

wet weight tissue concentration = dry weight tissue concentration x (% solids/100).[17]

where: % solids = 100 - % moisture

[17] Given a 230 mg/kg wet weight of lead in plants and 20% moisture content, the dry weight concentration would be 287.5 mg/kg.

4.5.6.8.2. If the literature benchmark study does not provide the needed values, they should be determined from appropriate data tables for the particular study species. For studies done with domestic laboratory animals, Registry of Toxic Effects of Chemical Substances (RTECS) (National Institute of Occupational Safety and Health [NIOSH], latest edition) can be consulted. When insufficient data exist for other mammalian or avian species, the allometric equations from Calder and Braun (1983), Nagy (1987), and USEPA (1988d, 1993d) can be used to calculate feeding and drinking rates (see Section 4.3.3.3.1). Reference food and water intake values for a variety of wildlife are also provided in ORNL (1998).

4.5.7. *Additional Considerations in Developing TRVs.* There are a number of additional factors that should be considered when conducting the effects characterization, reviewing the toxicological literature and determining TRVs. These are discussed in the following sections.

4.5.7.1. *Absorption Considerations*. Most toxicity values are based on administered, rather than absorbed, doses, and the absorption efficiency has not been considered. However, whatever absorption has occurred during the toxicological study is inherent in the toxicity value. Therefore, use of a toxicity value assumes that the extent of absorption observed in the study is also appropriate for the exposure pathway being assessed. Differences in absorption efficiencies between that applicable to the TRV, and that being assessed may occur for a number of reasons. Two factors that will influence absorption efficiencies are differences in chemical form and differences in the exposure medium.

4.5.7.1.1. The form of the chemical used in the literature benchmark wildlife study may not be the same as the chemical form present in the environmental medium being assessed, and may be absorbed to a different degree. Therefore, use of the toxicity value may over- or underestimate the actual absorption potentially occurring in receptors. This is especially important for certain metals where inorganic forms (e.g., metallic lead) differ widely from organic forms (e.g., lead acetate) in their potential toxicity. The basis of the chemical's TRV should be reported in the effects characterization and compared with the form (if known) in the site media. Often the form in site media is not known, but can sometimes be inferred based on site history or by the medium in which the chemical is found (for example, a metal in soil is unlikely to be present in its soluble form).

4.5.7.1.2. In toxicity studies, chemicals are often administered in drinking water, mixed with food, or mixed in an administration vehicle such as olive oil to facilitate absorption. In environmental settings, exposure to chemicals may occur in a medium similar to that used in the study (e.g., in drinking water) or in a medium quite different from that used in the study (e.g., the soil matrix). Certain media, particularly soil and sediments, may bind chemicals, reducing the amount that is available for absorption (i.e., bioavailability). In these instances, it may be appropriate to reduce the COPEC intake value in the exposure calculation with a matrix effects or bioavailability factor to account for this binding (see Section 4.3.3.3.5).

4.5.7.1.3. Numerous studies show that not only metals but organic chemicals, including pesticides, bind tightly to soil, reducing their bioavailability through both oral and dermal exposure. Calderbank (1989) showed that clays and organic colloids have a large surface area and cation exchange capacity, which permits significant adsorption of virtually all classes of pesticides; furthermore, the adsorbed fraction (20% to 70%) desorbs slowly and is effectively a bound fraction that increases over time as the soil-pesticide bond "ages". Shu et al. (1988) reported a bioavailability range of 25 to 50% for TCDD to rats from soils at Times Beach, Missouri. Goon et al. (1991) showed that benzo(a)pyrene (BaP) that had aged 6 months in soil was only 34 and 51% orally bioavailable for clayey and sandy soils, relative to BaP administered alone to rats. In general, differences in absorption between lab media and site media should not be assumed, unless there is adequate information to the contrary.

4.5.7.2. *Assessment of Inhalation Exposure Route for Wildlife*. Inhalation exposure routes are generally not addressed in ERAs due to the lack of toxicity information for wildlife species and the lesser significance of the inhalation exposure route to the oral ingestion route.[18] In general, VOC concentrations of 100 ppm or greater in air are needed to induce toxic responses in laboratory rats and mice from inhalation (NIOSH 1987). Concentrations in soils would have to be many times greater than this to produce these toxic levels in air, even near the soil surface.

4.5.7.2.1. In order to quantitatively evaluate this exposure route, the risk assessor may need to consider factors such as the target species' airway size, branching pattern, breathing rate (volume and frequency), and clearance mechanisms, whether the contaminant is a gas or aerosol, whether the chemical's effects are systemic or confined to the respiratory tract, as well as particle size distribution, temperature and vapor pressure and pharmacokinetic data (USEPA 1993d). In addition, the dose deposited, retained and absorbed in the respiratory tract is a function of species anatomy and physiology as well as physicochemical properties of the contaminant. Allometric equations are available from USEPA (1993d). A procedure for calculating inhalation exposure is also published by USDOI (1991).

4.5.7.2.2. Total petroleum hydrocarbon (TPH) contamination is one example where the inhalation of volatiles for small, burrowing animals is of concern in the ERA. W. Kappleman in Maughan (1993) provides a methodology for determining ecological effects levels for muskrat and beaver via inhalation and dermal exposure pathways for benzene, toluene, ethylbenzene, total xylenes (BTEX) and PAHs. These methodologies may be applied where site-specific conditions require inhalation exposure to be considered an important exposure route. The methodology for calculating inhalation concentrations for humans as discussed in USEPA's (1990b) *Interim Methods for Development of Inhalation Reference Concentrations* may be followed to some extent.

[18] A notable exception is the great number of studies conducted on response and uptake by birds and mammals from aerial pesticide spraying on agricultural crops.

4.5.7.3. *Assessment of Dermal Exposure Route for Wildlife*. Dermal exposure routes are generally not addressed in ERAs due to limited toxicity information for terrestrial wildlife species and the lesser significance of the dermal exposure route to the oral ingestion pathway. The dermal pathway may be of importance where wildlife are directly sprayed or frequent areas with surface-contaminated vegetation or where the animals are burrowing in contaminated soils/sediments.

4.5.7.3.1. Wildlife are generally assumed to be protected by their fur, feathers or scales, which prevent a chemical from reaching an animal's skin and may allow the chemical to dry or to be rubbed off during movement. Dermal absorption of contaminants is a function of chemical properties of the contaminated medium, the permeability of the receptor's outer covering, area in contact with the contaminated medium and the duration and pattern of contact. The methodology for calculating dermal exposure concentrations for humans is discussed in USEPA's (2004) *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)*(RAGS E), and may be followed to some extent where dermal exposure concentrations for wildlife need to be calculated.

4.5.7.3.2. Dermal exposures may be of concern for wildlife that swim or burrow. Mammals and birds groom themselves regularly and may receive an oral ingestion dose from dermal contamination of their fur or feathers. An oral ingestion dose for animals which groom themselves may be calculated based on a methodology published by USDOI (1991) for determining dermal exposure to representative western rangeland wildlife species from herbicide sprays. W. Kappleman in Maughan (1993) provides a methodology for determining ecological effects levels for muskrat and beaver via dermal exposure pathways for BTEX and PAHs. Such a methodology may be applied where site-specific conditions require dermal exposure to be considered an important exposure route.

4.5.8. *Special Chemicals.* Some commonly detected chemicals require special consideration in the generation of a TRV (e.g., their potential to biomagnify, need for a surrogate component evaluation, difficulty in obtaining toxicity information) or have specific chemical forms that greatly influence bioavailability and toxicity. The following chemicals are discussed in this light:

a. Metals,

b. PAHs,

c. Organochlorine Pesticides (OCPs) and PCBs,

d. Chlorinated Dibenzo-p-dioxins and chlorinated Dibenzofurans (CDDs/CDFs),

e. TPH and other petroleum groupings, and

f. Military chemicals.

4.5.8.1. *Metals.* The toxicity of metals depends foremost on chemical form. For example, chromium (+3) occurs naturally and is common in the environment and has a

relatively low toxicity. Chromium (+6) is largely related to anthropogenic releases and is very toxic, but is readily reduced in the environment to chromium (+3). Organometallic forms (methylmercury, alkylead) are more toxic than the elemental forms. Much of the literature does not specify the chemical form of an element when discussing its toxicity to biota. It may be assumed in these instances that only the total concentration of the metal was known.

4.5.8.1.1. To be toxic an element must be available to the receptors. In order for this to occur, the chemical must exist in a form that can enter tissues of the organisms. Total amounts of a chemical in the environment are not relevant to an adequate estimation of toxicity hazard unless it can be shown that the element exists in or is likely to assume, an available form under the environmental conditions in which it occurs and animals or plants are likely to contact this form either directly of indirectly (Gough et al. 1979).

4.5.8.1.2. *Aquatic Organisms.* The site-specific toxicity of a metal to aquatic organisms depends on the physical form of the metal, the effect of other metals and organic compounds (anthropogenic and naturally occurring) in the water, as well as the chemical or ionic form of the metal of interest. Metals results from surface water analyses can be reported in terms of the total recoverable metals, total metals, acid soluble metals, or dissolved metals. All four methods measure all of the dissolved metal present but differ (because of varying field or laboratory procedures) in the amount of particulate metal measured. While federal AWQC are reported as total recoverable metals, many states have standards based on dissolved metals. The basis and form (dissolved versus total) of the specific criteria should be verified before being applied at a site. The risk assessor may also need to take into account transformation of on-site metals to bioavailable forms with migration off-site.

4.5.8.1.2.1. In order to develop a better understanding of metals criteria, bioavailability, and toxicity, USEPA has issued a series of guidance documents (USEPA 1992g; 1993b; 1995d) to supplement the *Water Quality Handbook* (USEPA 1993f). These documents describe:

a. Relationships among the various physical forms reported in water quality results;

b. The importance of site-specific bioassays (if this level of effort is justifiable) to create a WER to account for the fact that *in situ* metals toxicities are frequently less than reported from laboratory bioassay tests; and

c. Observed ratios between dissolved metals and total recoverable metals in order to facilitate interpretation of AWQC and the more bioavailable dissolved metals.

4.5.8.1.3. *Plants.* Plants are intermediate reservoirs through which trace metals from primary sources move to other living things, as well as receptors directly exposed to metals in soils. Plants may be passive receptors of trace metals, as in root adsorption, or they may accumulate and store metals in nontoxic forms for later distribution and use (Tiffin 1977). A mechanism of tolerance in some plants apparently

involves binding of potentially toxic metals at the cell walls of roots and leaves, away from sensitive sites within the cell. The metal forms which occur in plants appear to have a decisive role in metal transfers to other organisms (Tiffin 1977).

4.5.8.1.3.1. There are a large number of processes that operate to regulate metal cycling, including ion exchange, adsorption, formation of organic complexes, and precipitation. All these have different, and often opposing effects; and all are very dependent on pH, and other soil/sediment characteristics. Since site conditions vary so much in these respects, both spatially and temporally, metal reactions and fates often vary. In addition to environmental variability, there are differences due to plant physiology and genotype (Outridge and Noller 1991). Therefore, it is very difficult to extrapolate from one study location or plant to another.

4.5.8.1.3.2. As described in Dunbabin and Bowmer (1992), there are some general trends that have been noted. Potential bioavailability generally increases with increases in acidity, reducing power, salinity, and concentration of organic ligands. However, if sulfur is present, a reducing environment will result in the production of insoluble metal sulfides. Other specific factors that influence bioavailability include sediment size (clay provides more surface area for adsorption and reactions), presence of hydrous iron and manganese oxides (which adsorb metals), and the nutrient regime (which, for example, affects the ability of microbes to transform elemental mercury to methylmercury) (Stewart et al. 1992).

4.5.8.1.4. *Terrestrial Fauna*. Several metals, while potentially toxic, are also essential micronutrients for plants and animals, e.g., zinc, selenium. All metals, whether essential or nonessential, can adversely affect terrestrial organisms, if included in the diet at excessively high levels. In general, tolerance levels vary from animal to animal and even from day to day in a single animal (NAS 1980). Many factors, such as age and physiological status of the animal (growth, lactation, etc.), nutritional status, levels of various dietary components, duration and route of exposure, and biological availability of the compound, influence the level at which a metal may cause an adverse effect in the organism (NAS 1980). Exposure of animals to excessively high concentrations of metals can result in acute signs of toxicosis, which may be quite different from the chronic effects displayed after the metal has been ingested at higher than normal levels over an extended period of time.

Metals that biomagnify (e.g., mercury, selenium) require the application of food chain multipliers (BAFs or biomagnification factor (BMF)) to concentrations in prey organisms for higher trophic level predators. Concentrations of inorganic metals in a BAF or BCF study should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the substance is a micronutrient (e.g., selenium), while still below levels which adversely affect the species (USEPA 1995b).[19] Bioaccumulation of inorganic metals may be inappropriately overestimated if

[19.] Care should be taken in using partitioning models to estimate BCFs or BAFs for soil dependent organisms such as earthworms and plants. Models based on diffusivity constants and anaerobic conditions can result in unrealistically toxic concentrations (>1 percent) in the soil organism.

concentrations are at or below normal background levels due to, for example, nutritional requirements of the test organisms (USEPA 1995b).

4.5.8.2. *PAHs.* PAHs, also known as polynuclear aromatics (PNAs), are a class of compounds containing hydrogen and carbon in multiple ring structures. There are numerous possible PAH molecules, several of which are common analytes in a semi-volatile compound analysis. PAHs are natural components of petroleum and are found in heavier petroleum fractions, such as lube oil, naphtha, etc. PAHs are also produced by the incomplete combustion of organic matter. For this reason, PAHs are ubiquitous in the environment at low levels, particularly in soil and sediments, to which they readily bind.

4.5.8.2.1. In general, PAHs are rapidly metabolized and considered unlikely to biomagnify despite their high lipid solubility (Eisler 1987b). Inter- and intra-species responses to individual PAHs are quite variable, however, and are significantly modified by many inorganic and organic compounds (Eisler 1987b). Until these interactive effects are clarified, extrapolation of laboratory test results to field situations where there is suspected PAH contamination should proceed cautiously.

4.5.8.2.2. Amphibians, are reported as quite resistant to PAH carcinogenesis when compared to mammals due the amphibian's inability to produce mutagenic metabolites of BaP and perylene (Anderson et al. 1982). The ability to metabolize PAHs in nonmammalian species, however, is extremely variable and cannot be predicted on the basis of phylogenic associations. When PAHs are not metabolized, they have been shown to bioaccumulate and therefore pose a significant dietary route of exposure to predatory species. In species which can metabolize PAHs, one significant mode of toxicity is impairment of reproductive cycles.

4.5.8.2.3. Small mammals which burrow and ingest soil are likely to be the ecological receptors with the greatest potential exposure and risk from PAHs. Data are generally lacking on the acute and chronic toxicity of PAHs on avian wildlife (Eisler 1987b). Eisler (1987b) reports PAHs show little tendency for bioconcentration or biomagnification, particularly in terrestrial ecosystems, probably because most PAHs are rapidly metabolized. Beyer and Stafford (1993) also found PAH concentrations in earthworms to be well below soil levels. Gile et al. (1982), however, report fairly high bioaccumulation factors for terrestrial species. In their 3-month mesocosm experiment using creosote coal tar distillate (which contained 21% phenanthrene and 9% acenaphthene), PAH concentrations in various animals were found to be elevated over average PAH soil concentrations.

4.5.8.2.4. PAHs can accumulate to some extent in terrestrial plants. Atmospheric deposition on leaves, however, is likely to be a more significant pathway than uptake from soil by roots (Vaughn 1984). Uptake of PAHs by plant roots are dependent on numerous factors including concentration, solubility, molecular weight of the PAH, and on the plant species (Edwards 1983).

4.5.8.3. *OCPs and PCBs*. OCPs and PCBs are extremely stable compounds and slow to degrade under environmental conditions. The toxicological properties of

individual PCBs and pesticides are influenced primarily by two factors: the partition coefficient, K_{ow}, based on solubility in n-octanol/water and stearic factors, resulting from different patterns of chlorine substitution. The more highly chlorinated forms of PCBs and pesticides tend to be more persistent, more strongly sorbed, less volatile, and less bioavailable (O'Connor et al. 1990, Sawhney 1988, Strek et al. 1981).

4.5.8.3.1. PCBs and pesticides are strongly sorbed in soils, sediments, and particulates in the environment, with levels usually highest in aquatic sediments containing microparticulates (Eisler 1986b, USEPA 1980, Duinker et al. 1983). PCB and pesticide uptake from contaminated soils and sediments is governed by processes that include both direct incidental ingestion of contaminated soil/sediment particles and indirect ingestion via food webs or from parents to the fetus or embryo. Toxicity reports based on plant (terrestrial) uptake of pure PCBs and pesticides can be misleading because these chemicals are often added to the exposure medium at unreasonably high concentrations to facilitate analysis or they are added to coarse-textured soils extremely low in organic matter (O'Connor 1989).

4.5.8.3.2. PCBs, dioxins, and pesticides are all highly lipophilic, with the greatest concentrations occurring in fatty tissues. PCBs, dioxins, and pesticides are of greatest concern to higher trophic level predators. In mammals, these chemicals are readily absorbed through the gut, respiratory system, and skin, and can be transferred to young mammals either transplacentally or in breast milk. In birds, particularly endangered raptors, a reduction in eggshell thickness has been the endpoint of greatest concern from pesticides. Evidence implicating PCBs as a major source of eggshell thinning is inconclusive (Eisler 1986b, Wiemeyer et al. 1984, Henny et al. 1984, Norheim and Kjos-Hanssen 1984). Consideration of the potential bioaccumulative effects of PCBs, dioxins, and pesticides is important in the selection of appropriate assessment and measurement endpoints.

4.5.8.3.3. The 197 PCB congeners that are not dioxin-like PCBs (see Section 4.5.6.4) are currently referred to as “non-dioxin-like” congeners. These congeners are also often referred to as the “non-coplanar” or “ortho-substituted” congeners. The NCEA, Ecological Risk Assessment Support Center has issued guidance for assessment of these PCBs in *Non-Dioxin-Like PCBs: Effects and Consideration in Ecological Risk Assessment* (USEPA 2003).

4.5.8.4. *CDDs and CDFs.* CDDs and CDFs, often abbreviated "dioxins and furans" are a group of chlorinated compounds based on the dibenzo-p-dioxin or dibenzofuran molecule (the two of which are structurally similar). CDDs/CDFs are not compounds used for commercial purposes in the past, and, outside of research, have no known use. Rather, CDDs/CDFs are byproducts of high temperature combustion of chlorinated compounds and impurities in other chemical products such as pentachlorophenol (CDDs) or polychlorinated biphenyls (CDFs). Although not considered a "natural" product, some forms of CDDs and CDFs (specifically octa-CDD and octa-CDF) are ubiquitous in the environment at very low concentrations.

4.5.8.4.1. There are 75 possible CDD congeners and 135 possible CDF congeners. As with PCBs, the degree of toxicity varies with the degree and location of chlorination, becoming greatest when the 2, 3, 7, and 8 positions of the molecule are substituted. The 2,3,7,8-TCDD is considered the most potent CDD, and is the reference against which all other CDDs and CDFs are compared.

