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	Environmental Quality Risk Assessment Handbook Volume II: Environmental Evaluation	
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DEPARTMENT OF THE ARMY
U.S. Army Corps of Engineers
Washington, DC 20314-1000

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CEMP-RT

Manual
No. 200-1-4

30 June 1996

Environmental Quality
RISK ASSESSMENT HANDBOOK, VOLUME II: ENVIRONMENTAL EVALUATION

1. Purpose. The overall objective of this manual is to provide U.S. Army Corps of Engineers (USACE) Hazardous, Toxic, and Radioactive Waste (HTRW) managers and technical proponents with the recommended basic/minimum requirements for planning, evaluating, and conducting ecological risk assessments, consistent with USACE principles of good science and in defining expected quality and goals of the overall program.

2. Applicability. This manual applies to ecological risk assessment aspects for all USACE HTRW investigations, studies, and designs under the Department of Defense, Defense Environmental Restoration Program (DERP), Base Realignment and Closure (BRAC), U.S. Environmental Protection Agency (EPA) Superfund Program, Civil Works, and Work for Others. EM 200-1-4, Risk Assessment Handbook, Volume I: Human Health Evaluation, provides guidance on human health risk assessments performed for all HTRW projects.

3. General. Chapter 1 of this manual presents the purpose, scope, concept, and policy considerations, and the use of risk assessment in HTRW programs. It provides a description of the USACE HTRW program, the quality required for performance of ecological risk assessment, and an understanding of how risk assessments serve management decision needs. Relevant Federal statutes/regulations, agency guidance and directives and state requirements are also highlighted in this chapter. Chapter 2 presents the major scoping and project planning elements 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. Particular emphasis is placed on the early development of an Ecological Conceptual Site Model (ECSM). utilizing the data quality objectives planning process presented in EM 200-1-2, Technical Project Planning Guidance for HTRW Data Quality Design, to identify data needs and optimize data collection efforts. Chapters 3 through 8 are intended to provide the risk assessor with the minimum content expected to be included in an ecological risk assessment to adequately serve site decision requirements. They summarize the key components of a Screening Ecological Risk Assessment (Chapter 3), the four tiers employed for Baseline Ecological Risk Assessments (Chapters 4, 5, 6, and 7), and Ecological Risk Assessment of Remedial Alternatives (Chapter 8). These chapters stress the importance of properly identifying the receptors and chemicals of concern and a thorough understanding of the dynamics of interrelationships of multiple receptors and pathways in the development/refinement of an ECSM before embarking on estimating exposure point concentrations. They also highlight the need for characterizing site hazard or risk objectively and realistically to satisfy the regulatory requirement of protection of the environment. Chapter 9 concerns presentation of the risk assessment results for use in risk management and decision-making, focusing on the decisions and criteria needed for making those decisions. Both risk and nonrisk factors are presented for consideration by the manager. This chapter

emphasizes the need for balancing protection of the environment with other project constraints based on the level of confidence and uncertainty in the risk assessment results. Risk results are used for evaluating the need for a removal action, interim corrective measures, or remediation, and to provide the decision criteria and rationale for the selection of remedial alternatives, if required for site closeout. The chapter concludes that the HTRW project team has the responsibility to present risk information as management options to the customer, documenting the uncertainty and rationale.

FOR THE COMMANDER:

ROBERT H. GRIFFIN
Colonel, Corps of Engineers
Chief of Staff

NOTICE

BACKGROUND: The Hazardous, Toxic, and Radioactive Waste (HTRW) risk assessments are performed by USACE on behalf of Federal entities/agencies, pursuant to CERCLA/RCRA. under the Defense Environmental Restoration Program (DERP). Base Realignment and Closure (BRAC), and Work for Others Programs. The overall objective of this handbook is to provide USACE HTRW managers and technical proponents with the recommended basic/minimum requirements for planning, evaluating, and conducting risk assessments, consistent with USACE principles of "good science" and in defining expected quality and goals of the overall Program. The resulting risk assessment should be scientifically sound, defensible, and site-specific for use by site managers or agencies in making site decisions.

STATUTES: CERCLA, Section 120 (Federal Facilities) and Section 121 (Response Actions); RCRA Section 3004(u)(Technical Requirements for Corrective Action), 3OO5(c)(Permitting and Omnibus provision), 3008 (h)(Corrective Action Orders), and Section 6001 (Federal Facilities).