4.5.8.4.2. Analysis of CDDs and CDFs is most commonly reported by congener group (i.e., as either tri-, tetra-, penta-, hexa-, hepta-, or octachlorodibenzo-p-dioxin or -dibenzofuran). Within these groups, the results are often further separated into "2,3,7,8- substituted" or "other" categories. This form of reporting is needed to appropriately assess CDDs and CDFs. Reporting as "total dioxins" or even just by congener group may require the assumption that all CDDs/CDFs present are as toxic as 2,3,7,8-TCDD, resulting in an overestimate of potential risk posed by the presence of CDDs/CDFs.

4.5.8.4.3. Piscivorous fish and wildlife are thought to be particularly at risk from these chemicals due to their large exposure through aquatic food chains. The limited available toxicological data indicate that fish, especially salmonid sac fry, and mink (*Mustela vison*) are among the most sensitive animals to TCDD and related compounds. Assessment of the toxicity of these compounds along with environmental concentrations associated with TCDD risk to aquatic life and associated wildlife has been released by USEPA (1993g, 2006).

4.5.8.4.4. Two basic methods are recommended for evaluating the toxicity of mixtures of dioxin-like PCBs, PCDFs, and PCDDS in environmental samples to determine sample "toxic equivalents" relative to TCDD (USEPA 1993g). In the first method (commonly used in screening ERAs), individual PCB, PCDF, and PCDD congeners are determined and multiplied by toxic equivalent factors (TEFs) to express potential toxicity in TCDD-equivalents (EQs). In the TEF approach for dioxin-like PCBs/CDDs/CDFs, the toxicity of the TCDD compounds are expressed relative to the toxicity of 2,3,7,8-TCDD for mammalian systems (Safe 1990, Ankley et al. 1992). Soil or prey tissue doses of dioxin-like PCBs/CDDs/CDFs may be calculated by applying congener-specific TEFs to the concentrations prior to conversion of concentrations to doses. TEFs, however, are a species-specific construct and the TEF multipliers vary widely among species, depending on their ability to metabolize specific congeners. TEFs recommended by USEPA (1995b, 2006) and Safe (1990) are frequently used in screening ERAs. Further discussion of TEFs for dioxin-like PCBs/CDDs/CDFs can be found in *Interim Report on Data and Methods for Assessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin Risks to Aquatic Life and Associated Wildlife* (USEPA 1993g), USEPA's (1994e) dioxin wildlife workshop report, the Framework document (USEPA 2006), and in the GLWQI (USEPA 1995b).

4.5.8.4.5. In the second method, the total PCB/PCDF/PCDD mixture is extracted from the environmental samples and then tested for potency, relative to TCDD, using a standard biological response (rat hepatoma cytochrome induction) as an endpoint (USEPA 1993g). This latter approach bypasses the assumption of an additive model of toxicity for complex mixtures. If the latter biological approach for measuring TCDD-EQ

is to be used for quantitative risk assessment, it is important to calibrate the biological system used with specific toxicological endpoints in the receptors of concern (USEPA 1993g).

4.5.8.5. *TPH and Other Petroleum Groupings.* TPH are common contaminants at DoD sites. Petroleum hydrocarbons originate from a variety of petroleum-derived fuels including jet fuel, fuel oils, and gasoline. Determination of the actual source material (gasoline versus fuel oil) is not always possible, particularly where site history is unknown. Composition of any given fuel will also vary depending on the source of the crude oil, refinery processes, and product specifications. Also, due to differential volatilization and biodegradation, the composition of the original fuel mixture in the environment is altered over time. Therefore, the toxicity of the insoluble and nonvolatile components remaining some time after a spill is often of more interest than volatile compound toxicity.

4.5.8.5.1. Because of the originally unknown and potentially altered composition of the spilled fuel, TPH toxicity is frequently assessed based on individually measured constituent toxicity, rather then by assessing the measured TPH concentration as a whole mixture. The primary constituents of petroleum components, such as paraffins and naphthenes, are generally not considered to be highly toxic (Amdur et al. 1991; Clayton and Clayton 1981) and are typically not included as COPECs in ERAs. Aromatic constituents such as benzene and xylene and the carcinogenic PAH compounds are the primary COPECs for risk assessments. Noncarcinogenic compounds, such as toluene, ethylbenzene, xylenes, naphthalene, and other noncarcinogenic PAH compounds, may be of concern for potentially acute toxic effects.

4.5.8.5.2. The impacts of TPH on terrestrial ecosystems are not as well documented as the impacts on aquatic ecosystems.[20] Some attempts have been made in human health risk assessment to derive critical toxicity values for TPH. However, since the composition of TPH varies from place to place (even within the same site) as well as change in time (fresh versus aged product), it is unlikely that using critical toxicity values for this group of chemicals provides valuable descriptors of the potential toxicity of the components comprising the TPH detection.

4.5.8.6. *Military Chemicals.* Many DoD sites contain potentially toxic chemicals not commonly found on non-military sites. Military-specific chemicals may include explosives, rocket fuels, radioactive materials, chemical agents, or degradation products of these compounds. Because of the unique status of many military compounds, USEPA is often unable to supply toxicity information. Profiles containing toxicological information relevant to an ERA can be obtained from USACHPPM WTAs and the TTD. Technical reports that summarize environmental fate and behavior (plant

[20] The American Petroleum Institute (API) lists numerous reports regarding TPH toxicity in aquatic ecosystems. Effects concentrations in water for various oil products (bunker, crude, diesel, gasoline, jet fuel, lube oil), taxonomic group (invertebrates, fish, algae), and presence/absence of free product, can be found in *A Critical Review of Toxicity Values and An Evaluation of the Persistence of Petroleum Products for Use in Natural Resource Damage Assessments*, API, April 5, 1993.

uptake, mammalian and aquatic toxicology) of munitions material are also available in the open literature (Burrows et al. 1989, Cataldo et al. 1990, Layton et al. 1987). Pertinent information can also be obtained from site-specific environmental studies at installations such as Joliet AAP and Rocky Mountain Arsenal and by contacting the regional USEPA or TSERAWG persons.

4.5.8.7. *Toxicologic Uncertainties*. Use of USEPA-derived aquatic and wildlife toxicity values should be examined with regard to the degree of uncertainty associated with their development. The uncertainties associated with the values should be stated in the effects characterization, and the impact of applying the value estimated, specifically (when the assessment is complete) for chemicals that are major contributors to overall site risks and hazards. The following factors should be addressed:

a. What are the cumulative uncertainties and modifying factors applied to derive the TRV?

b. Is the form of the chemical used in derivation of the toxicity value the same or similar to that in the environmental medium being assessed?

c. Is the duration of the toxicological benchmark study relevant to the exposure conditions for the key receptors being assessed? Actual exposure durations for key receptors may or may not exceed the test duration periods on which the TRVs are based.

d. Was the medium applicable to the toxicological study used to derive the toxicity value (e.g., the chemical was administered to the test animal in food, water) similar to the medium being assessed? Could matrix effects or water effects be important in bioavailability?

e. Has any route-to-route extrapolation been performed? Was it reasonable to do so, and were assumptions used in the extrapolation appropriate?

f. Were surrogate toxicity values (toxicity values for other chemicals that are structurally and/or chemically similar) used for chemicals that do not possess values? Was this approach reasonable?

g. Were BCFs or BAFs applied in the development of the TRV? BAFs and BCFs developed for one study may be quite different than bioaccumulation factors at other areas.

h. If multiple contaminants are detected, is additivity assumed and is it a reasonable assumption for the exposures expected? Note that some toxicity tests can evaluate the toxicity of mixtures, but lack the ability to discriminate which contaminant is causing the toxicity.

4.5.8.7.1. The potential exists for wildlife species to be more or less sensitive than laboratory test species and the derived toxicological benchmarks. Toxicity benchmark values for laboratory organisms may be substantially lower than those for wildlife due to

the sensitive strains of laboratory animals used, the direct means by which they are dosed, and the need to obtain a satisfactory toxic response. The LD_{50} studies are usually designed to promote maximum exposure (absorption) because less of the chemical complexes with dietary material. The LD_{10} dietary studies probably give a better indication of the toxicity of the chemical tested, while no observed effects levels from longer studies are the best (still imperfect) laboratory studies to be used as predictors of field effects. On the other hand, laboratory species may be less sensitive than their wild counterparts in that they must be hardy enough to be amenable to culturing in a laboratory setting or endure animal husbandry and handling.

4.5.8.7.2. In contrast to laboratory tests of terrestrial organisms, laboratory tests of aquatic invertebrates or fish show that the tested chemicals may be less toxic to the same or similar animals under natural conditions. This is because the tested chemical is not as bioavailable in natural waters due to the modifying effect of other water quality characteristics (e.g., pH, hardness, suspended solids). In order to estimate the toxicity of a chemical under natural conditions, a parallel series of toxicity tests are run using site water and laboratory test water as dilution water and then calculating a water effects ratio (site water LC_{50}/lab water LC_{50}).

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CHAPTER 5
Risk Characterization

Per ERAGS (USEPA 1997a), risk characterization includes two major components: risk estimation and risk description. Risk estimation integrates the exposure profiles with the toxicity information and summarizes the associated uncertainties. Then, the risk description provides the risk manager with information useful for interpreting the assessment results.

USEPA has two requirements for the full characterization of risk (USEPA 1995a,c). First, the characterization should address qualitative and quantitative features of the assessment. Second, it should identify the important strengths and qualitative as well as quantitative uncertainties in the assessment as part of a discussion of the confidence in the assessment. Risk characterization as the final part of the ERA process provides:

Integration of the individual characterizations from the ecological effects and exposure characterizations (see Chapter 4);

Evaluation of the overall quality of the assessment and the degree of confidence in estimates of risk and conclusions drawn (see Chapter 6);

Description of risks in terms of extent, severity, and probable harm; and

Communication of risk assessment results to the risk manager.

5.1. Risk Characterization – SLERA.

5.1.1. Risk characterization is the summarizing step of the SLERA. The risk characterization integrates information from the preceding components of the risk assessment, performs a screening evaluation (or calculation) and synthesizes an overall conclusion about risk that is complete, informative, and useful for decision-makers (USEPA 1995c). The preliminary risk screen employs a conservative approach to ensure that potential ecological threats are not overlooked.

5.1.2. For the risk estimation, the HQ approach, which compares point estimates of TRVs and exposure values, is standard practice. 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 HQ is expressed as the ratio of a potential exposure level to the applicable toxicity-based benchmark. A complete discussion of the HQ method is presented in Section 5.3.3. below. Decision rules are applied to the results for interpretation of potential risks. For HQ values exceeding unity (1.0) the potential for adverse effects to the receptor is concluded to be possible. In contrast, if

the resulting HQ is equal to or less than unity, the potential for risks due to that chemical can be considered negligible and therefore may be dropped from further consideration of risk for that exposure pathway. The results of the SLERA can remove COPECs, pathways, or even receptors from further consideration. This logic is supported through the consistent application of conservative assumptions, biasing towards overestimating potential risks. The other possibility is that the present information available is insufficient to determine potential risks of exposure to the chemical, and hence that chemical is retained for further review in the BERA.

5.2. Refinement of the SLERA. In circumstances where the results of the human health assessment indicate lack of concern, it may be worthwhile to refine some exposure parameters to evaluate less conservative exposures for the SLERA. This decision would be based on the likelihood that more realistic exposure parameters would bring the calculated HQs below one. This step (Step 3A) would occur prior to beginning problem formulation for the BERA (Step 3 in the ERAGS process)(See Chapter 3). For a complete discussion of the Step 3A process, see USA BTAG (2005a). For this refinement, the following parameters can be reevaluated, as appropriate and information is available, and HQs can be recalculated for those receptors and pathways indicating the potential for ecological risk:

a. Area use percentage (home range).

b. Bioavailability < 100%.

c. Diet composition < 100% from the most contaminated media.

d. COPEC concentration in food items.

e. Detection frequency.

f. Comparison to background.

5.3. Risk Characterization – BERA. For the BERA, the risk characterization will provide data on exposure and effects, analyzing the weight-of-evidence from various studies employed for the risk assessment, and discussing the associated uncertainties. The risk estimation consists of integrating the exposure and toxicity profiles, as well as estimating and summarizing the associated uncertainties and assumptions (see Chapter 6) to characterize current and potential adverse biological effects posed by the COPECs. The potential impacts from all exposure routes and all media (water, sediment, soil, and air) are included in this evaluation as appropriate. The risk description provides information to the risk manager for interpreting the results and identifies a threshold for adverse effects. The risk description can also include a discussion of additional data or analyses that might reduce the uncertainty in the risk estimates. These additional data collection efforts or analyses, if deemed necessary, would be conducted in subsequent field efforts.

5.3.1. *Risk Estimation.* In a BERA, risk estimation can be either qualitative or quantitative, depending on the data available, DQOs, and the stated level of effort.

Quantitative risk estimation techniques can be fairly simple or more complex, depending on the complexity of the food webs and exposure pathways that are to be quantified. Other quantitative approaches that may be used include comparing probabilistic distributions of effects, and exposure and simulation modeling.

5.3.1.1. Characterization of adverse effects on key receptor species at the population, community, or ecosystem level is generally more qualitative in nature than characterizing human risks. This is because the toxicological effects of most chemicals are not well documented for most wildlife species. In the estimation and characterization of risk, the adverse effects of chemicals on populations and habitats should be considered rather than the effects on individual members of a species, except in the case of threatened and endangered species, where individuals require protection in order to preserve the population.

5.3.1.2. True risk estimation therefore also involves interpretation of results, with professional judgment, to provide the ecological implication of the observations, made at the level of the measurement endpoint. In some cases, this may involve a great deal of professional judgment. In others, the ecological implications are either obvious or inherent due to the level of the chosen measurement endpoint.

5.3.2. *Terrestrial Ecosystem Methodologies***.** The following sections present descriptions of two methodologies for performing quantitative risk characterization for terrestrial and aquatic ecosystems. Methodologies for characterizing risk to receptors in terrestrial and aquatic ecosystems are similar in some aspects, but are discussed separately because of differences in the data forming the basis for the final risk calculations.

5.3.3. *HQ Method*. The HQ method as applied to ERAs is similar to that for calculating an HQ for human health risk characterization. The objective of a risk characterization for a specific receptor is to compare the estimated chemical intake of one chemical through one exposure route with the "threshold" concentration, that is, the level of intake that is recognized as unlikely to result in adverse ecological effects (i.e., the TRV). The comparison (quotient) of estimated intake and acceptable exposure level is called a HQ and is derived in the following manner:

$$HQ = \frac{\text{Intake (mg/kg-bw/day)}}{\text{TRV (mg/kg-bw/day)}}$$

where the intake is the chronic or sub-chronic daily intake (expressed as a dose in mg/kg-bw/d) of the chemical (whichever is appropriate for the exposure being assessed) and the TRV is the corresponding threshold value (sub-chronic or chronic, oral) expressed as a dose. Short-term, sub-chronic, and chronic exposures should be assessed separately.

5.3.3.1. There may be times when it is necessary and appropriate to examine the potential for the occurrence of adverse ecological effects as a result of exposure to multiple chemicals through multiple exposure pathways. In other words, even if

exposure to each individual chemical is below its TRV (HQ less than 1), the sum of the HQs for multiple chemicals may exceed unity, and adverse ecological effects could occur. This is quantitatively derived in the following manner:

$$HQ_i + HQ_i + HQ_i \ldots . + HQ_i = HI_j$$

where HQ_i is the HQ for an individual chemical and HI_j is the HI for a specific exposure pathway. To derive an overall HI, considering multiple co-occurring exposure pathways (and multiple chemicals), the following is performed:

$$HI_j + HI_j + HI_j \ldots . + HI_j = \text{Overall HI}$$

5.3.3.2. Determination of when to calculate an HI requires an expert understanding of toxicology and should be performed only by qualified individuals. Factors that need to be considered include the critical toxicological effect upon which the TRV is based, as well as other toxicological effects posed by the chemical at doses higher than the critical effect. Major categories of toxic effects include neurotoxicity, developmental toxicity, immunotoxicity, reproductive toxicity, and individual target organ effects (hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, dermal, and ocular) (USEPA 1989d).

5.3.3.3. Deriving an overall HI using an additive approach assumes the following:

a. All chemicals will result in a similar adverse effect by the same mechanism of action (or same target organ); and

b. Each chemical exerts its effect independently (i.e., there is no synergism or antagonism).

5.3.3.4. Applying the assumption of additivity is a conservative approach that likely overestimates the actual potential ecological risk presented by the exposure. However, if the overall HI is greater than unity, consideration should be given to the known types of adverse ecological effects posed by exposure to the chemicals. If the assumption of additivity is not valid (i.e., if the chemicals most strongly contributing to the exceedance of the HI display very different types of adverse effects), the HI should be segregated according to toxicological endpoint. These segregated HIs may then be examined independently.

5.3.3.5. HQs should be expressed to one significant figure only, because of the uncertainties involved in deriving the TRVs. In addition, HQs should be reported in decimal form (e.g., 0.001, not 0.0012 or $1x10^{-3}$).

5.3.3.6. It should be noted that an HQ is not a statistical value, nor a measurement of risk. For example, an HQ of 0.01 does not indicate a one-in-one hundred probability of the adverse effect occurring. Rather, it indicates that the intake is one hundred times less than the TRV for the chemical. In addition, the HQ does not infer a linear relationship, i.e., the hazards posed by exposure to the chemical do not increase linearly as the HQ increases. This is so for several reasons, including the fact that

TRVs are not precise descriptors of hazard, and the severity of potential ecological effects varies with different chemicals (dose-response relationships differ). It is also important to note that HQs are not directly population-based (although some measures, such as reduced fercundity, can more clearly infer potential effects to populations). The TRV is based on production of effects in individuals under laboratory conditions, which may or may not extrapolate to the population or higher level of organization. Many field studies have found levels of COPECs that have resulted in calculated HQs exceeding several orders of magnitude. These unrealistically high values represent a major limitation of the procedure, and are not a reflection of magnitude of the potential for risks. For a more complete discussion of the limitations of the HQ method, see Tannenbaum, et al, 2003.

5.3.4. *Probabilistic Methodologies.* A point estimate approach to risk assessment is typically employed for work under CERCLA, where single values are used to represent variables in the risk equations. The output, then, is a point estimate of risk, which can be a CTE or RME, depending on the input values used. A probabilistic risk assessment (PRA) uses probability distributions for one or more variables in the risk equations to quantitatively characterize variability and/or uncertainty. The output of the PRA is a probability distribution of risks, reflecting the combinations of the input distributions. Monte Carlo Analysis is the most widely used probabilistic method in PRA. It uses computer simulation to combine multiple probability distributions in a risk equation.

5.3.4.1. A risk assessment performed using probabilistic methods is very similar in concept and approach to the point estimate method, with the main difference being incorporation of variability and uncertainty into the risk estimate. For some sites, PRA can provide a more complete characterization of risks and uncertainties in the risk estimates as opposed to the point estimate method. If a PRA is conducted, all assumptions and inputs to the model need to be documented such that the results can be independently evaluated.

5.3.4.2. In order for a PRA to be effective, the risk assessor must be familiar with the distinction between variability and uncertainty. Variability reflects the true heterogeneity or diversity of a population. Uncertainty results because of a lack of knowledge. Uncertainty can be reduced by collecting additional data, whereas variability can be better characterized, but cannot be reduced or eliminated. Efforts to clearly distinguish between variability and uncertainty are important for both the risk assessment and for risk communication.

5.3.4.3. For a PRA, inputs to the risk equation are described as random variables and can be defined mathematically by a probability distribution. For continuous random variables, the distribution may be described by a probability density function, and for discrete random variables, the distribution may be described by a probability mass function. The key feature of these functions is that they describe the range of values that the variable may assume and indicate the likelihood of each value occurring within that range.

5.3.4.4. A work plan should be developed for review prior to beginning the PRA. The work plan should document the decisions made during problem formulation, the software to be used, the exposure routes, the models to be used and the probability functions and their bases, including appropriate references. For human health risk assessments, the USEPA allows probability distributions for exposure parameters only. In ERAs, however, the USEPA allows distributions to reflect both exposure parameters and toxicity information (USEPA 2001b).

5.3.5. *Aquatic Ecosystem Methods***.** The HQ and probabilistic quantitative methods can also be used for the estimation of risk to aquatic ecological receptors. The primary difference between aquatic and terrestrial receptors is that contaminant concentrations in surface water or sediments are used as input to the calculations instead of body weight-based dose concentrations.

5.3.5.1. For calculation of an aquatic HQ, the comparison of a measured concentration in water or sediment with an appropriate aquatic TRV is as follows:

$$HQ = \frac{\text{Measured Concentration (mg/L)}}{\text{Aquatic TRV (mg/L)}}$$

where the measured concentration may be the overall RME concentration, maximum concentration, or other appropriate measurement of exposure concentration and the aquatic TRV is the AWQC, sediment criteria (units would be mg/kg), or a species-specific TRV.

5.3.5.2. HIs for multiple chemicals and multiple exposure pathways are the sums of individual HQs and pathway-specific HIs, respectively. It is only appropriate to sum the HQs for contaminants with the same toxic effect mechanisms (e.g., PAHs). As was noted for terrestrial systems, above, determination of when to calculate an HI requires an expert understanding of toxicology and should be performed only by qualified individuals.

5.3.5.3. Probabilistic methods can also be used to estimate aquatic risk. Instead of using exposure concentrations in soils or forage, however, probability distributions of chemical concentrations in surface water or sediments are used. Comparisons of measured chemical concentrations can be made to probability distributions or point estimates of aquatic TRVs.

5.3.5.4. A number of other potential quantitative methods are available for use with aquatic receptors. In fact, nearly all of the ecological evaluation techniques previously listed are applicable to aquatic receptors.

Per USEPA (2001b), the following requirements must be met for the PRA, ensuring that adequate supporting data and credible assumptions have been used throughout:

The purpose and scope for the assessment should be clearly articulated in a problem formulation section, including a full discussion of any highly exposed or highly susceptible subpopulations evaluated. Assessment endpoints must be well defined.

The methods used for the analysis are to be documented and easily located in the report. Sufficient information is to be provided to allow the results to be independently reproduced.

The results of sensitivity analyses are to be presented and discussed in the report.

The presence or absence of moderate to strong correlations or dependencies between the input variables is to be discussed and accounted for in the analysis, along with the effects these have on the output distribution.

Information for each input and output distribution is to be provided in the report. Selection of distributions is to be explained and justified. Variability and uncertainty are to be differentiated where possible, for both input and output distributions.

The numerical stability of the central tendency and the higher end of the output distributions are to be presented and discussed.

Calculations of exposures and risks using deterministic methods are to be reported if possible. This will allow comparisons between the probabilistic analysis and past or screening-level risk assessments.

Since fixed exposure assumptions are sometimes embedded in the toxicity metrics, the exposure estimates from the probabilistic output distribution are to be aligned with the toxicity metric.

Several computer-based proprietary simulation programs are available with which to conduct this simulation. Performance of a Monte Carlo simulation should only be performed by professionals with an understanding of the assumptions and limitations of using it, including such factors as identifying the appropriate number of runs and correlated input variables.

5.3.6. *Weight of Evidence.* In the characterization of ecological risk, the information collected concerning the identified hazards, the receptors, and the exposure characterization are integrated through a comprehensive ecotoxicological evaluation of source-receptor exposure pathways.

5.3.6.1. After identifying sensitive receptors and habitats, complete exposure pathways, exposure points, and COPEC exposure point concentrations, the potential for impacts is evaluated either quantitatively, qualitatively, or a combination of the two. Results from a variety of measurement techniques, such as toxicity tests and HQs, may be used in the weight-of-evidence characterization of potential and actual ecological risk.

5.3.6.2. If actual or potential adverse impacts are found, those impacts are further evaluated to determine to what extent they are site-related and to determine appropriate remediation goals. The ERA also includes conclusions regarding impacts from site chemicals, and a qualitative evaluation of limitations and uncertainties associated with those conclusions.

5.4. Risk Description. A key to risk description is documentation of environmental contamination levels that bound the threshold for adverse effects on the assessment endpoints (USEPA 1997a). Of most importance, however, is the ability to convey to the risk manager the likelihood of adverse effects at the site and the ecological significance of those effects.

5.4.1 *Factors Influencing Ecological Significance*. The relative significance of different effects may require further interpretation, especially when changes in several assessment or measurement endpoints are observed or predicted. If the ERA is concerned with adverse impacts on a variety of receptors and different ecosystems, qualitative discussions should be presented as to the nature and magnitude of the potential adverse effects associated with each receptor and ecosystem.

5.4.1.1. The spatial and temporal distributions of the effect provide another perspective important to interpreting ecological significance (USEPA 1998a). Adverse effects to a resource that is small in scale relative to the site and/or area of contamination (e.g., a wetland or nesting grounds), may have a small spatial effect, but may represent a significant degradation of the resource because of its overall scarcity. Recovery potential is another factor influencing ecological significance that may need to be considered depending on the assessment endpoints.

5.4.2 *Interpreting Site-Wide Ecological Significance*. It is often the case at large federal facilities that individual chemicals and ecological receptors are not isolated in the environment, and adverse effects are not necessarily related to a limited number of chemicals confined to the immediate location of discharge. Organizing the ERA to interpret the ecological significance of various chemicals to which a variety of ecological receptors are exposed at sometimes distant locations is challenging.

5.4.2.1. Matrix ranking processes may be subjective or quantitative (depending on data availability) based on site characterization, ecotoxicological information, and

USEPA guidance. The ranking process may incorporate weighing factors to emphasize specific factors (e.g., area use, toxicity, exposure area, bioavailability, and biomagnification potential) which affect the ability of the chemicals considered to have a deleterious impact on the ecological receptors.

5.4.2.2. Matrices can be updated or revised during the risk assessment process should additional data regarding the COPECs, exposure pathways, or key receptors be identified. The additional data will enhance risk decisions for smaller locations within the facility (e.g., OUs/SWMUs) for which the risk assessment process has not been completed.

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CHAPTER 6
Uncertainty in Ecological Risk Assessments

6.1. Introduction.

6.1.1. EPA has two requirements for the full characterization of risk (EPA 1995a,c). First, the risk characterization should address qualitative and quantitative features of the assessment (see Chapter 5). Second, it should identify the important strengths and qualitative as well as quantitative uncertainties in the assessment as part of a discussion of the confidence in the assessment. In the uncertainty discussion, the risk assessor should also try to distinguish between variability and uncertainty. Variability arises from true heterogeneity in characteristics such as dose-response differences between species and individuals, or differences in contaminant levels in the environment. Uncertainty, on the other hand, represents lack of knowledge, or data gaps, about factors such as adverse effects of select contaminants on select species.

6.1.2. Particularly critical to full characterization of risk is a clear and open discussion of the uncertainty in the overall assessment and in each of its components. The discussion of uncertainty should highlight those uncertainties, which would tend to reduce the degree of confidence in the conclusions drawn and therefore lessen confidence that the site can pose no threat whatsoever. A discussion of uncertainty requires comment on such issues as the quality and quantity of available data, gaps in the database for specific chemicals, quality of the measured data, use of default assumptions, incomplete understanding of general biological phenomena, and scientific judgments or science policy positions that were employed to bridge information gaps (EPA 1995c).

6.2. Characterization of Uncertainty – SLERA. In the SLERA, conservatism and therefore uncertainty is introduced to insure that the potential for risk is not overlooked. When the potential for risk is shown, the extent of the exceedance of the screening criteria, and the appropriateness of the screening value itself, help clarify uncertainty and should be evaluated as part of the initial screen decision-making process. As a minimum requirement, the potential effect of the following uncertainty factors should be discussed:

a. Uncertainties associated with the (limited) chemical database for the site (availability of site-specific data for medium of concern);

b. Use of the maximum chemical concentration (instead of the 95% UCL) for representing the exposure point concentration;

c. Use of surrogate or generic receptors and worst-case exposure scenarios; and

d. Use of screening criteria and the assumptions associated with those values.

As was noted above, uncertainties in the SLERA are essentially associated with the conservative nature of the assessment itself. Step 3A (see Chapter 3) addresses these uncertainties by allowing the risk assessment to adopt parameters more representative of actual exposures. This refinement step also introduces uncertainty by minimizing the conservatism of exposure parameters, allowing the possibility of underestimating site risks.

6.3. Characterization of Uncertainty – BERA. In a BERA, uncertainty is usually presented as a qualitative discussion about the range of confidence in the risk estimation (i.e., low, medium, or high) accompanied by the factors that may contribute to an overestimation or underestimation of risk. Wherever possible, risk should be expressed in terms of magnitude, direction (over or underestimation), and probability, using either a sensitivity analysis (examining the appropriateness of the risk estimation by maximizing one or more input variables) or a probabilistic analysis. By expressing risk in quantitative terms of probability, plus magnitude and direction, the risk manager is better enabled to make judgments on risks relative to other factors (such as costs), and not simply decide that uncertainty levels in the risk assessment must be reduced by further study.

6.3.1. *Objectives.* This section discusses methods of identifying and describing uncertainties in a BERA. Full disclosure and clear articulation of risk uncertainties are guiding principles for this portion of the risk assessment (EPA 1992d, 1995a,c).

> "EPA risk assessors and managers need to be completely candid about confidence and uncertainties in describing risks and in explaining regulatory decisions. Specifically, the Agency's risk assessment guidelines call for full and open discussion of uncertainties in the body of each EPA risk assessment, including prominent display of critical uncertainties in the risk characterization. Numerical risk estimates should always be accompanied by descriptive information carefully selected to ensure an objective and balanced characterization of risk in risk assessment reports and regulatory documents." (EPA 1992d)

6.3.1.1. Identification and discussion of uncertainty in an assessment is important for several reasons (EPA 1992d):

a. Information from different sources carries different kinds of uncertainty, and knowledge of these differences is important when uncertainties are combined for characterizing risk.

b. Decisions must be made on expending resources to acquire additional information to reduce uncertainties.

c. A clear and explicit statement of the implications and limitations of a risk assessment requires a clear and explicit statement of related uncertainties.

d. Uncertainty analysis gives the decision-maker a better understanding of the implications and limitations of the assessments.

6.3.1.2. The output from the uncertainty analysis is an evaluation of the impact of the uncertaintires on the overall assessment and, when feasible, a description of the ways in which uncertainty could be reduced.

6.3.2. *Sources of Uncertainty in a Risk Assessment***.** Sources of uncertainty in a risk assessment exist in almost every component of the assessment. Uncertainty generally can arise from two main sources: variability and data gaps. Model error is an additional,

potential main source of uncertainty that a risk assessor may encounter. Uncertainty from variability can enter a risk assessment through random or systematic error in measurements and inherent variability in the extent of exposure of receptors. Uncertainty from data gaps is most prominently seen when numerous approximations are made regarding exposures, chemical fate and transport, intakes, and toxicity.

In the following sections, specific sources of uncertainty in a risk assessment are identified and discussed. Following this discussion, different approaches to conducting an uncertainty evaluation are presented.

6.3.2.1 *Sampling Uncertainty.* The identification of the types and numbers of environmental samples, sampling procedures, and sample analysis all contain components that contribute to uncertainties in the risk assessment. Decisions regarding the scope of sampling and analysis are often made based on the ECSM developed at the planning stages of the investigation. While appropriate planning may minimize the uncertainty associated with these components, some uncertainty will always exist, because the "real" state of the site is unknown prior to sampling and, in fact, may not be fully elucidated even after sampling.

6.3.2.1.1. Some of the assumptions in this component that contribute to uncertainty in the assessment include:

a. Media Sampled. Unless a decision has been made to sample all media, often a subset of media is selected for sampling and analysis. This selection is usually based upon the anticipated presence of a chemical in a medium from the site history and the chemical's chemical and physical properties and may not include consideration of potential transport through biological media. If all abiotic media in which a chemical is actually present have not been sampled, appropriate risks may not be described.

b. Locations Sampled. The type of sampling strategy selected may impact the uncertainty associated with the results. For example, purposive sampling (sampling at locations assumed to contain the chemicals) will likely result in a higher frequency of chemical detection and concentration than random sampling or systemized grid sampling. Therefore, use of the results may skew the assessment towards greater assumed exposures.

c. Number of Samples. Fewer samples result in a higher degree of uncertainty in the results. This is demonstrated in the summary statistics, specifically the 95% UCL, in which the statistical descriptor ("t" or "H" value), and hence the 95% UCL, increases with a smaller number of samples. Planning for and success in obtaining a specific number of samples to reach a specific degree of statistical confidence can limit the degree of uncertainty.

d. Sampling Process. The sampling process itself can contribute to uncertainties in the data from a number of factors, including sampling contamination (cross-contamination from other sample locations, introduction of chemicals used in the field); poorly conducted field procedures (poor filtering, incomplete compositing); inappropriate sample storage

(head-space left in containers of volatile sample containers, inappropriate storage temperatures); sample loss or breakage; and other factors. Some of these factors can be controlled, however, planning does not prevent the occurrence of sampling errors.

e. Analytical Methodology. The analytical methodology can contribute to uncertainty in a number of ways, including the scope of the chemicals analyzed (if analysis of all important chemicals was not performed); the detection or quantitation limits applied (if not sufficient); and limitations in the analysis due to matrix effects, chemical interferences, poorly conducted analyses, or instrumentation problems. Some of these factors can be addressed in up-front planning (such as selection of the analytical method); others cannot (e.g., instrumentation problems).

f. Stochasticity. Natural variability is a basic characteristic of ecological systems, as well as the factors which influence such systems (e.g., weather). Of all the contributions to uncertainty, stochasticity is the only one that can be acknowledged and described but not reduced (Suter in EPA 1992a).

6.3.2.2. *Uncertainty in COPEC Selection.* Evaluation of the data to select COPECs for the ERA may result in uncertainties. Application of selection criteria may inadvertently result in the inappropriate exclusion or inclusion of chemicals as COPECs. Improper inclusion or exclusion of chemicals can result in an underestimation (if inappropriately removed) or overestimation (if inappropriately retained) of potential ecological risks. Uncertainties associated with the selection criteria include the following:

a. Background Comparison. If background measurements are not truly representative of background conditions, chemicals may be inappropriately retained or removed from the list of COPECs.

b. Sample Contamination. Uncertainty in the assessment can occur if chemicals are not recognized as being present as a result of sampling or laboratory introduction and are excluded as COPECs.

c. Frequency of Detection. Use of detection frequency (say, over 5%) as a selection criterion may result in the inappropriate exclusion of chemicals as COPECs.

d. Toxicity/Concentration Screening. Removal of chemicals as COPECs as a result of using a toxicity/concentration screen can result in uncertainty in the assessment, since some chemical contributors to the risk (even if not significant) have been removed.

6.3.2.3. *Uncertainty in Selecting Key Receptors*. It is possible that the wildlife selected as key receptors in an ERA are not those receptors that have the greatest likelihood of being at risk or are sensitive to a particular chemical. Reptiles and amphibians are typically not addressed in ERAs, as exposure and toxicity information on which to base an assessment are generally lacking. Ecosystem and community level assessment endpoints such as adverse impacts to nutrient cycling, predator-prey relationships, community metabolism, and structural shifts are typically not addressed in ERAs. Uncertainty is associated with the professional judgement used in the selection of key receptors.

6.3.2.4. *Uncertainty in the ECSM.* The ECSM is the product of the problem formulation phase, which in turn, provides the foundation for the effects characterization and risk estimation. If incorrect assumptions are made during development of the ECSM regarding the potential toxic effects or the ecosystems and receptors potentially impacted, then the final risk characterization may be seriously flawed.

6.3.2.5. *Uncertainty in Exposure Assumptions.* Numerous assumptions regarding the amount of chemical intake by a receptor are commonly made as part of the exposure characterization. Such exposure estimates are associated with a number of uncertainties that relate to the inherent variability of the values for a given parameter (such as body weight) and to uncertainty concerning the representativeness of the assumptions and methods used. Uncertainties associated with chemical intake and exposure include:

a. Potential Exposure Pathways. Potential exposure pathways are identified by examining the current and future land uses of the site and the fate and transport potential of the COPECs. While current land use and potential exposure pathways are often easy to identify, potential future uses can only be inferred from information available at the current time. For many ERAs, potential future land use is assumed to be the same as current land use. This and any assumption regarding future land use, any potential future migration of contaminants off-site, and exposure pathways will add uncertainty to the assessment.

b. Potentially Exposed Receptors. As discussed in the preceding bullet, identification of potentially exposed receptors is based upon information currently available. Assumed exposed receptors under future use scenarios can only be guessed at, and this adds uncertainty to the assessment.

c. Exposure and Intake Factors. Point values (e.g., maximum or 95% UCL) for exposure estimates are commonly used in risk assessments rather than a distribution of exposure values that describe the distribution of exposures. These point values are usually conservative, and their use results in introduction of conservatism into the risk assessment that should be addressed. Use of average (i.e., central tendency), rather than upper-end exposure and intake factors may underestimate potential health risks, since only half the population is exposed to that degree or less; the other half is exposed to a greater degree. Using average values, therefore, also contributes to uncertainty that should be addressed in the assessment.

Food and soil/sediment intake values for most wildlife are either unknown or highly variable and very site-specific. Food and sediment intake values for key receptors may be derived from allometric equations. Determining chemical concentrations in food may require the use of bioconcentration or bioaccumulation factors. Uncertainty exists in the use of such equations and factors.

d. Exposure Point Concentrations. Exposure point concentrations may be derived either from measured site media chemical concentrations alone or in combination with fate and transport modeling. With regard to estimating exposure point concentrations from sampling data alone, use of 95% UCL and mean concentrations is associated with some degree of uncertainty. The 95% UCL concentration is used to limit the uncertainty of

estimating the true mean concentration from the sample mean concentration. This value may overestimate the true mean concentration. Use of the sample mean concentration may under - or overestimate the true mean concentration.