REGULATIONS: 40 CFR 300.430 (d), 40 CFR 300.430 (e), 40 CFR 264 Subpart S, and 40 CFR 270.32(b)(2)

AUTHORITY: Executive Order 12580, CERCLA Sections 104 and 115 delegate President's authority for response action to the lead agency (DoD and other Federal agencies) which are also the Natural Resource Trustees having jurisdiction, custody, and control over their lands. Within the definition of a Natural Resource Trustee, DoD is authorized under CERCLA Section 211 to be the lead agency for CERCLA or the National Priority List (NPL) sites at current or former DoD facilities and to implement the Defense Environmental Restoration Program.

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FUTURE REVISIONS: This handbook will be reviewed on an annual basis for revisions, and updates issued accordingly.

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Introduction

1.1 Purpose and Scope

This manual, ***Risk Assessment Handbook: Volume II - Environmental Evaluation,*** provides technical guidance to the U.S. Army Corps of Engineers (USACE) risk assessors and risk assessment support personnel for planning, evaluating, and conducting ecological risk assessments (ERAs) in a phased Hazardous, Toxic, and Radioactive Waste (HTRW) response action. The manual, a compendium to the ***Risk Assessment Handbook: Volume I - Human Health Evaluation*** (EM 200-1-4, USACE 1995a), encourages the use of "good science*' within the framework of existing U.S. Environmental Protection Agency (EPA) ERA guidelines. The purpose of this manual is to provide USACE HTRW program managers and technical proponents with recommended basic/minimum requirements for planning, evaluating, and conducting ERAs and to define the expected quality and goals of the overall program.

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) ecological effects characterization, (3) exposure characterization, and (4) risk characterization.

This manual 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.

1.1.1 Objectives

The overall objective of this manual is to allow the users to be familiar with the ERA process so that quality data will be collected and used in preparing a site-specific ERA. Specifically, the objectives are:

- To provide guidance for all ERAs completed under contract with USACE or those which USACE provides technical oversight (including active and formerly used defense sites [FUDS] and other Federal agencies/facility sites), in compliance with Federal environmental laws and regulations.
- To allow users to be familiar with the application of the data quality design process with respect to conducting ERAs, so that data collected will support ERA conclusions.
- To highlight those decision criteria specific to each phase of project execution that support risk management decision-making within the framework of USACE's HTRW programmatic approach.
- To provide minimum requirements for evaluating contractor-prepared ERAs, ensuring that the assessment will adequately support site decisions of an HTRW response action.
- To acknowledge areas of uncertainties where "good science," based on professional judgment and sound scientific principles, is used to determine the need for removal actions or interim measures, further investigation, further action, or no further action needed (site closeout).
- To refine understanding of EPA's concepts and application of ERA guidelines for site assessment and remediation, especially to support the USACE HTRW program goals.

1.1.2 Scope

This guidance manual is not intended to be a "how to" manual which prescribes step-by-step procedures or instructions for preparing an ERA. Rather, the manual presents recommendations for scoping, managing, evaluating, and communicating to risk managers and other stakeholders the potential ecological risks posed by hazardous chemicals of ecological concern (COECs) at Resource Conservation and Recovery Act (RCRA) sites, Comprehensive Environmental Response, Compensation. and Liability Act (CERCLA) sites, and other sites managed under the HTRW program. This manual provides concepts for performing an ERA consistent with "good science" and accepted regulatory procedures. The following areas are not covered herein:

- Biological hazards - microbes (natural or genetically engineered) and other biological agents, including their use and impact to the indigenous species and environment.

- Radioactive hazards - radioactive wastes, radiation-generating devices, and radioactively contaminated materials.

- Study elements and regulatory requirements of a Natural Resource Damage Assessment (NRDA) -- (However, information presented in Chapter 2 of this manual could be helpful to HTRW sites mandated for NRDA actions.)

1.1.3 Intended Audience and Use

This manual is primarily for use by USACE personnel who are responsible for scoping, directing, and reviewing ERAs performed for HTRW response action sites. The guidelines provided herein are consistent with and should be considered in addition to existing EPA guidance contained in the *Risk Assessment Guidance for Superfund.* Volume *II, Environmental Evaluation Manual* (EPA 1989a), the *Framework for Ecological Assessment* (EPA 1992a), and the National Research Council's *Issues in Risk Assessment* (NRC 1994). The engineer manual entitled, *Technical Project Planning - Guidance for HTRW Data Quality Design* (USACE 1995b) should be reviewed, particularly for understanding the process described in Chapter 2 herein on how to determine data quality objectives (DQOs) to support an ERA.