Application of fate and transport modeling adds an additional tier of potential uncertainty to exposure point estimates. Models cannot predict "true" exposure point concentrations at different times and places or in different media, but provide an estimate of the potential concentration under certain assumptions. Often, the assumptions used in the models are conservative to avoid underestimating potential concentrations. In addition, not all applicable processes are or can be considered (e.g., degradation, removal processes).

6.3.2.6. *Uncertainty in Toxicity Values*. TRVs are developed from literature benchmark values by applying conservative assumptions, and are intended to protect sensitive species or populations. Use of non site-specific, generic TRVs will usually result in overestimates of potential risk. Factors that contribute to uncertainty include:

a. Use of uncertainty factors (UFs) in the TRV. TRVs are primarily derived from laboratory animal toxicity studies performed at high doses to which UFs of 10 or more are applied.

b. Choice of Literature Benchmark Study to Derive an TRV. The inclusion or exclusion of studies in the derivation of a TRV is usually made by professional judgement; this affects the numerical TRV value.

c. The Assumption of the Most Sensitive Species. When deriving TRVs, the animal study showing an adverse effect at the lowest exposure or intake level, is often the basis for deriving the TRV. EPA assumes that wildlife receptors are at least as sensitive as the most sensitive laboratory animal used (toxicological data on wildlife are still very limited). The LD_{10} dietary studies probably give a better indication of the toxicity of the chemical tested than LD_{50} studies, while NOAELs from longer studies are the best (still imperfect) laboratory studies to use as predictors of field effects. The potential exists for wildlife species to be more or less sensitive than test species (some biota can adapt) and the toxicological benchmarks used. Various uncertainty factors may be used to account for differences in taxonomic levels (i.e., species, genus, order, family) between the test species for the TRV and the key receptor(s) under consideration.

d. Exposure Duration. Actual exposure durations for key receptors may or may not exceed the test duration periods on which the toxic literature benchmark value and resultant TRV are based. Because mobile receptors are likely to feed or visit several locations, or avoid contaminated areas, their daily dose, if averaged over time, could be less than that used for evaluating risk. Unless exposure modifying factors are used, risk is likely to be overestimated.

6.3.2.7. *Additional Uncertainties*. Standardized algorithms to calculate chemical intakes and associated risks are generally lacking for many wildlife receptors. There are numerous assumptions inherent in use of such equations that add uncertainty to the assessment. These include:

Assumption of Additivity. Calculation of HIs assumes (at least as a first line approach) additivity of toxic effects. This assumption adds uncertainty to the assessment, and may result in an overestimate or underestimate of potential risks, depending on whether synergistic or antagonistic conditions apply.

Omission of Certain Factors. Exposure modifying factors, such as absorption, bioavailability, soil matrix effects, area use, and exposure frequency should be considered. In cases where these processes are important, use of a standard algorithm without modification may result in an overestimation of potential chemical intakes.

6.3.3. *Level of Effort*. Various approaches can be applied to describe the uncertainties of the assessment, ranging from descriptive to quantitative. The method selected should be consistent with the level of complexity of the assessment. It may be appropriate to conduct an in-depth quantitative evaluation of uncertainty for a detailed, complex assessment, but may not be appropriate or even needed for a screening level or simplistic assessment. In the section below, qualitative and quantitative approaches to expressing uncertainty are discussed.

6.3.3.1. *Qualitative Evaluation*. A qualitative evaluation of uncertainty is a descriptive discussion of the sources of uncertainty in an assessment, an estimation of the degree of uncertainty associated with each source (low, medium, high), and an estimate of the direction of uncertainty contributed by that source (under- or overestimation). A qualitative uncertainty assessment does not provide alternate risk values, but provides a framework in which to place the risk estimates generated in the assessment.

6.3.3.2. *Quantitative Evaluation*. A quantitative uncertainty assessment is any type of assessment in which the uncertainty is examined quantitatively, and can take several forms. A sensitivity analysis is one form in which specific parameters are modified individually and resultant alternate risk estimates are derived. Probabilistic approaches are more complex forms of uncertainty analyses that simultaneously examine the combined uncertainty contributed by a number of parameters.

6.3.3.2.1. A sensitivity analysis is the process of changing one variable while leaving the others constant and determining the effect on the output. These results are used to identify the variables that have the greatest effect on exposure. This analysis is performed in three steps:

a. Define the numerical range over which each parameter varies;

b. Examine the relative impact each parameter value has on the risk and hazard estimates; and

c. Calculate the approximate ratio of maximum and minimum exposures obtained when range limits for a given parameter are applied to the risk algorithm. Exposure parameters should not, however, be combined in ways that are not reasonable; for example, combining maximum intake rates with minimum body weight.

6.3.3.2.2 A probabilistic uncertainty analysis, such as the Monte Carlo simulation, examines the range of potential exposures associated with the distribution of values for

select or all input parameters of the risk algorithm. Probability density functions are assigned to each parameter, then values from these distributions are randomly selected and inserted into the exposure equation. After this process is completed many times, a distribution of predicted values is generated that reflects the overall uncertainty of inputs to the calculation. The results are presented graphically as the cumulative exposure probability distribution curve. In this curve, the exposure associated with the 50th percentile of the exposure may be viewed as the "average" exposure and those associated with the 90th or 99.9th percentile may be viewed as "high end" exposure. An example of this approach, *Analysis of Extrapolation Error*, is presented in Barnthouse et al. (1986).

CHAPTER 7
Alternative Evaluation

7.1. Introduction. Various types of ERAs may be applied to conduct an evaluation of remedial alternatives or a more detailed analysis of a selected alternative. Generally, the SLERA procedures will be sufficient in providing the risk inputs for selection of potential remedial alternatives or corrective measures (including the no-further action alternative) or the need for procedural changes or engineering controls to minimize short-term risks or residual risks. Use of more involved studies may be necessary for sites requiring implementation of remedial action for a large areal extent and/or multiple years of remediation, and sites with complex ecosystems and many effected trophic levels. Again, early project planning with involvement of expert ecological risk assessors, BTAG or ecological technical assistance group (ETAG) persons, regulatory agencies, and stakeholders will be the key to identifying the level of effort most appropriate for specific site conditions.

7.1.1. As part of FS activities, different remedial alternatives are examined from a number of perspectives as part of the selection process. The NCP specifies nine selection criteria to be examined as part of remedial alternative evaluation: (1) protection of human health and the environment, (2) compliance with ARARs, (3) long-term effectiveness and permanence, (4) reduction of toxicity/mobility/volume through treatment, (5) short-term effectiveness, (6) implementability, (7) cost, (8) state acceptance, and (9) community acceptance.

7.1.2. Generally, there are two applications of the ERA methodology useful for the FS: 1) development of comparative risk assessments between different remedial options, and 2) the development of remediation goals to be applied to site cleanup. The first type of ERA is not commonly performed, but it can be useful in distinguishing the advantages and disadvantages between potential remedial options. The second type is sometimes performed as a component of the RI, but is distinguished in this section because of its use in the development of remedial options. Each type of ERA is discussed individually in the following sections.

7.2. Comparative Risk Assessment of Remedial Alternatives. For a remedial alternative to be acceptable, it must be protective of the environment as well as human health. However, more than one alternative may meet this (and the remaining criteria). An ERA can evaluate the potential for long-term residual risks as well as the short-term risks associated with the remedial action (i.e., habitat destruction or alteration).

7.2.1. *Evaluation of Residual Ecological Threats*. The potential risks to be addressed in this type of comparative risk assessment are those remaining after the implementation of the remedial alternative (those potentially incurred during the implementation are discussed in Paragraph 7.2.2.). The methodology for performing the comparative risk assessment is the same as for a SLERA. The potential exposure pathways and receptors should also be the same unless exposure pathways would be

modified due to habitat removal, for example. The main factor that will change is the chemical concentration to which the key receptors may be exposed.

7.2.1.1. An assessment of the potential for long-term residual risks associated with multiple alternatives can be developed as a tool to assist in selecting an alternative. By comparing the degree to which an alternative reduces potential threats with respect to other factors such as cost, acceptability, and effectiveness, one alternative may be identified preferable. For example, Alternative A may reduce potential risks to an HQ of well below 1, but cost $5 million to implement; Alternative B may reduce potential risks to an HQ of slightly below 1, but cost only $1 million to implement. Since both risk (hazard) levels are acceptable in terms of the assessment endpoint, it may be preferable to select Alternative B because of its cost/benefit advantage.

7.2.1.2. The reduction of risk offered by the alternative should also be examined with respect to the nature of the assessment endpoint and the size of the population affected by the contamination. Although protection of all key receptors is the primary goal, a modest reduction of risk for large populations of key receptors may be preferable to a large reduction of risk for a small group of key receptors.

7.2.1.3. When developing an estimate of potential exposure point concentrations after remediation, careful consideration must be given to where remediation is to take place and where no action is anticipated. It is not uncommon for remedial actions to focus in some areas of a site, leaving others untouched. Therefore, estimating the potential exposure point concentration is not as simple as assuming exposure to the remedial level, but to a combination of attaining the remedial level in some locations, being below the remedial level at others, and perhaps exceeding the remedial level in some isolated areas where remediation is not anticipated. The potential risks associated with different combinations of remedial alternatives can be addressed by examining each medium separately, and then combining the associated risks.

7.2.2. *Evaluation of Short-Term Ecological Threats.* Ecosystems are dynamic and capable of recovery from many different types of assaults. Implementing a remedial action that destroys habitat will require time for the receptors to reestablish and the ecosystem to recover. Obviously, the more habitat destruction necessary, the longer recovery will take. Therefore, from a purely ecological point of view, in situ technologies are preferable to ex situ technologies, as habitat impacts are minimized.

7.2.2.1. Sometimes habitat destruction or alteration during implementation of a remedial action can cause more problems for the environment than performing no remediation at all. A key aspect often overlooked is the evaluation of the short-term impacts to the environment from remediation for human health concerns. The receptors effected and the extent of those effects from various alternatives can be significantly different. Displacement of large numbers of key receptors can have greater impacts than displacement of only a few key receptors.

7.2.2.2. The ERA for the FS should compare the short-term impacts of the various alternatives in terms of habitat destruction, displacement of receptors and the benefits

potentially realized. Although an ERA to evaluate these threats will most likely not be quantitative, it can give a clear indication of which alternative presents greater short-term threats, and can help determine if remedial action will provide the necessary long-term benefits to the site.

7.3. Development of PRGs. Preliminary remediation goals (PRGs) for aquatic systems may be derived by sorting and screening site-specific data on chemical concentration and co-occurring bioeffects in a manner analogous to the derivation of ER-Ls, threshold effects levels (TELs), and AETs. Remedial levels may also be derived by performing the HQ calculation in reverse by rearranging the terms in the terrestrial or aquatic HQ equations.

7.3.1. For calculation of a medium-specific PRG, the HQ is set equal to an acceptable level (e.g., HQ = 1), the exposure route-specific intake factors developed during the ERA are applied, and the chemical concentrations associated with the ingestion factors and HQs are calculated.

7.3.2. PRGs are receptor-and chemical-specific. They should be based upon all key receptors and all significant exposure pathways assessed in the ERA for that medium. However, since the pathways resulting in the highest degree of risk will most greatly influence the PRG, exposure pathways that have minimal contribution to overall risks can be excluded from the remedial level development with little or no impact.

7.4. Development of Remediation Levels. Remediation (remedial) levels, which are not synonymous with PRGs, are media-specific chemical concentrations that are associated with acceptable levels of chemical exposure for the site-specific ecological receptors. Remedial levels, also referred to as target cleanup levels, are considered along with other factors, such as ARARs, in identifying chemical concentrations to which impacted media may need to be remediated in order to achieve acceptable risk. Remedial levels differ from PRGs in that site-specific factors are considered.

7.4.1. PRGs may be developed as a screening level tool prior to the performance of an RI. Conversely, remedial levels are developed from the site-specific BERA, conducted during the RI. Remedial levels are just one element of the weight of evidence the risk assessment can provide to the risk manager to assist in remedial decision-making. Some regulatory agencies recommend including the development of remedial levels as part of the BERA in order to assist the risk manager in the decision-making process.

7.4.2. Establishing remediation levels is not without problems. If the only line of evidence available is comparison of site concentrations to conservative benchmarks or TRVs (e.g., HQ method), establishing the need to remediate is confusing, as HQs are not measures of risks (see Section 5.3.3.). The comparison may show that exposures are greatly exceeding TRVs (e.g., HQ much greater than one), yet indications of risks may not be present in the field. Some have attached descriptors to HQs indicating various levels of concern (i.e., an HQ between 1 and 10 is identified as a small potential for risks), however, HQs are not linear measures, and an HQ of 10 is no more indicative of actual impacts than is an HQ of 1. Recent procedures developed by the USEPA have applied

the “rule of five,” which balances remedial decisions to the concentrations between a NOAEL-based benchmark and a LOAEL-based benchmark. This, too, is not without controversy, as laboratory studies of toxicity may not clearly translate to actual adverse effects the field. Generally, if the only line of evidence is an HQ, establishing remedial goals is not advisable.

Chapter 8
Risk Management

8.1. Introduction. The NAS defines risk management as "a process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision" (NAS 1983). NAS has identified four key components for managing risk and resources: public participation, risk assessment, risk management, and public policy decision-makers (NAS 1994). Risk characterization is considered the "bridge" or "interface" between risk assessment and risk management. USEPA recommends that risk characterization should be clearly presented and separated from any risk management considerations. USEPA (1995c) policy indicates that risk management options should be developed using risk input and should be based on consideration of all relevant factors, both scientific and non-scientific.

8.1.1. Consistent with NAS, USACE has developed the HTRW risk management decision-making (RMDM) process. This process identifies factors to consider when making decisions, developing and recommending options, and documenting of risk management decisions (Figure 8-1, 8.2). The process establishes a framework to manage risk on a site-specific basis. It emphasizes that risk management must consider the strengths, limitations and uncertainties inherent in the risk assessment; the importance of public and other stakeholders' input; and other non-risk factors.

8.1.2. Risk and uncertainty are important factors to be considered in RMDM (USEPA 1991a, 1995c). Other factors, including the customer's and stakeholders' concerns, cost, schedule, value of resources to be protected, political, and technical feasibility are also to be considered before selecting the best option for a project decision. The consideration of risk is critical, since site actions are driven by statutes and regulations, which explicitly require the "protection of human health and the environment".[21] Therefore, selecting the proper risk tool and collecting data to assess environmental risk is a primary responsibility of the PM and the risk assessor.

8.1.3. The HTRW risk management decision-making process can be represented by the following equation, with many variables contributing to the final decision:

$RM = f(X_1, X_2, X_3, X_4....X_N)$

where,

RM = Risk Management Decision

f = Function of

X_i = Input variables (e.g., risk and uncertainty)

[21] Examples of these requirements are 40 CFR 300.430(e)(1) of the NCP for deciding if remedial action is needed for a CERCLA site.

8.1.4. In addition to risk and uncertainty, there are many non-risk variables influencing the risk management decision. The major ones are cost, schedule, value of resources to be protected, competing priorities among sites managed by the customer, economic, compliance/regulatory, political, and technical feasibility. A relatively sensitive political and/or economic factor to be considered is "Environmental Justice or Equity". This phrase relates to the government's initiatives to cleanup sites located in "poor and disadvantaged" areas.

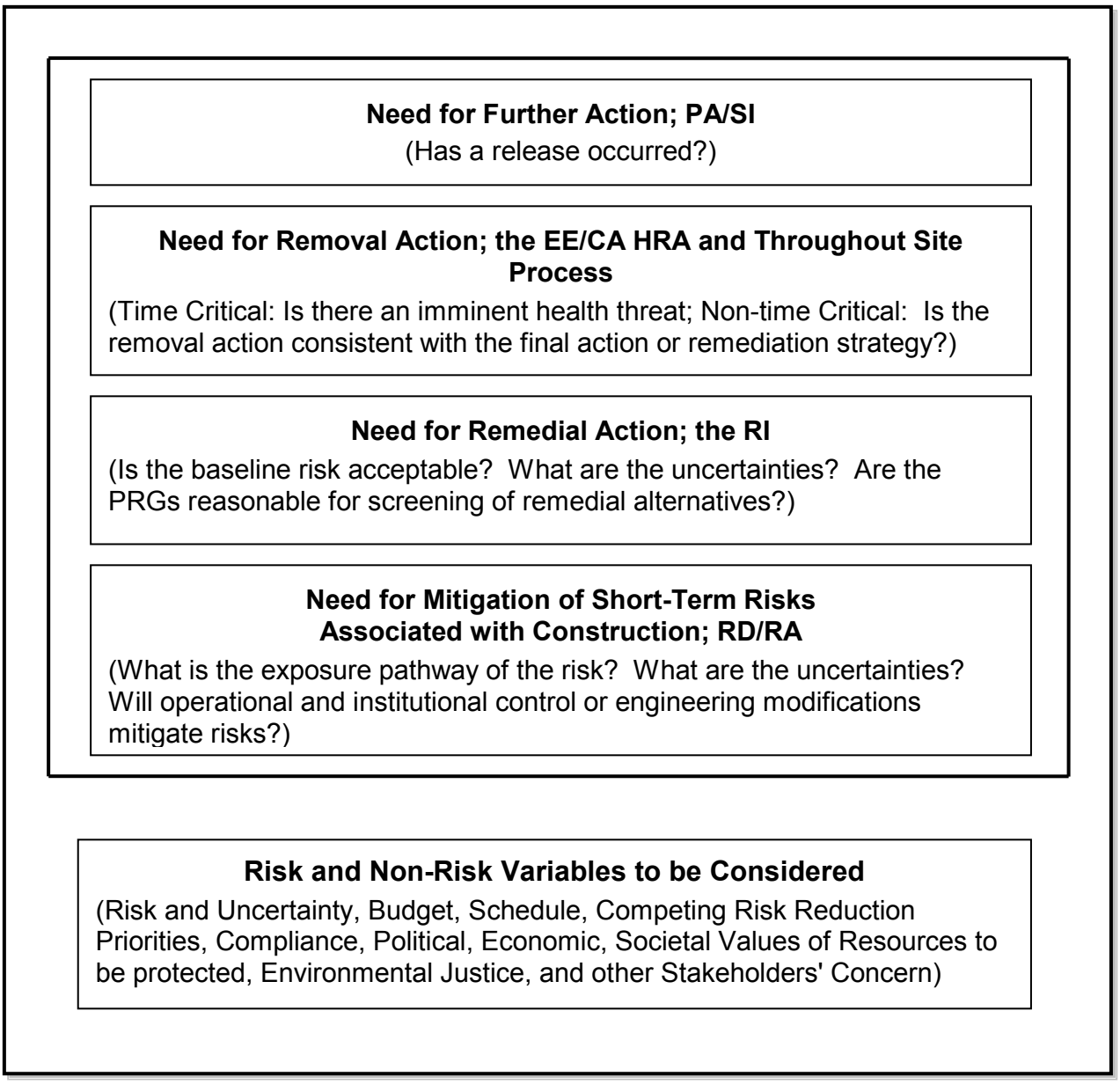

Figure 8-1. Inputs for Risk Management Decision-Making HTRW Project Decision Diagram.

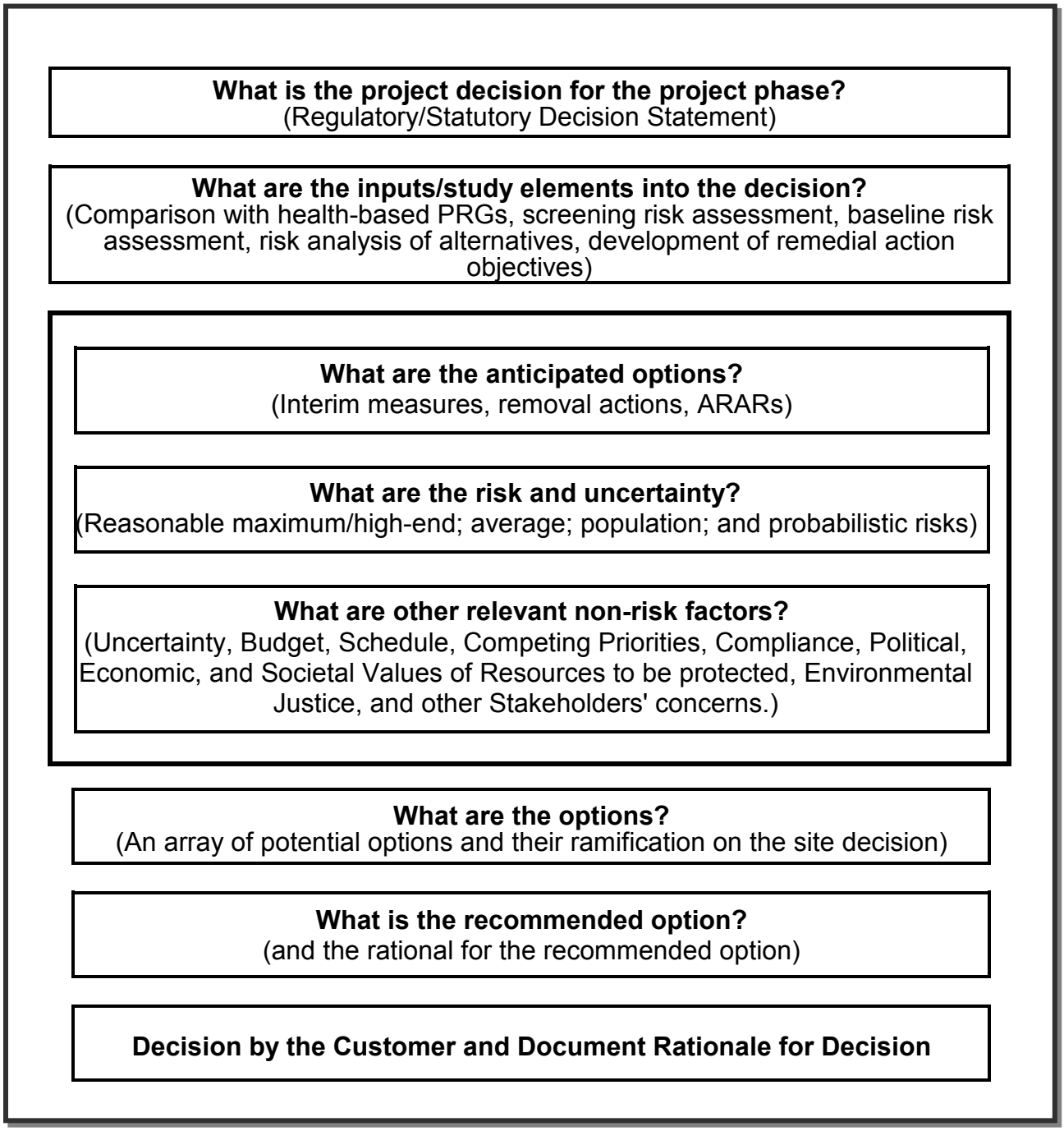

Figure 8-2. HTRW Risk Management Decision-Making Process Flow Diagram

8.1.5. The risk assessment, in conjunction with other important "non-risk" decision criteria, provides information on the need for remedial or early actions. Therefore, a clear understanding of the risk assessment results and their uncertainties is essential. Informed risk management decision-making will lead to protection of human health and

the environment; cost saving; meeting the agreed schedule; political harmony; better management of resources; and other social and economic benefits. The HTRW RMDM process is consistent with recent initiatives by various USEPA officials: Habicht (USEPA 1992d); Denit (USEPA 1993h) and; Browner (USEPA 1995a), USDOD (1994a), and various proposed legislations by the 104th Congress (e.g., Dole-Johnston Bill (S-343) and HR 1022) that suggest the need for risk reduction based on "real world" or realistic risk assessment, cost benefit analysis, and prioritization of environmental issues. The HTRW risk management decision-making paradigm (Figure 8-3) presents an overview of this process.

8.1.6. Prior to gathering data and performing the ERA, the PM defines the site decision for the project phase, the required study elements (types of ERA or risk tools to be used), and the potential uncertainties associated with the outputs of the study element. Based on risk information and other considerations, the customer can select from an array of recommended risk management options. Options can include gathering additional data, recommending no further action, interim measures, or removal and/or remedial actions. To facilitate RMDM, the USACE PM should anticipate potential risk management options early in the project planning phase. Examples of the use of risk assessment in various project phases include:

a. PA/SI: A screening risk assessment, environmental mapping, and an exposure pathways analysis may be performed to determine the need for further investigations.

b. RI (prior to FS): The baseline ERA determines the need for the remedial action.

c. FS: Results of the ERA are used to develop preliminary remedial goals (i.e., chemical concentrations which pose acceptable hazard or ecological effects).

d. FS: Qualitative or quantitative risk assessments to compare and evaluate potential ecological impacts from the remedial alternatives. A qualitative or simple quantitative risk assessment (like those used in the baseline ERAs) may be conducted to screen alternatives for their potential short-term and residual risks.

e. RD (prior to conducting RA): Detailed risk analysis may be performed to determine if protective measures should be taken to minimize the impact to health and the environment during remediation. For example, a toxicity assessment may be conducted to evaluate the short-term acute, subchronic and chronic ecotoxicities of potential releases from the remediation process. A hazard-response assessment should also be conducted to determine the design measures to reduce the impact of non-chemical stressors, e.g., habitat alteration and destruction, siltation, or other physical or chemical changes in the environment caused by construction of the remediation.

8.1.7. This section describes how the results of risk assessment procedures are to be used in risk management decision-making. The decisions include the need for further investigation, removal and remedial actions, selection of remedy, and provision of measures for designing removal or remedial actions that are protective of the environment (Figure 8-1). Information provided by the risk assessment is a key for selecting risk management options. Further, potential removal or remedial alternatives

should be evaluated and compared according to their effectiveness to reduce site risks, and any associated short-term risks posed by implementation of the alternatives.[22]

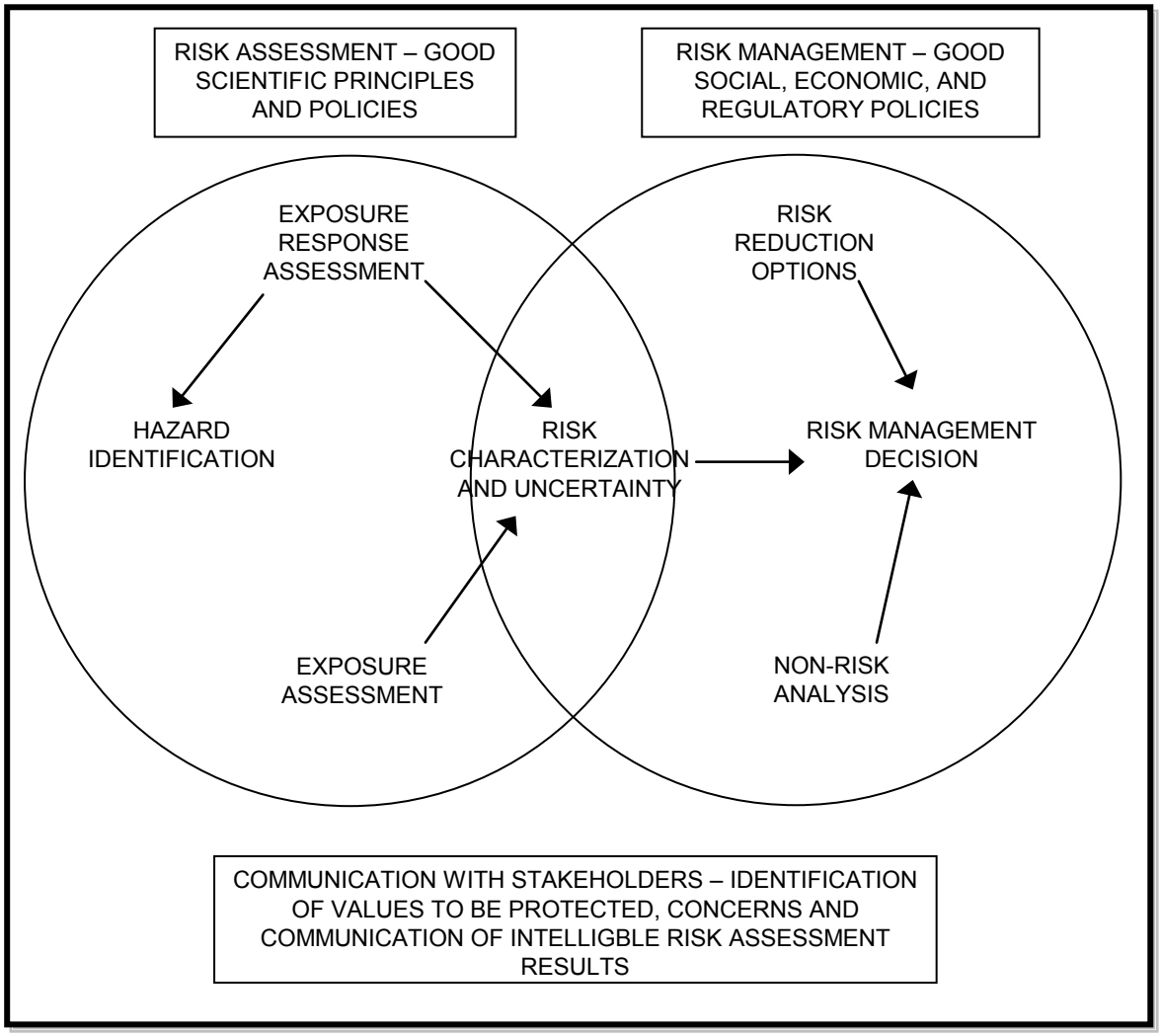

Figure 8-3. HTRW Paradigm for Risk Management Decision-Making.

[22] This chapter does not address comparative analyses of other environmental risks, i.e., risks from radon gas, cigarette smoking, exposure to ultra violet light due to stratospheric ozone depletion, ingestion of pesticide contaminated food products, etc. These risks, although they may be significant in terms of the total risk posed to human receptors at a Superfund or RCRA site, are not related to HTRW site response actions and are considered background risks which are addressed by other environmental laws and policies. This chapter, however, does address the importance of risk assessment inputs in setting priorities for resource management with respect to environmental cleanup under RCRA and CERCLA. In making site risk management decisions, the project manager should be familiar with the statutory language/limitations regarding the application of funds under the defense environmental restoration account (DERA), BRAC, and other HTRW response actions.

8.1.8. It is important to recognize that risk managers often make difficult decisions with considerable uncertainties in both risk and non-risk information. Therefore, a focused and balanced risk approach is recommended that recognizes the reasonable limits of uncertainty for the protection of human health and the environment as the primary consideration, along with the considerations for non-risk issues. The risk manager should clearly communicate the decision and the associated assumptions, and document the basis for the decision. This chapter is organized to present the following information:

8.1.9. Paragraph 8.2 describes how risk information can be used to support project decisions at various project phases (e.g., determining whether the project should proceed to the next phase or to site closeout). The section highlights key non-risk considerations and emphasizes the importance of integrating the ERA results and uncertainties into an overall risk management decision.

8.1.10. Paragraph 8.3 discusses the design considerations for implementing an overall site remediation strategy. Such a strategy considers issues such as off-site source areas, current and future land uses, compliance with chemical and site-specific ARARs (USEPA 1989l) and verification of cleanup.

8.2. Determining Requirements for Action. The fundamental requirement associated with any HTRW response action is the "protection of human health and the environment". This requirement focuses on the acceptability of site risks from the potential actions. Section 300.430 (d) and (e) of the NCP (USEPA 1990a) require a baseline risk assessment or environmental evaluation to be performed to assess threats to the environment. Risk management options are exercised in key phases of the HTRW project life cycle (see Table 8-1). Risk information required to support a decision is presented below:

8.2.1. *Preliminary Assessment/Site Inspection.* The purpose of PA/SI under CERCLA is to identify if chemical releases have occurred, or if the site can be eliminated from further action. The PAs are typically performed by the State, USEPA, or the federal agency, and are generally preliminary in nature. Under some circumstances, federal agencies may perform these activities with greater depth and vigor under Executive Order 12580. Unless good evidence exists that a site is contaminated, it is a crucial for the PM to methodically review each identified site, area of contamination, and AOC, and decide if these units should be eliminated from the next project phase. In addition, it may be important to determine if an environmental threat or a substantial site risk potentially exists that would require an early response action (e.g., non-time critical removal actions or interim remedial action).

8.2.1.1. *Actual or Potential Release/Exposure.* Under the PA/SI phase, the risk management decision will be based on documented past spills and releases, the likelihood of such spills/releases, the presence of endangered or threatened species, sensitive environments or resources to be protected, and the existence of transport mechanisms that could bring the chemicals in contact with these receptors.

8.2.1.2. *Potential Natural Resource Damage Assessment Action.* Under CERCLA Section 104(b)(2) and 107(f)(2)(C), the lead agency for clean-up (e.g., USD0D, USEPA) must notify appropriate Federal and State trustees of natural resources for any discharges or releases that may have injured natural resources under their jurisdiction. The project manager is responsible for coordinating all response activities with the natural resource trustees. The project manager should also consult with the U.S. Department of the Interior (USDOI) (i.e., USFWS), the Department of Energy (USDOE), or Department of Commerce (USDOC) where a discharge or release may adversely affect an endangered or threatened species or result in destruction or adverse modification of the habitat of such species. The trustees are responsible for assessing damages (i.e., monetary compensation) and presenting a "demand in writing for a sum certain" to the potentially responsible parties. Although the PA/SI is an early project phase and the potential for a NRDA action may not be known, the project manager and the risk assessor should be cognizant of the potential when reviewing site history and background information. Any findings with potential implications for NRDA uncovered in this process should be provided to the customer and its legal counsel. This is recommended because the customer's goals for site closeout may be different upon further review of the potential for NRDA. By coordinating and working with Federal co-trustees, an overall remedial action (which might include restoration or mitigation) can be devised which will reduce an installation's NRDA liability.

8.2.1.3. *Risk Screening and Prioritization of Units of Concern.* Initial risk screening is an important tool for ranking or prioritizing units (OUs). This tool can result in substantial savings of resources, allowing the implementation of a more focused site investigation. The risk screening results are likely to provide significant inputs into the risk management decision-making for this project phase.[23]

8.2.1.3.1. It is not uncommon to have tens or hundreds of "sites" within a site or facility boundary. Risk managers at these facilities are faced with potentially complex investigations. Rather than taking a "piece meal" approach of investigation, the list of sites should be pared down if possible. The risk manager may negotiate with the agencies and enter in the Interagency Agreement (IAG) or Federal Facility Agreement (FFA) to permit the use of an approach that "addresses the worst sites first," and at the same time, group OUs within the same ecological receptor exposure units or geographical locations, as appropriate. This prioritization should result in the greatest

[23] USEPA's Deputy Administrator (1994a) is concerned with the need for ensuring consistency while maintaining site-specific flexibility for making remedial decisions (from site screening through final risk management decisions) across programs. USEPA stresses that priority setting is reiterative throughout the decision-making process because limited resources do not permit all contamination to be addressed at once or receive the same level of regulatory oversight. USEPA suggests that remediation should be prioritized to limit serious risks to human health and the environment first, and then restore sites to current and reasonably expected future uses, whenever such restorations are practicable, attainable, and cost effective. USEPA further suggests that in setting cleanup goals for individual sites, we must balance our desire to achieve permanent solutions and to preserve and restore media as a resource on the one hand, with growing recognition of the magnitude of the universe of contaminated media and the ability of some cleanup problems to interact with another.

environmental benefit with limited available resources. Site prioritization should include the following:

a. Eliminate sites administratively by record review (including ascertaining if endangered or sensitive species/environment or valued resources are present on site), and/or interviews with current and former workers.

b. Conduct a site reconnaissance and group sites with common exposure pathways or exposure units, if appropriate.

c. Rank the remaining sites or groups of sites qualitatively or quantitatively based on the ECSM or a screening risk analysis.

8.2.1.3.2. Generally, the above tools will serve well if they are objectively and uniformly applied. The use of site prioritization:

a. Provides justification for No Further Action (NFA) for low priority sites.

b. Allows better resource allocation for investigation of the remaining sites.

c. Provides the opportunity to develop ECSMs to guide data collection (see Chapter 3).

d. Helps identify potential boundaries where the ecological receptors of concern are to be protected.

e. Identifies high priority sites for non-time critical response actions.

8.2.1.3.3. USDOD's (1994) *Relative Risk Site Evaluation Primer* recommends evaluation based on three criteria: (1) contaminant hazard factor; (2) migration pathway factor; and (3) receptor factor (Figure 8-4). Information generated from the initial ecological risk screening can be used as a decision-making basis using a similar site ranking process. Sites may be ranked high, medium or low based on non-quantitative exposure pathway considerations such as the following:

a. Significant Contaminant Levels

(1) High Relative Risk: Sites with complete pathways (contamination in the media is moving away from the source) or potentially complete pathways in combination with identified receptor or potential receptors;

(2) Low Relative Risk: Sites with confined pathways (i.e., contaminants not likely to be release or transported) and limited potential for receptors to exist; and

(3) Medium Relative Risk: Sites with characteristics not indicated in the above.

b. Moderate Contaminant Levels

(1) High Relative Risk: Sites with complete pathways or potentially complete pathways in combination with identified receptor; or sites with complete pathways in combination with potential receptors;

(2) Low Relative Risk: Sites with confined pathways and any receptor types (i.e., identified, potential, or limited potential), or sites with potentially complete pathways in combination with limited potential for receptors to exist; and

(3) Medium Relative Risk: Sites with characteristics not indicated in the above.

c. Minimum Contaminant Levels

(1) High Relative Risk: Sites with complete pathways in combination with identified receptor;

(2) Medium Relative Risk: Sites with potentially complete pathways in combination with identified receptor or sites with evident pathway in combination with potential receptors; and

(3) Low Relative Risk: Sites with characteristics not indicated in the above.

8.2.1.3.4. The relative risk site ranking process may also be modified to include consideration of the degree of confidence in the relative risk rating. Sites with a low degree of confidence and a low relative risk may then be given a higher rating than sites with a high degree of confidence and a low degree of risk.