The data collection, assessment, characterization of risk and uncertainty, and the risk management decision-making aspects presented in the following chapters are intended to satisfy RCRA and CERCLA regulatory requirements. The assessment of ecological risks under these two functionally equivalent programs is essentially the same. The concepts and assessment techniques presented below 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 EPA or states.

1.1.4 Contents of the Manual

- Chapter 1 presents the purpose, scope, concept, and science/policy considerations, and the use of ERA in HTRW programs. It provides a description of the USACE HTRW program, quality required for performance of an ERA, and an understanding of how ERAs serve management decision needs. Relevant Federal statutes/ regulations, agency guidance and directives, and state requirements are highlighted in this chapter.

- Chapter 2 presents the major scoping or project planning elements under CERCLA as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986, and RCRA as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984. Particular emphasis is placed on the early development of an ecological conceptual site model (ECSM) in the data quality design process to identify data needs, optimize data collection efforts, and recommend options for site decisions.

- Chapters 3 through 8 are intended to provide the risk assessor with the minimum requirements expected to be included in the ERA to adequately serve site decision requirements. They summarize the key components of the baseline ERA and other risk analyses. A running case study is presented throughout these chapters and Chapter 9 to explain key steps in an ERA and to demonstrate how risk management decisions may be made at each project phase in the HTRW program.

- Chapter 9 presents the information for risk management decision-making by focusing on the decision statements specific to the regulatory program and project phase, and criteria for decisions.

- Figures, tables, exhibits, and a continuous case study designed to illustrate or enhance readers' understanding of the materials are presented throughout. A glossary is presented also.

- Appendices A and B contain publication information for the references cited in the manual and additional sources of information, respectively.

Appendices C through H contain information that will be helpful to users of the manual in the prep aration of ecological risk assessments.

1.2 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 national environmental cleanup programs:

- EPA Superfund Program (a.k.a. CERCLA).
- Defense Environmental Restoration Program (DERP):
  - Installation Restoration Program (IRP).
  - Formerly Used Defense Sites (FUDS).
  - Department of Defense and State Memorandum of Agreement/Cooperative Agreement Program (DSMOA/CA).
- Base Realignment **and** Closure (BRAC).
- Environmental Compliance Assessment System (ECAS) (USACE 1992a).
- HTRW environmental restoration support for Civil Works projects and other Federal agencies (Department of Defense [DoD] and non-DOD).

For the purpose and intended use of this risk assessment manual, the focus is on the DERP and BRAC cleanup programs to address CERCLA- and RCRA-related issues.

1.2.1 DERP

DERP, codified in 10 USC Chapter 160, provides central program management for the cleanup of DoD hazardous waste sites consistent with the provisions of CERCLA. The goals of the program are: (1) the identification, investigation, research, and cleanup of contamination from hazardous substances: (2) correction of other environmental damage which creates an imminent and substantial endangerment to the public health and welfare, or to the environment; and (3) demolition and removal of unsafe buildings and structures.

1.2.2 BRAC

BRAC is an environmental restoration program with the mission to restore or clean up Army installations in preparation of real property disposal or transfer. The Base Closure Account (BCA), authorized under the Defense Authorization Amendments and Base Closure and Realignment Act of 1988 and the Defense Base Closure and Realignment Act of 1990, funds the BRAC program, which defines the nature and scope of contamination, performs remedial action, and documents the condition of real property by issuance of the Finding of Suitability to Lease (FOSL) (DoD 1993) and the Finding of Suitability to Transfer (FOST) (DoD 1994a). The Community Environmental Response Facilitation Act (CERFA) (Public Law 102-426) amends CERCLA Section 120(h) and requires Federal agencies to define “real property” on which no hazardous substances and no petroleum products or their derivatives were stored for one year or more. known to have been released, or disposed of before the property can be transferred. Transfer of contaminated property is allowed as long as the remedial action to clean up the site is demonstrated to be effective to EPA.