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Table 8-1.
The Potential Use of Risk Assessment Concepts/Procedures as a Risk Management Tool.

Project Phase	Objectives	Risk Management Options	Product/Deliverable
PA/SI	Should the site be eliminated from further evaluation? Identify sites with no release or insignificant release Site ranking/prioritization Need for Removal action Need for RI	NO FURTHER ACTION (NFA); LIMITED SAMPLING/VER.; STAB, REMOVAL, RESP; LIMIT SCOPE OF RI; PHASED RI SAMPLING	chemical fate and transport properties; toxicity assessment (chemicals not expected to pose an ecological concern; environmental mapping (sensitive receptors and food source identification); and exposure pathway analysis/food web and use of ECSM; land use assessment
RI	Does the site pose an ecological risk? Need for FS	NFA; MONITORING; INTERIM REMEDIAL ACTIONS; CONDUCT FS	baseline risk assessment - comparison with published criteria or benchmark toxicity values - toxicity-based ERA to assess stress-response relationship
FS	Preliminary Remediation Goals Select remedial alternatives	REMEDIAL ACTION OBJECTIVES; ON-SITE/OFF-SITE MANAGEMENT; NFA; MONITORING	development of site-specific PRGs or benchmark toxicity values assessment of short-term risks from remedial alternatives
RD/RA	Protective control measures/remedy	EFFECTIVENESS AND DESIGN BASIS FOR CONTROLS TO REDUCE SHORT-TERM RISKS	comparison with short-term acute risk levels; exposure pathway analysis identification of impact areas, traffic patterns, and discharges
Delisting/ site closeout	Residual risks/5-year review, permit review	NFA; MONITORING; RA; ADDITIONAL FS AND RD	land use/pathway analysis comparison with PRGs or RAOs provide justifications for meeting cleanup objectives or technical impracticability

Legend:
Technical Impracticability = Technology not practical, e.g., remediation of groundwater aquifer contaminated by Dense Non-Aqueous Phase Liquids (DNAPL);

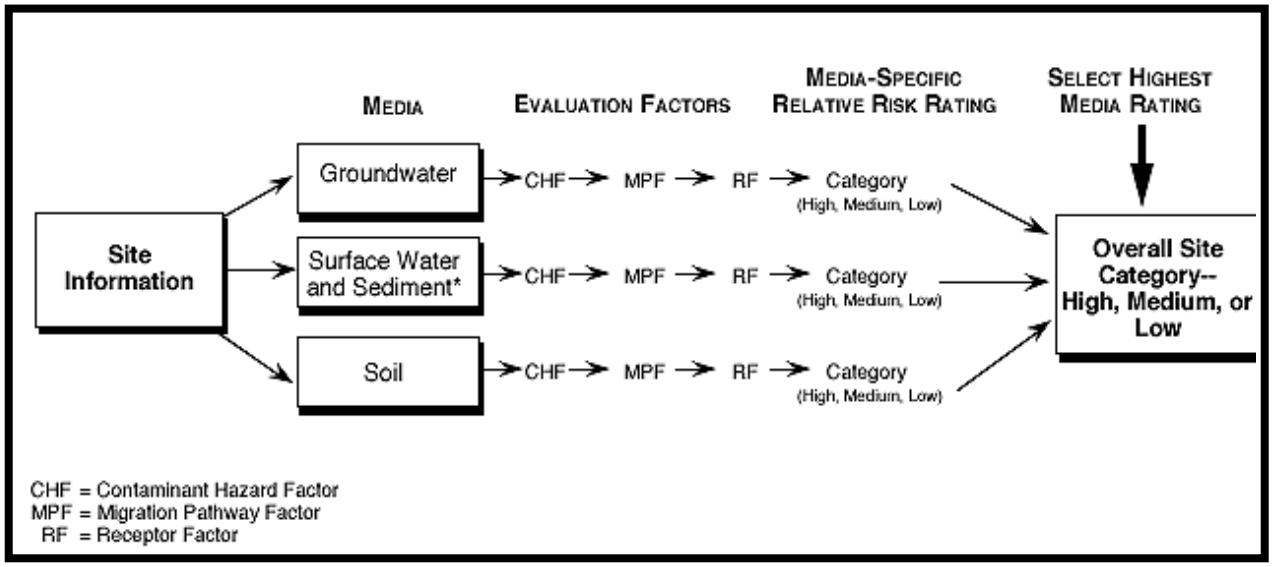

Figure 8-4. Flow Diagram of Relative Risk Site Evaluation Framework.

8.2.1.4. *Risk Management Decisions and Options.* Risk management decisions, risk information needs, risk assessment tools to satisfy the information needs, and risk management options are presented in this section. ("Non-risk" factors to be considered in the decision-making are presented in Paragraph 8.2.4.)

Risk Management Decision

Should a site be eliminated from further investigation in the RI project phase?

Risk Management Options/Rationale

Further Evaluation Needed

Rationale: If a site cannot be justified for NFA, further evaluation (Expanded SI; Extent of Contamination Study; RI) will be needed.

No Further Action (NFA)

Rationale:

a. Environmental mapping, functional group characterization, database search published lists from natural resources agencies indicate that endangered species are not present, and there are no sensitive environments or valued resources on and nearby the site.

b. No knowledge of documented releases or major spills/low likelihood of spills/procedures existed to promptly cleanup all spills.

c. Transport mechanisms do not exist, e.g., presence of secondary containment.

d. The substances released are not expected to be present due to degradation and attenuation under the forces of the nature.

e. Spills or releases have been addressed by other regulatory programs (e.g., the Underground Storage Tank program or RCRA closure under Subpart G of 40 CFR 264 or 265).

f. The unit does not meet the definition of a "SWMU."

g. The unit is part of another identified unit or site, which will be addressed separately.

8.2.1.4.1. Although risk assessment is traditionally performed in the RI phase of HTRW response actions, risk assessment can assist the risk managers in all project phases. Results of risk assessment activities are used to answer three key questions: 1) whether or not there is a need to go forward with the next project phase, 2) whether or not early response actions (removal actions, interim measures, or interim remedial actions) should be taken to mitigate potential risks, and 3) effectiveness of the potential response action and the short-term risks associated with implementation of the removal actions.[24] Providing an understanding of the usefulness of risk assessment in the HTRW removal phase is the focus of this section.

Risk Management Decision

Should early response action be undertaken to mitigate risk?

Risk Management Options/Rationale

No Early Response Action

Rationale:

a. No imminent endangerment to ecological receptors of concern; lack of food sources to support or attract ecological species, lack of endangered species or sensitive environment/valued resources, low likelihood of exposure by the receptors. (Uncertainty for the determination is related to thoroughness by the record search, visual observation, or purposive limited sampling.)

b. Transport mechanisms probably do not exist, e.g., presence of secondary containment.

[24] Removal actions must be flexible and tailored to specific needs of each site and applicability i.e., complexity and consistency should be used in evaluating whether non-time critical removal actions are appropriate. Examples of removal actions are: (1) sampling drums, storage tanks, lagoons, surface water, groundwater and the surrounding soil and air; (2) installing security fences and providing other security measures; (3) removing and disposing of containers and contaminated debris; (4) excavating contaminated soil and debris, and restoring the site, e.g., stabilization and providing a temporary landfill cap; (5) pumping out contaminated liquids from overflowing lagoons; (6) collecting contaminants through drainage systems, e.g., French drains or skimming devices; (7) providing alternate water supplies; (8) installing decontamination devices, e.g., air strippers to remove VOCs in residential homes; (9) evacuating threatened individuals, and providing temporary shelter/relocation for these individuals (*Superfund Emergency Response Actions*, USEPA 1990c). Items (3) through (5) could be used to reduce exposure to ecological receptors of concern.

c. Low concentration of site contaminants or the levels measured probably do not pose an acute hazard, and it is questionable whether the levels pose unacceptable chronic risk or hazard.

d. There is no anticipated risk of stress or physical hazards.

e. Site contaminants are not likely to be persistent or the contaminants are relatively immobile.

Early Response Action

Rationale:

a. There is no current impact, but if uncontrolled, the site could pose a substantial threat or endangerment to humans or the environment. (Examples are: physical hazard, acute risk from direct contact of the unit or site, or effluents or contaminated media are continuously being discharged to a sensitive environment, e.g., a spill that could impact salmon spawning, egg hatching, or survival of fry.)

b. The principal threat has reasonably been identified because of the evidence of adverse impacts. In this context, the contaminants of ecological concern (COECs) are known and the exposure pathways are judged to be complete, e.g., the exposure point or medium has been shown to contain the COECs.

c. Due to the slow rate of degradation, excretion, or depuration, the potential COECs may pose a threat to the food web via bioconcentration and biomagnification.

d. The boundary of contamination is reasonably well defined, so that removal action(s) can be readily implemented.

e. There is a potential risk to ecological receptors or valued resources and the removal or early response actions have been demonstrated to be highly effective in reducing exposure to ecological receptors of concern, although candidate removal actions may differ in terms of cost and magnitude of risk reduction achieved.

f. The early actions are consistent with the preferred final remedy anticipated by the customer, reducing risks to both human and ecological receptors.

g. The response action will be used to demonstrate cessation or cleanup of releases, resulting in substantial environmental gain which is the basis for early site close-out or further investigation.

h. If removal actions are justified (e.g., addressing hot spots or high concentration plumes discharging to a receiving body of water with sensitive aquatic species, food chain or valued resources), the removal actions will then be evaluated for their potential short-term risks and hazards, based on ECSM developed for the specific removal actions.

i. A high likelihood of releases and transport of site contaminants to the ecological receptors of concern, e.g., runoff from the site is expected to reach a receiving body of water containing endangered species or valued resources.

j. High concentration (acute hazard level) of site contaminant is found in the exposure medium.

k. Highly toxic chemicals or highly persistent and bioaccumulative chemicals found on-site which may be transported off-site.

l. Documented unacceptable sediment, soils, surface water or groundwater seep contamination in media that could be contacted by endangered species.

m. Ecological impacts have been observed due to volume of the release and the habitat destruction of valued resources.

n. A high risk of physical hazards or stress to the environment.

o. The exposure pathway(s) for ecological species was one of reasons for the basis for NPL listing or ongoing enforcement actions on spills or releases.

p. Non-complex site (no cost recovery issue, limited exposure pathways, small area sites, etc.)

8.2.1.4.2. Early response actions or removal actions, consistent with the final remedial action, may be taken to prevent, limit or mitigate the impact of a release. To encourage early site closeout or cleanup, USEPA has encouraged early response actions at sites where such actions are justified. To the extent possible the selected removal actions must contribute to the efficient performance of long-term remedial actions. USEPA's *RCRA Stabilization Strategy* (USEPA 1992h) and *Superfund Accelerated Cleanup Model* (SACM) (USEPA 1992i) emphasizes controlling exposure and preventing further contaminant migration. While these concepts are intended to expedite site actions, risk assessment provides important information for justifying cleanup actions. The applicable risk assessment methods include:

a. Environmental mapping/functional group assessment,

b. Exposure pathway analysis; development of ECSM,

c. Identifying short-term (acute) benchmark toxicity values for screening site data,

d. Qualitative evaluation of removal actions for their effectiveness to reduce exposure to ecological receptors, and

e. For complex sites (sites with multiple pathways, without ARARs, large geographic areas, and with a need for cost recovery), activities to support a baseline ERA may be appropriate.

8.2.1.4.3. In order to allow input for the removal actions, the risk assessment should be conducted in a timely manner. As an initial and highly conservative screening tool, comparison of worst-case exposure point concentrations can be compared with short-term (acute or subchronic) ecological benchmark values. Such risk evaluation should be qualitative, simple, and concise.

8.2.1.4.4. Early actions or accelerated cleanup can often be justified as long as the actions are consistent with the preferred site remedy. Since remedies are generally not selected until late in the FS, the customer's concept of site closeout and anticipated action is critical for deciding which types of early actions are appropriate. Based on experience gained in the Superfund program, USEPA has identified certain site types where final remedies are anticipated to be the same (presumptive remedies). The current list of presumptive remedies includes:

a. Municipal Landfill – capping and groundwater monitoring,

b. Wood Treatment Facility – soil and groundwater remediation,

c. Groundwater contamination with VOCs – air stripping/capture wells, and

d. Soil contamination with VOCs – soil vapor extraction.

8.2.1.4.5. Additional presumptive remedies are being developed by USEPA Region 7 for PCB sites, manufactured gas plants and grain fumigation silos. USEPA is continuing to identify site types for which early actions are likely to result in substantial environmental benefits. However, it should be noted that certain sites are not conducive to early actions based on ecological concerns. Examples can include where: current and future land use is highly industrial; there is a lack of food sources on site or nearby the site for the ecological receptors of concern; there is low or generally low level, wide-spread contamination; spilled or released substances are not bioavailable; contaminants have short halve-lives or are anticipated to degrade rapidly under natural conditions; there is a lack of viable environmental transport media (highly arid regions).

8.2.1.5. *Qualitative Evaluation of Response Actions for Their Effectiveness to Reduce Risks.* Removal of hot spots can sometimes provide substantial improvements in the site environment. In some cases, actions can reduce exposure to receptors drastically, and allow natural attenuation to further reduce exposure point concentrations. If removal actions are needed, the risk manager should request two types of risk information. First, if there is more than one removal option, what is the comparative effectiveness of the options to reduce exposure and risks? Second, what is the risk or environmental impact associated with the proposed removal action? To answer the first question, the HTRW risk assessor or risk manager provides information on how the removal option can reduce risk or reduce the level of exposure both on-site and off-site, if contaminant migration has occurred to off-site exposure points. If substantial risk reduction can be obtained by all options, the risk manager should consider other factors, such as effectiveness, reliability, etc. To answer the second question, the project engineer estimates the destruction or treatment efficiency of the medium to be treated or disposed, and the type/quantity of wastes or contaminated debris to be generated for each potential option. This information is important if an action is likely to generate waste or damage sensitive environments in the course of the remediation.

8.2.1.5.1. It is important to communicate and obtain an early buy-in of the removal action from the local community. If the proposed removal actions are likely to pose unacceptable short-term risks to on-site or off-site ecological receptors, the removal

action should either be discarded or monitoring/control measures be instituted. (As discussed later, the risk assessor and HTRW technical project planning team members provide options for making decisions when there are divergent interests between the protection of humans and the protection of ecological receptors of concern.) The risk assessor should work with other project team members to evaluate the potential for chemical releases or habitat destruction potentially associated with a remedial option. These evaluations should be qualitative and not extensive, and can be based on a consensus of professional judgment/opinion. These individuals should recommend alternatives or precautionary/protective measures to the risk manager to mitigate any potential risks.

8.2.2. *Remedial Investigation.* The primary objective of the RI or other equivalent HTRW project phases is to determine if site contamination could pose potentially unacceptable human health or environmental risks. Determination of unacceptable risk, according to the NCP, is identified through a baseline risk assessment under "Reasonable Maximum Exposure".

The ERA associated with the RI project phase can assist the risk management decision-making process in the following ways:

a. The ERA presents the degree of site risk posed to ecological receptors and the associated uncertainties. Risks are generally assessed based on individual effects, although effects on populations and communities may be studied, as required.

b. Results of the ERA can be used to answer questions relating to the site decisions on: 1) whether sufficient information exists to confidently eliminate a site as posing no significant risk or there is a need to proceed to the next project phase; and 2) whether or not removal actions are still appropriate and should be implemented to mitigate potential ecological risks.

c. If a site poses unacceptable acute or chronic hazard to ecological receptors, remediation will be needed for the significant exposure pathways. Pathways which do not pose an unacceptable risk may be eliminated from further concern. Algorithms developed in the ERA can be used in reverse to develop site-specific environmental-based preliminary remediation levels in the FS.

d. If removal actions are still appropriate and are to be implemented, the short-term impact of such actions should be evaluated.

Risk Management Decision

Should remedial action be required based on the baseline ecological risk?

Risk Management Options/Rationale

Further Evaluation Needed

Rationale: The ERA indicates unacceptable risk or the risk cannot be confidently established, and therefore the customer has weighed all options and determines the uncertainty associated with the ERA should be reduced. Further evaluation and/or data

evaluation is needed to reduce uncertainty and determine ecological risk. Since risk assessment is an iterative process, data used to support the risk estimates should be critically reviewed by the PDT. The review may lead to the need for additional data to more fully characterize potential risk. Alternatively, the PM may ask for a more detailed analysis of uncertainties so that the decision for remedial action can be made.

Undertake Interim Response Action

Rationale: Action is based on finding of unacceptable risk to ecological receptors, after giving consideration to the uncertainties associated with the ERA. The selected interim remedial action or interim measure should be part of, or is consistent with, the final anticipated remedy.

No Further Action (NFA)

The rationale for no action based on the ERA could be any (or a combination) of the following:

a. Documentation that endangered species or sensitive environments are not going to be impacted by the site due to the lack of complete exposure pathways, or the impact is judged to be insignificant or acceptable by the risk assessor and/or expert ecologist(s)/advisory panel such as BTAG/ETAG.

b. Lack of habitat or food sources to support the ecological receptors of concern and potential off-site migration of site-related COECs to any nearby habitats or food-webs of concern is negligible, or site land use will remain industrial/commercial based on stakeholder's inputs.

c. The HQ is below unity or ten, as appropriate, based on uncertainty of the toxicity data (or the frequency of exceedance of this point of departure value is low), given the uncertainty inherent in the ERA involving multiple surrogate or indicator species (measurement endpoints).

d. An existing ERA has been revised, reflecting that removal actions or interim measures taken have substantially reduced the exposure to the level that the estimated risks are acceptable.

e. The potential environmental risk or injuries associated with any and all remediation is greater than the baseline risk (i.e., further efforts should be expended to find a suitable remedial action or viable alternatives, such as off-site mitigation, restoration, or compensation).

f. With source control in place, given natural attenuation of the COECs (based on fate and transport properties), risk is expected to be short-term, and remediation is judged to be cost-prohibitive.

g. There could be marginal risks, however considering uncertainties, the potential incremental gain does not justify the action.

h. No practical remedial action objectives or target cleanup levels can be established to sufficiently document risk or such levels would be highly uncertain and the environmental gain cannot be readily measured.

i. Potential remedy will cause substantial economic or scenic damage and is not consistent with the public and stakeholders' goals and objectives.

j. Interim remedial action has removed the migration/transport mechanisms to impact ecological receptors.

k. Site contaminants are not likely to ever pose unacceptable risk as they are not persistent or the contaminants are relatively immobile and not bioavailable.

Remediation/Removal Action Required

a. The requirements for removal action taken at the RI/FS project phase is the same as that described under Paragraph 8.1. above. Upon completion of RI/FS (and before signing of the Superfund Records of Decision), a decision will be made whether remedial action should be required. If there are site ARARs, such as State water quality standards, remediation will be required unless an ARAR waiver is successfully completed. From the risk assessment standpoint, if the baseline ERA is valid and the uncertainty deemed to be acceptable, requirements for remediation for part of, or the entire site, will be based on the following considerations:

b. Endangered species or sensitive environments/valued resources such as viable wetlands or wildlife refuge, could be impacted by the site, and the estimated risk is judged to be significant or biologically relevant.

c. There is viable habitat and sufficient food sources to sustain the ecological receptors of concern.

d. The COECs are persistent or bioaccumulative and will potentially impact ecological receptors of concern.

e. The site poses an unacceptable risk.

f. The environmental risk associated with the remedial action is acceptable.

g Short-term impacts from remediation, although potentially severe, are not permanent and outweigh the alternative of long-term, chronic exposure.

h. COECs are persistent and expected to pose a long-term threat to the ecological receptors of concern.

i. The RAO or target cleanup level (TCL) is based on a reliable or adequately characterized exposure-response relationship and is practical for use to verify cleanup and the environmental gain is measurable.

j. There is a low potential for recovery without removal or remedial actions.

k. Remediation is consistent with the stakeholders' goals and objectives.

8.2.2.1. *Risk Characterization/Uncertainty Information for Risk Management Decision Making*. The sources of uncertainty in a baseline ERA were presented in Chapter 6. The objective of the risk characterization and uncertainty analysis is to make the ERA transparent to the risk managers and the stakeholders so that informed risk management decisions can be made. Given proper early project planning, it is expected that uncertainties will be acceptable to the risk managers and other stakeholders, including the BTAG members and other independent expert ecologists. The risk manager can balance his or her selection of options with the findings of the risk assessment and the degree of uncertainty in mind.

8.2.2.1.1. From the risk manager's perspective, the baseline ERA should adequately present risk estimates in an objective and unbiased manner. The PM understands that although the risk assessment is a scientific tool, the results cannot be easily used to determine specifications. Moreover, it is a tool for risk management decision-making, and is rarely a tool for the prediction of actual occurrence of environmental effects. Therefore, as long as the uncertainties are presented and understood by the customer and other decision-makers, the results can be accepted or rejected for use in site decisions.

8.2.2.1.2. When making site decisions, the risk manager or PM can substantially benefit from by consultation with responsible technical experts (risk assessors, expert ecologist[s]/advisory panel [BTAG/ETAG]). It is the responsibility of these experts to document and present uncertainties so the RM makes an informed decision. In the final baseline ERA, the risk assessment summary presents risks and the associated uncertainty information in a weight-of-evidence discussion which focuses on strengths and weaknesses of the risk estimates, providing information to assist in determining the overall objectives and decisions to be made in this project phase.

8.2.2.1.3. In order to make informed risk management decisions, the risk manager should have a clear understanding of the following:

a. What are the receptors or resources to be protected?

b. Does the ecological risk involve individual organisms, communities, populations, or different trophic levels?

c. What is the aggregate hazard (HI)? (this assumes that calculation of an HI is justified for the contamination and the exposed receptors)

d. How do effects or ecosystem characteristics between the site and the reference locations compare?

e. What is the likelihood of recovery based on consideration of the contaminants' fate and transport properties, the substrate or media characteristics, natural attenuation, and lessons learned from similar sites?

f. How do hazards under RME and CTE compare? What are the "order of magnitude" differences?

g. What is the key and overall uncertainty of the baseline ERA in terms of chemical data, COEC selection, exposure assessment and modeling, toxicity information, and characterization method? Is uncertainty quantifiable to the extent that the TCLs could be substantially altered?

h. If the risk estimates are unacceptable, will quantitative analysis of uncertainty be able to demonstrate that the risk estimate is based on overly conservative assumptions, i.e., in the theoretical upperbound range?

i. What are the COEC(s) and exposure pathways that constitute the principal threat?

j. How are the exposure units defined in the baseline ERA?

k. Are there any "hot spots" which would require further characterization, or removal action?

l. Are there any acute hazards or risks which will require emergency response or removal action? Is there a risk of further spills, releases, or physical hazards that could further degrade the environment or adversely impact the ecological receptors of concern?

m. If removal or early response actions are desirable, how effective are the proposed removal actions to reduce site risk?

n. Which are the anticipated or preferred options for actions?

8.2.3. Feasibility Study/Remedial Design/Remedial Action. The FS is triggered when the baseline risk is unacceptable and remediation is needed to mitigate risks and prevent further contaminant migration. In some instances, the FS could be driven by a legal requirement to meet ARARs, although ARARs are not necessarily risk-based. The FS evaluates potential remedial alternatives according to established criteria in order to identify the appropriate remedial alternative(s). The FS can be performed for the entire site or any portion of the site that poses unacceptable risks. The results of the FS include recommendations for the risk managers or site decision-makers, including an array of remedies for selection, RAOs, or TCLs for verification of cleanup.[25] The selected remedies or revisions thereof will be entered into the record of decision (ROD).

Risk Management Decision

What are the Remedial Action Objectives?

Risk Management Options/Rationale

The risk management decision for selection of final remedies depends substantially on the RAOs. Uses of RAOs are summarized below:

[25] For the purpose of protecting the environment, the TCLs sometimes known as RAOs, may be the same as the environmental-based preliminary remediation levels, or they may be a different. TCLs or RAOs are negotiated levels for verification of cleanup and take into consideration performance of the proposed cleanup technology, practical quantitation limits, and uncertainties associated with the preliminary remediation levels to protect ecological resources of concern.

a. Developed or agreed upon by the agencies prior to the FS or signing of the ROD, RAOs are used to evaluate the feasibility of candidate remediation technology in the FS;

b. Initial estimation and costing of remediation (e.g., excavation and stabilization);

c. Delineation of cutlines for remediation;

d. For use in negotiation or final determination of specific areas, or site-wide cleanup goals, by considering uncertainties, technology, and cost.

Before embarking on an FS, RAOs should be developed using site-specific risk information consistent with site conditions. Factors to be considered when RAOs are used as the basis for designing and implementing remediation are presented below:

8.2.3.1. *Remedial Action Objectives Must be Based on Ecological Conceptual Site Model*. The ECSM provides the framework for the baseline ERA and identifies the specific pathways of concern; RAOs must be able to address these pathways and the associated risks. A refined ECSM, based on the results of the ERA is paramount to the establishment of focused RAOs. The RAOs are based on preliminary remediation levels developed as the project strategy goals in Phase I of the HTRW project planning under RI/FS.

8.2.3.2. *Remediation Goals Must be Protective and Practical*. Remedial goals are performance and numerical objectives developed in the FS to ensure that the remedial alternative will contribute to site remediation, restoration, and closeout/delisting. As such, they must be protective and workable. To ensure protectiveness, risk-based preliminary remediation goals should be first derived using the screening or baseline ERA procedures in reverse (see procedures described in Chapter 7). The uncertainty associated with development of the remediation goals should be discussed and quantified. Preliminary remediation levels can be derived early in the site investigation process or at the end of the RI, when it is determined that remediation may be needed because of unacceptable risks. Site decision-makers carefully consider technology, practical quantitation limits, ARARs or to-be-considered criteria, reference location concentrations, acceptable hazards, field or laboratory analytical uncertainties, etc., before setting the RAOs.

8.2.3.3. *Action Must Be Consistent with Other Project Phases*. Understanding of the nature and extent of contamination, as well as the media and exposure pathways of concern, is a critical requirement for successful completion of the FS and remedy selection. Therefore, data used in the FS must interface with the RI and other previously collected site data. Inadequate data or data of poor quality misrepresent site contamination and may lead to an inadequate baseline risk assessment and FS. For each exposure pathway that presents an unacceptable ecological risk, the risk assessor and the appropriate project team members (e.g., chemist, geologist or hydrogeologist) should review the RI data before conducting the FS. This is particularly important when the FS is performed simultaneously with the RI, based on assumptions and PA/SI data.

8.2.3.3.1. RAOs may be selected based on one of the following:

a. Background.

Rationale: The environmental concentrations at the reference area or upgradient area will be used as RAOs since the ecological receptors or the valued resources to be protected are also located at the background locations. The reference area has the same current land use as the site and the levels are reasonable and attainable.

b. RAOs are performance-based.

Rationale: No reasonable chemical-specific cleanup level can be derived due to high uncertainty in the hazard-response relationship. For the purpose of remedy selection, the best available or best demonstrated remedial technology will be utilized to achieve certain risk reduction objectives according to the ECSM.

c. Risk-based Remediation Goals (Cleanup Goals).

Rationale: In lieu of performance based RAO or cleanup to the levels at the reference area, risk-based RAO can be developed using dose-response information for the ecological receptor of concern or its surrogate species. The risk-based RAOs may be adjusted upward or downward according to other risk management factors or considerations.

8.2.3.3.2. Minimal information or guidance has been developed by USEPA regarding the development of RAOs for Superfund sites. RCRA has issued the Alternative Concentration Limit (ACL) Guidance based on 264.94(b) criteria and case studies (USEPA 1988c) which may be applied to developing ACLs at the source if the acceptable groundwater/surface water mixing zone concentrations and the dilution/attenuation factors are defined. Generally, ACLs are allowed under CERCLA, as well. For the protection of aquatic receptors, cleanup levels can be set to chemical-specific water quality criteria. Nonetheless, the key risk management issue concerning the above is that the cleanup goals must be practical and verifiable. When cleanup goals are developed to protect both humans and ecological receptors, according to Section 300.340 of the NCP, the goals must be so adjusted that both receptor types are protected.

8.2.3.3.3. Environmental and human health-based RAOs should be developed together and proposed to the risk manager and agencies for use in the FS for the evaluation of remedial alternatives. It should be noted that the RAOs may have to be revised or refined based on other considerations, e.g., technology, matrix effects, target risks, uncertainties, and costs (associated with the extent of the remediation, management of remediation wastes, cost of cleanup verification analyses).

Risk Management Decision

What are the Remedial Alternatives?

What are the Preferred or Optimal Remedial Alternatives?

Risk Management Options/Rationale

a. In addition to a cost and engineering evaluation of the potential remedial alternatives, each alternative must be evaluated for its ability to reduce site risk. Among the nine criteria identified by the NCP for remedy selection, protection of human health and the environment and satisfying ARARs are considered to be the threshold (fundamental) criteria which must be met by any selected remedy. More recently, USEPA has placed increased emphasis on short- and long- term reliability, cost, and stakeholders' acceptance in the overall goal to select remedies. Therefore, the assessment of residual risk (a measure of the extent of site risk reduction) is a critical task.

b. Screening and detailed analyses of remedial alternatives will be conducted in the FS project phase. The preferred remedial alternative will be proposed. As warranted, analysis of short-term risks to assess the need for control measures will be conducted in the RD project phase, and the control measure(s), if appropriate, will also be proposed.

c. In the FS, potential risk reductions associated with remedial alternatives are assessed. The relative success of one alternative over another is simply the ratio of the residual COEC concentrations in the exposure medium of concern. This screening evaluation does not take into account short-term risks posed by the alternative or technology due to acute hazards, releases or spills.

8.2.3.4. *Screening Evaluation of Alternatives*. This evaluation focuses on determination of short-term risks posed by the removal or remedial alternatives. The findings of this evaluation is compared among the alternatives to determine preferred remedies based on the effectiveness of the remedies to satisfy remedial action goals with the least environmental impact. This screening evaluation should focus primarily on effectiveness, risk reduction and cost.

8.2.3.4.1. Risk screening of alternatives should generally be qualitative or semi-quantitative. If a remedy has already been selected or is highly desirable for selection, a detailed risk analysis may not be needed. Instead, the evaluation should focus on the risk reduction of the preferred remedy, and identify any concerns or data gaps which need to be addressed. The data needed to perform this screening evaluation may come from many sources: RI data, bench scale or pilot scale treatability studies conducted for the site or from comparable sites, compatibility test, test of hazardous characteristics, field monitoring measurements, vendor's or manufacturer's information, literature values, and professional judgment.[26] Key information needed prior to conducting the screening evaluation of remedial alternatives include:

a. Identity and quantity of emissions, effluent, byproducts, treatment residues, which may be released to the environment (during normal, start-up and shut-down operations);

[26] The bench scale or pilot scale treatability studies may provide valuable information for the estimation of remediation action or residual risks. Treatability studies provide data or information on the degree of removal and/or destruction of the COECs, quantity and identity of chemicals in the emissions or effluent discharges, and potential treatment standards to be applied to satisfy remedial action goals. This information is important to quantify the magnitude of risk reduction and will be useful in the comparative analysis of potential remedial alternatives.

b. Toxicity of chemical substances or COECs in the above discharges;

c. Potential for dilution and attenuation;

d. Existence of exposure pathways and likelihood of the pathways to be significant and complete;

e. Potential for spill or releases during remediation, material handling, storage and transportation of remediation wastes;

f. Potential for the causation of non-chemical stressors such as destruction of critical habitat for threatened and endangered species, wetlands, or other sensitive environments, increased siltation and reduction of food sources for the ecological receptors of concern or other receptors/valued resources;

g. Temporal attributes associated with a remedial action which could be altered to reduce the action's impact; and

h. Potential release of additional COECs to the environment (e.g., re-suspension of toxic sediments during dredging, and changes of pH, redox potential, oxygen, and chemical state that may increase solubility and bioavailability).

8.2.3.4.2. The following are lists of qualitative evaluation criteria:

a. Risk Reduction Attributes (environmental protection, permanence, and toxicity reduction).

(1) Able to remove, contain or effectively treat site COECs.

(2) Able to address the exposure pathways and media of concern.

(3) Able to meet the remedial action and overall project strategy goals.

b. Assessment of Residual Risk Potential.

(1) Reasonable anticipated future land use (for example, if the site remains industrial/commercial in a foreseeable future, residual risk assessment should not be performed for the potential return of and exposure to terrestrial receptors).

(2) Quantity of residues or discharges to remain on site.

(3) Toxicological properties of the residues.

(4) Release potential of residues based on their fate/transport properties (e.g., log octanol/water partition coefficient, water solubilities, vapor pressure, density, etc.).

(5) Properties or characteristics of the environmental medium which facilitate transport (e.g., hydraulic conductivity, organic carbon contents, wind speed and direction, etc.).

(6) Potential for dilution and attenuation for residues released into the environment.

(7) The extent of and permanence of remediation habitat destruction and alteration, for example, the construction of an access road through wetlands would be considered permanent.

8.2.3.5. *Detailed Analysis of Alternatives*. Detailed analysis is usually conducted for the preferred remedial alternatives (or removal actions), identified in the screening evaluation described above. This detailed analysis has three objectives: (a) detailed assessment of potential short-term risk during remedial action, and residual risks if appropriate; (b) assess the potential for the risks to be magnified due to simultaneous implementation of this and other preferred alternatives; and (c) identify potential risk mitigation measures for the preferred remedies. The findings of these tasks are presented for final selection of remedies prior to ROD sign-off. All preferred remedies or options should satisfy remedial action goals and should pose minimum health and environmental impact.

8.2.3.5.1. This evaluation may be qualitative, semi-quantitative, or quantitative. If the analysis is quantitative, procedures and approaches similar to the baseline risk assessment may be followed. USEPA's (1995e) *Air/Superfund National Technical Guidance Study Series* includes documents providing guidance for rapid assessment of exposure and risk. For example, guidance on determining the volume of soil particulates generated during excavation is provided in *Estimation of Air Impacts for the Excavation of Contaminated Soil* (USEPA 1992j). The data sources used to perform this risk analysis task should be similar to those identified for the screening evaluation of remedial alternatives. Although it is conceivable that the level of effort required for this analysis may be high (particularly, if the same analysis has to be performed for a number of preferred remedies), it is anticipated that the documentation and report writing will be focused and streamlined.

8.2.3.5.2. The report should focus on the risk analysis approaches, sources of data, findings/recommendations for risk mitigation measures, and appendixes. Key factors or criteria to be considered in the screening evaluation of remedial alternatives are:

a. The criteria or considerations in the assessment of short-term and residual risks are substantially similar to those identified for the screening evaluation of remedial alternatives. The key difference may be additional use of quantitative data input into the risk calculations, e.g., sediment transport modeling to evaluate the potential for migration of toxic sediment, amount of discharges or emissions, dilution/attenuation or atmospheric dispersion factors, exposure frequency, duration, and other activity patterns which could impact existing flora and fauna in time and space, and any indirect effects such as food source reduction and the extent of habitat destruction/alteration.

b. Time required and extent of recovery from exposure to the above COECs and non-chemical stressors.

c. The potential for fire, explosion, spill, and release of COECs from management practice of excavated or dredged materials should remain qualitative or semi-quantitative. Fault-tree (engineering) analysis for accidental events may be attempted under special

circumstances (e.g., to address public comments or if demanded by citizens during public hearing of the proposed remedies).

8.2.3.6. *Risks from Simultaneous Implementation of Preferred Remedies.*

a. Common exposure pathways for effluent or discharges from remedies.

b. Period of exposure to the ecological receptors of concern via the common locations, time and pathways.

c. Sensitive environments and other threatened or sensitive wildlife or aquatic populations.

d. Risk estimates or characterization results.

e. Toxicological evaluation for the validity of biomagnification and additivity of risk (e.g., under the Quotient Method), based on literature review, mode of action, and common target organs, etc.

f. Qualitative or quantitative assessment of potential short-term or residual risks.

8.2.3.6.1. *Short-Term Risks Associated with Construction; the Design Risk Analysis*. All removal or remedial alternatives have a potential to pose short-term risks to on-site mitigation workers, ecological receptors, and off-site humans. Risks may be associated with vapors, airborne particles, treatment effluent, resuspension of sediment resulting in an increase in the total suspended solids or siltation of substrate for macroin-vertebrates, and residues generated during operation of the remedial alternative. Therefore, all the alternatives should be reviewed for their short-term risks in conjunction with data from their bench scale or pilot scale treatability studies or data from implementa-tion of the remedy at comparable sites. The risk assessor should estimate the period of recovery from these short-term insults and determine if biological or chemical monitoring of the effects of remediation activities should be implemented. For all practical purposes, risk may remain upon completion of the remedial action (residual risk).

8.2.3.6.2. *Long-Term Risks Associated with Alternatives; the Residual Risks*. Unless all sources of contamination are removed or isolated, there will be residual risks at the site upon completion of the remedial action. The COEC residuals could either remain or be quickly degraded, depending on the COEC's physical and chemical properties. The level of residual risk will depend on the effectiveness of the remedy in containing, treating or removing site contaminants, and the quantity, and physical, chemical, and toxicological characteristics of residues or byproducts remaining at the site. Site COECs which remain on-site after the remedial action should be assessed for their potential risks.

8.2.3.6.2.1. This evaluation step focuses on a risk reduction assessment to determine if a potential remedial alternative is able to meet the remedial action goals; and an assessment of residual risk potential. The findings of these tasks are compared among the alternatives to determine an array of preferred remedies based on the effectiveness of

the remedies to satisfy remedial action goals with the least long-term health and environmental impact.