1.2.3 Others

Other components of the USACE HTRW program include:

- EPA Superfund Program Support -- Through an Interagency Agreement (IAG) and upon EPA request, USACE acts as the Federal government’s contracting officer in conducting “Federal Lead” remedial design and construction activities. USACE may also provide other technical assistance to EPA in support of response actions.
- DSMOA/CA -- DoD reimburses states and territories up to one percent of the costs for technical services for environmental restoration cleanups. USACE is responsible for execution of activities which include establishing, managing, implementing, and monitoring the DSMOA/CA program.
- Non-Mission HTRW Work for Others -- Through IAG. non-DOD Federal agencies utilize the technical expertise and experience in work

relating to the RCRA, CERCLA, and underground storage tank (UST) investigation and response actions under the HTRW program for non-DOD Federal agencies.

- Guidance for Civil Works Projects -- The Civil Works districts may request technical support and guidance from HTRW program elements.

1.2.4 HTRW Program Organization

OM 10-1-1 (HQUSACE, October 31, 1990) and USACE HTRW Management Plan (USACE 1992b) describe the USACE organizational elements in support of DERP, BRAC, and other programs. Their major responsibilities include, but are not limited to, the following:

- The Assistant Secretary of the Army for Installations, Logistics, and the Environment (ASA (I,L,E)

- Headquarters, U.S. Army Corps of Engineers (HQUSACE) -- The Military Programs Directorate -- Environmental Restoration Division (CEMP-R) develops, monitors, coordinates, and proposes program management policies and guidance, and provides funding and manpower requirements to the program customers.

- The Director of Environmental Programs (DEP) within the office of the Assistant Chief of Staff for Installation Management (ACSIM) is responsible for interfacing with Department of Army (DA) components for policies and funds for IRP/FUDS/BRAC executed by USACE.

- HTRW Center of Expertise (CX) has the primary responsibility for maintaining state-of-the-art capability, providing technical assistance to other USACE elements, providing mandatory review of designated HTRW documents, and, as requested, providing technical and management support to HQUSACE.

- Ordnance and Explosives (OE) CX has the primary responsibility for maintaining state-of-the-art technical capabilities in OE, performing site inspections, engineering evaluations and cost analyses (EE/CA), and removal design phases of OE projects.

- Divisions are responsible for providing program oversight of all HTRW environmental restoration projects and designating project management assignments for HTRW projects.

- HTRW Design Districts provide the Division Commander with technical support in the areas of health and safety, chemical and geotechnical data quality management, environmental laws and regulations, risk assessment, contracting and procurement, and technical design and construction oversight.

1.3 Overview of 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:

- Preliminary Assessment (PA).

- Site Inspection (SI).

- Remedial Investigation (RI), including Baseline ERA.

- Feasibility Study (FS).

- Remedial Design/Remedial Action (RD/RA).

- Site Closeout.

The HTRW response action process is phased and performed in accordance with EPA procedures for assessing uncontrolled hazardous waste sites under CERCLA or RCRA. The following sections generally describe the CERCLA and RCRA processes, which are functionally equivalent to one another in objectives and types of site decisions to be made throughout each process.

1.3.1 CERCLA Process

CERCLA, commonly known as “Superfund,” establishes a national program for responding to uncontrolled releases of hazardous substances into the environment. The regulation implementing CERCLA is the ***National Oil and Hazardous Substances Pollution Contingency Plan*** (NCP) (40 CFR 300, EPA 1990a). In general, the CERCLA process consists of the site assessment phase and the remedial phase as described below; however, removal actions (as allowed by the NCP) may be taken at any time during the CERCLA process. It should be noted that

the general framework established under the CERCLA process has been adopted for use in environmental cleanup under other programs, e.g., the cleanup of petroleum, oil, and lubricants (POLs) at FUDS or active installations not listed on the proposed or final National Priorities List (NPL). Therefore, certain CERCLA project phases described below (specifically, the Hazard Ranking System [I-IRS], NPL, and site deletion), are not applicable to these types of facilities.

1.3.1.1 Site Assessment Phase - To Identify Sites for Further Evaluation

- **Site Discovery** - EPA identifies and lists in the CERCLA Information System (CERCLIS) possible hazardous substance releases to be evaluated under Superfund.

- **PA** - While limited in scope, a PA is performed on sites listed in CERCLIS to distinguish sites which pose little or no threat to humans and the environment and sites that require further investigation or emergency response.