8.2.3.6.3. *Remedial Action/Residual Risks vs. Baseline Risk*. There are notable differences between remedial action/residual risks and the baseline risk. The key difference is that baseline ecological risk refers to the potential risk to the receptors of concern under the "no remedial action" alternative, and remedial action and residual risks refer to short-term risks during remedial action and long-term risks which may remain after completion of the remedial action, respectively. Residual risk may be considered comparable to baseline ecological risk after remediation; since in both cases, the risks are chronic or subchronic in nature. Remedial action risks are generally short-term (acute or subchronic) risks.[27]

8.2.4. *Non-Risk Issues or Criteria as Determining Factors for Actions*. The NCP recognizes that it is not possible to achieve zero risk in environmental cleanup; therefore, the approach taken by Superfund is to accept non-zero risk and return the site to its best current use (not to conditions of a pre-industrialization era). This section presents and discusses the non-risk factors, and recommends a balanced approach for resolution of issues to enable quality risk management decision-making. These factors can be categorized into scientific and non-scientific factors, as explained below.

8.2.4.1. *Scientific Factors.* The scientific factors, including engineering design and feasibility, should be considered in risk management decision-making. These factors focus on technology transfer (realistic performance of the technology), duration of protection, and feasibility study data uncertainties. These factors will influence the decision whether or not to proceed with selection of a particular remedy. They are detailed below:

8.2.4.1.1. *Technology Transfer*. This factor concerns the treatability of the contaminated debris or media by a preferred technology or early action. Although the recommended technology may appear attractive, a number of problems must be overcome before actual selection or implementation of the action. The following are a few examples:

a. Scale up,

b. Downtime and maintenance (including supplies),

c. Ownership/control,

d. Throughput to meet the required completion schedule,

[27] One exception (i.e., remedial action risk which is long-term) is a pump-and-treat remedy of groundwater to meet maximum contaminant levels for organics which pose a threat to human health but not ecological receptors. If the effluent is discharged to a surface water body and happens to contain trace elements at high levels (or other COECs not reduced by the treatment process), then an exposure route to environment receptors may remain which is not addressed by the baseline ERA, and which will exist for the operational life-span of the remedy.

e. Skills required or training requirements,

f. Quantitation and detection limits, and

g. Space requirements for the remediation process and management of remediation wastes.

8.2.4.1.2. *Duration of Protection*. This factor concerns the duration of the removal or remedial technology designed to treat or address site risk. This factor is particularly important for site radionuclides or non-aqueous phase liquid (NAPL) compounds in the aquifer. The maintenance or replacement of barriers or equipment is also a primary concern for this factor. Although a technology or alternative is effective, its effectiveness may not last long if there is no source control or contamination from off-site sources is not controlled

8.2.4.1.3. *Data Uncertainty*. This factor considers reliability and uncertainty of certain site or feasibility study data for use in selecting a remedy, or for determining whether no further action is appropriate. Uncertainty in the following data may also impact the risk analyses or baseline risk assessment results:

a. Adequacy of bench-scale or pilot-scale treatability data,

b. Data uncertainties (volume, matrices, site geology/hydrogeology),

c. Field data and modeling data, and

d. Overall uncertainty of the source of site contamination.

8.2.4.2. *Non-Scientific Factors*. Non-scientific factors should also be considered in risk management decision-making because some of these factors are key to a successful site remediation. Most of these factors are internal, but can also be external. Examples of these factors are enforcement, compliance, schedule, budget, competing risk reduction priorities, community inputs, and societal/economic value of the resources to be protected. These factors will influence the decision on whether or not certain removal or remedial actions should be taken, or on which remedies are to be selected. These factors are detailed below.

8.2.4.2.1. *Enforcement and Compliance*. Certain courses of action (including risk management decisions) have been agreed upon early in the process and have been incorporated in the IAG or FFA. This is particularly germane to some earlier HTRW sites. Nonetheless, the requirements specified in the enforcement documents or administrative order of consent, IAG, FFA should be followed by the risk manager or PM with few exceptions. When risk-related factors or other non-risk factors are over-arching, the risk manager should then raise this issue to higher echelon or to the legal department for further action or negotiation.

8.2.4.2.2. *Competing Risk Reduction Priorities*. Although related to risk, this factor represents the competing interest among programs or within the project for a limited source of funding to perform risk reduction activities. Since it is likely that not all sites will

be cleaned up at an equal pace, the planning and execution of environmental restoration among these units should follow a prioritization scheme. However, the scheme developed according to risk may not be the same according to the customer, the base commander, or the agencies. The risk manager or PM must seek common ground to resolve this issue so that resources can be expended to produce incremental environmental benefits.

8.2.4.2.3. *Schedule and Budget*. These factors usually go together because the more protracted the project life, the more resources the project will demand. While each PM would like to comply with risk-based considerations with little margin of error, the PM may have no choice but to make risk management decisions with larger uncertainties than he or she would prefer, due to schedule and budget constraints.

8.2.4.2.4. *Community Input***.** Opportunity for the stakeholders or community to provide input into the permit modification is provided when primary documents are prepared, i.e., RI Work Plan, RI/FS reports, the proposed remedies, and the RA Work Plan. Superfund also provides similar opportunities for public participation. To be successful in site remediation and closeout, the risk managers must be able to communicate risks effectively in plain and clear language without bias. Early planning and solicitation of community input is essential to democratization of risk management decision-making. Some of the following issues may be of concern to the communities:

a. Ineffective communication of risks and uncertainties.

b. Lack of action (some action is preferred to no action).

c. Not in my backyard (off-site transportation of contaminated soil, debris or sediment should avoid residential neighborhoods).

d. Any treatment effluent or discharge is unacceptable (on-site incineration is seldom a preferred option except for mobile incinerators, in certain instances).

e. The remedy should not impede economic growth or diminish current economic and recreational value of resources to be protected.

f. Cleanup will improve the quality of life and increase property values or restoration of recreational/economic resources.

8.2.4.2.5. S*ocietal/Economic Value of the Resources to be Protected.* This non-risk factor concerns the community sentiment on how fast, or in what manner, the resources impacted by site contaminants should be restored. These resources may include surface water bodies, wildlife, and game animals. Most communities would like to see impacted resources restored to original use, however, this can be difficult to achieve. Some communities may be willing to accept natural attenuation or no action options for impacted surface water bodies, given the opportunity to examine the pros and cons of all options. Therefore, it is recommended that the risk manager execute a community relations plan in earnest in order to solicit the citizens' input on the risk reduction

approach and issues of concern. Key community spokespersons may also be appointed to the site action committee to facilitate such dialogue and communication.

8.2.4.3. *A Balanced Approach*. In conclusion, the risk manager should consider all risk and non-risk criteria before making risk management site decisions. Due to uncertainties associated with ERA or analysis, the decision-maker must review risk findings and the underlying uncertainties, and consider other non-risk factors in the overall risk management equation. When making risk management decisions, the risk manager should keep an open mind regarding the approaches to meet the project objective. In order to make informed site decisions, the risk assessor must present risk estimates in an unbiased manner. With an understanding of the volume of contaminants of concern, significance and biological relevance of the ecological effects and potentially impacted receptors, fate/transport properties of the COECs, and completeness of the exposure pathways and the food web, the risk manager, PM, and stakeholders will be better equipped to make informed decisions. These decisions should be consistent with the overall site strategy, which is developed early in the project planning phase (see Chapters 2 and 3), and which may evolve throughout the project.

8.3. Design Considerations. Risk assessment methodology can be an important tool in the design phase of CERCLA remedial actions. During the early phase of RD/RA, risk assessment results can help determine: 1) whether the selected remedy can be implemented without posing an unacceptable short-term risk or residual risk; and 2) control measures (operational or engineering) to mitigate site risks and to ensure compliance with ARARs, and to-be-considered requirements, and permit conditions. The risk and safety hazard information will be evaluated by the site decision-makers, along with information concerning design criteria, performance goals, monitoring/compliance requirements prior to making risk management decisions regarding the above questions. Further, the decision-makers consider potential requirements such as ARARs and to-be-considered (TBCs) in determining design changes or control measures.

This section addresses the above issues, i.e., risk management considerations in remedial design, compliance with ARARs, including the clean air act (CAA), CWA, ESA, and other major environmental statutes, and control measures required to mitigate risks.

8.3.1. *Potential Risk Mitigation Measures*.

8.3.1.1. *Engineering Control.* Where appropriate (when short-term risks are determined to be unacceptable), engineering controls should be recommended by the design engineer with inputs from the risk assessor, aquatic ecologist, compliance specialist, and the air modeler. Examples of these control measures include:

a. VOC and semi-volatile organic compound (SVOC) emissions - activated carbon canisters, after burners, or flaring, prior to venting.

b. Metals and SVOC airborne particles - wetting of work areas; particulate filter/bag house, wet scrubber, or electrostatic precipitator (for thermal treatment devices or incinerators).

c Fugitive emissions - monitoring of valves, pipe joints, and vessel openings; and barrier/enclosure of work areas (e.g., a can or shield over the augering stem).

d. Neutralization or chemical deactivation of effluent (continuous process or batch).

e. Use of remote control vehicle for handling, opening or cutting of drums containing explosive or highly reactive or toxic substances.

8.3.1.2. *Operational Control*. Where appropriate, administrative control measures (procedural and operational) safeguards should be recommended by the PM, design engineer, field supervisor during RA, with inputs from the risk assessor and other relevant technical and compliance specialists. Examples of these control measures include:

a. Establish short-term trigger levels which will require work stoppage or upgrade of the remediation procedures (e.g., dredging of toxic sediments). Either biological or chemical indicators, or their combination could be used as the trigger levels. These levels should be developed in the RD/RA project phase by the risk assessor and other technical specialists, including the modeler.

b. Consistent with the above trigger or acute concern levels, evaluate on-site performance with field equipment to ensure adequate remediation.

c. Afford the proper protection of sensitive environments by careful planning and positioning of staging area, storage or management of remediation wastes, selection of equipment with low load bearing, and season or time period when the remediation should be completed.

d. Establish a zone of decontamination and proper management of effluent or waste generated from this zone.

e. Secure and control access to areas where remedial actions are being implemented at all time.

8.3.1.3. *Institutional Control*. Although institutional control may not be relevant for ecological receptors, it can be relevant in the sense that institutional control measures may be needed to reduce human intrusion, thus allowing the sensitive environments to recover or the ecological receptors to re-establish. Institutional controls are particularly pertinent for remedies which involve containment, on-site disposal of wastes, or wetlands remediation. Institutional controls should be recommended by the customer, PM, and other site decision-makers. Examples of these control measures include:

a. Recording land use restrictions in the deeds (deed restrictions) for future use of certain parcels or areas where hazardous substances or wastes are contained.

b. Erection of placards, labels, and markers which communicate areas where human exposure may pose short-term or residual risks.

c. Security fences and barriers.

8.3.2. *Risk Management; Degree of Protectiveness*. Not only should a selected remedial action be able to meet balancing criteria, the remedial action must be protective, i.e., in terms of reducing site risks. In designing a selected remedy, the site decision-makers may face operational or engineering issues which are likely to require risk management decisions. For example, if a detailed analysis of a selected remedy reveals potential short-term or residual risks, the decision-makers must decide to what extent and with what control measures are necessary to abate the risk. Inputs from the risk assessor will be needed to help make informed risk management decisions. The following are examples of key risk management considerations for designing an effective remediation strategy:

a. Acceptability of control measures. There are potential operational (procedural) or engineering control measures to address the short-term risks. The risk assessor, in coordination with the design engineer, expert ecologist(s)/advisory panel, and other project team members, assesses the effectiveness of any proposed control measures.

b. Removal of control measures. Before a control measure is implemented, the decision on the minimum performance and when to stop requiring the control measure has to be addressed. This is particularly important if control measures are costly to implement and maintain.

c. Effectiveness of the remediation. Remediation should effectively address on-site contamination if there is a continuing off-site (regional) source. This consideration is particularly important for groundwater and sediment contamination remediation. This regional source control strategy should not be confused with the identification of PRPs since some of the discharges could be a permitted activity. Nonetheless, this issue has to be resolved if the RAOs are risk-based and do not consider off-site influences or contribution to the contaminants requiring remediation. Off-site source control and containment, waste minimization, and closure issues should be raised by the risk manager to the agencies, USACE customers, and higher echelon.

d. BRAC. With BRAC, the land use of closed defense facilities may not be indefinitely controlled and the legislation governing BRAC holds the U.S. government responsible for future cleanup of contamination caused by government activities. Cleanup criteria and long-term remedies should take land use into consideration for implementation of an effective site closeout strategy (see Chapter 2). For example, conversion of military bases into a state park or refuge area will require different cleanup objectives than cleanup to the level acceptable for industrial/commercial usage. This issue should be addressed early in the site strategy development phase with input from customers, local re-development commissions, state, and other stakeholders.

e. Verification of cleanup. The risk management decision concerning verification of cleanup, i.e., the numerical value of the RAO should be based on a combination of factors: risk, uncertainty, statistics, analytical detection limits/matrices, and costs. Although RAOs have been negotiated or determined in the ROD, the sampling method and statistical requirements must be clearly articulated before design and implementation of the corrective measures or remedial alternatives.

f. Risk management decisions during the design phase of a CERCLA remediation should be flexible, considering the uncertainty in the risk assessment results, acceptable risk range, confidence level of toxicity data or criteria to support the assessment, engineering feasibility, reliability of the measures (operational changes vs. pollution control equipment), state and community acceptance, and cost. It is recommended that risk managers and site decision-makers request input from all members of the project team for pros and cons of proposed control measures to address the short-term risks.

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APPENDIX A
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A.1. *Required Publications*

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GLOSSARY

Acronyms

ACL	alternative concentration limit
AET	apparent effects threshold
AOC	Area of Concern
API	American Petroleum Institute
AQUIRE	Aquatic Information Retrieval Database
ARAR	ARAR applicable or relevant and appropriate requirement
ASTER	Assessment Tools for the Evaluation of Risk
ASTM	American Society for Testing and Materials
ATSDR	Agency for Toxic Substances and Disease Registry
AVS	acid volatile sulfide
AWQC	ambient water quality criteria
BAF	bioaccumulation factor
BAF_{PLANT}	Plant-soil bioaccumulation factor
BaP	benzo(a)pyrene
BCF	bioconcentration factor
BERA	Baseline Ecological Risk Assessment
BLM	Bureau of Land Management
BMF	biomagnification factor
BRAC	Base Realignment and Closure
BTAG	Biological Technical Assistance Group
BTEX	benzene, toluene, ethylbenzene, and total xylenes
BW	body weight of receptor
C	chemical concentration
CAA	Clean Air Act
CAMU	Corrective Action Management Unit
CDDs	chlorinated dibenzo-p-dioxins
CDFs	chlorinated dibenzofurans
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
COEC	Contaminants of ecological concern
COPEC	contaminant of potential ecological concern
CTE	central tendency exposure
CWA	Clean Water Act
DC	dietary composition
DDT	p,p'-dichlorodiphenyltrichloroethane
DERA	Defense Environmental Restoration Account
DERP	Defense Environmental Restoration Program
DQO	data quality objective
DSMOA/CA	Department of Defense and State Memorandum of Agreement/Cooperative Agreement Program
ECAS	Environmental Compliance Assessment System

Eco-SSL	ecological soil screening level
ECSM	ecological conceptual site model
Eh	oxidation-reduction potential
EM	Engineer Manual
EMF	exposure modifying factors
EP	Engineer Pamphlet
EQ	equivalents (normally associated with CDDs or PCBs)
ERA	ecological risk assessment
ERAGS	Ecological Risk Assessment Guidance for Superfund (USEPA 1997)
ER-L	effects range-low
ESA	Endangered Species Act
ETAG	Ecological Technical Assistant Group
FDA	U.S. Food and Drug Administration
FFA	Federal Facility Agreement
FI	food ingestion/food intake
FS	Feasibility Study
FUDS	formerly used defense sites
GLWQI	Great Lakes Water Quality Initiative (USEPA 1995b)
HHRA	human health risk assessment
HI	hazard index
HQ	hazard quotient
HTRW	Hazardous, Toxic, and Radioactive Waste
IAG	Interagency Agreement
IBI	Index of Biological Integrity
IF	ingestion factor
IRIS	Integrated Risk Information System
IRP	Installation Restoration Program
K_{oc}	Organic Carbon Partition Coefficient
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LEL	lower effects level
LOAEL	lowest observed adverse effect level
Log K_{oc}	logarithm of the organic carbon partition coefficient
Log K_{ow}	logarithm of the n-octanol-water partition coefficient
Log P	see log K_{ow}
NAPL	non-aqueous phase liquids
NAS	National Academy of Science
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
ND	not detected
NFA	no further action
NOAA	National Oceanic and Atmospheric Administration
NOAEL	no observed adverse effect level
NPL	National Priorities List
NRC	National Research Council

NRDA	Natural Resource Damage Assessment
NRI	Natural Resource Injury
OCPs	organochlorine pesticides
OE	Ordnance and Explosives
ORNL	Oak Ridge National Laboratory
OSWER	Office of Solid Waste and Emergency Response (U.S. EPA)
OU	operable unit
PA	Preliminary Assessment
PAHs	polycyclic aromatic hydrocarbons
PCBs	polychlorinated biphenyls
PDF	portable document format
PM	project manager
PNA	polynuclear aromatics
PRA	probabilistic risk assessment
PRGs	Preliminary Remediation Goals
QSAR	quantitative structure activity relationship
RA	remedial action
RAGS	Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (USEPA, 1989)
RAO	Remedial Action Objective
RCRA	Resource Conservation and Recovery Act
RD	Remedial Design
RI	Remedial Investigation
RMDM	risk management decision-making
RME	reasonable maximum exposure
ROD	Record of Decision
RTECS	Registry of Toxic Effects of Chemical Substances
SEEM	spatially explicit exposure model
SEM	simultaneously extracted metal
SI	Site Inspection
SLERA	Screening-Level Ecological Risk Assessment
SOW	Statement of Work or Scope of Work
SSL	soil screening level
SVOC	semivolatile organic compound
SWMU	Solid Waste Management Unit
TBC	to-be-considered
TCDD	2,3,7,8-tetrachlorodibenzo-p-dioxin
TCL	Target Cleanup Levels
TEF	toxicity equivalence factor (normally associated with CDDs or PCBs)
TEL	threshold effects level
TPH	total petroleum hydrocarbons
TPP	Technical Project Planning (USACE 1998)
TRV	toxicity reference value
TSERAWG	Tri-Services Environmental Risk Assessment Working Group

TTD	terrestrial toxicity database
TU	temporary unit
TWEM	terrestrial wildlife exposure model
UCL	upper confidence limit
UF	uncertainty factor
USACE	U.S. Army Corps of Engineers
USAECBC	U.S. Army Edgewood Chemical Biological Center (formerly USAERDEC)
USAPHC (Prov)	U.S. Army Public Health Command (Provisional) (Formerly U.S. Army Center for Health Promotion and Preventive Medicine [USACHPPM])
USDA	U.S. Department of Agriculture
USDHHS	U.S. Department of Human Health Services
USDOC	U.S. Department of Commerce
USDOD	U.S. Department of Defense
USDOE	U.S. Department of Energy
USDOI	U.S. Department of the Interior
USEPA	U.S. Environmental Protection Agency
USFS	U.S. Forest Service
USFWS	U.S. Fish and Wildlife Service
VOC	volatile organic compound
WER	water effect ratio
WERF	Water Environment Research Foundation
WET	wetland evaluation technique
WI	water ingestion/water intake
WTA	wildlife toxicity assessment

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