- **SI** - An SI identifies sites which (1) have a high probability of qualifying for the NPL or pose an immediate health or environmental threat that requires a response action, (2) require further investigation to determine the degree of response action required, and/or (3) may be eliminated from further concern.

- **HRS** - At the end of both the PA and SI, EPA applies a scoring system known as the I-IRS to determine if a site should receive a "no further remedial action planned" recommendation or be listed on the NPL for further action. An I-IRS can also be used to support other site evaluation activities under CERCLA (see ***The Revised Hazard Ranking System: Background Information,*** frtEPA 1990b). I-IRS scoring, however, is usually not applied at Federal facilities, especially for facilities within the IRP Program.

  DoD (1994b) has developed ***the Relative Risk Site Evaluation Primer*** to rank sites primarily for resource allocation and program management purposes. Although not a replacement nor alternative for I-IRS scoring, this model suggests that stakeholders consider evaluation factors (contaminant hazard factor, migration pathway factor, and receptor factor) to categorize sites according to "high," "medium," and "low."[1]

- **NPL** - Sites placed on the NPL (based on an HRS score of 28.5 or greater, state nomination, issuance of a health advisory by the Agency for Toxic Substances and Disease Registry (ATSDR), or other method) are published in the Federal Register and are eligible for Superfund-financed remedial action. DoD sites on the NPL. although not eligible for Superfund-financed remedial action, are eligible for Defense Environmental Restoration Account (DERA)-funded response actions.

1.3.1.2 Remedial Phase - To Determine the Degree of Risk Based on Nature and Extent of Contamination and Implement Cleanup Remedies if Warranted

- **RI** - The RI is a field investigation to characterize the nature and extent of contamination at a site and implement cleanup remedies if warranted. A baseline risk assessment, which includes both a human health risk assessment and an ERA, is performed as part of the RI. The baseline risk assessment is a component of the RI/FS report.

- **FS** - Based on data collected during the RI, remedial alternatives are developed, screened, and analyzed in detail. After potential alternatives are developed, the alternatives are screened against three broad criteria: effectiveness, implementability, and cost. Those alternatives which pass this initial screen will be

[1] *The Relative Risk Site Evaluation Primer* (DoD 1994b) has replaced the Defense Prioritization Model (DPM) which has features comparable to the HRS. DPM was used to predict whether the site may be a candidate for NPL listing or should receive priority funding under DERP.

further evaluated according to the nine criteria[2] and other risk management considerations not included in the criteria (e.g., environmental justice under Executive Order 12898) before one or more of such remedies is proposed for selection.[3]

- **Proposed Plan/Record of Decision (ROD) -** After the RI/FS process has been completed, a Proposed Plan is made available for public comment. The Proposed Plan identifies the remedies for the site jointly selected by the lead agency and the support agencies, and indicates the rationale for the selection. All final decisions and response to public comments are entered in a legal administrative record, the ROD.[4]

- **RD/RA** - RD is a subactivity in remedial implementation where the selected remedy is clearly defined and/or specified in accordance with engineering criteria in a bid package, enabling implementation of the remedy. RA is a subactivity in remedial response involving actual implementation of the selected remedy.

- **Five Year Review/Site Deletion -** Upon completion of all remedial actions, CERCLA and the NCP allows for the reclassification or deletion of the site from the NPL. If a remedial action results in any hazardous substances remaining on site, CERCLA Section 121(c) requires a review of the remedy once every five years to assure that: (1) the site is maintained, i.e., the remedy (including any engineering or institutional controls) remains operational and functional: and (2) human health/environment is protected, i.e., the cleanup standards (based on risk or ARARs) are still protective.

1.3.1.3 Removal Action - To Prevent, Minimize, Stabilize, or Mitigate Threat to Humans and the Environment

CERCLA Section 104 Removal Actions can take place at anytime during the entire CERCLA process. Unlike RAs, removal actions are not designed to comprehensively address all threats at the site. Removal actions may be emergencies (within hours of site discovery), time-critical (initiated within 6 months), nontime critical (planning for the removal action takes 6 months or longer), or early actions. Engineering evaluations and cost analyses (EE/CAs), comparable to FS, are required for removal actions that are deemed to be non time-critical.

1.3.2 RCRA Corrective Action Process

RCRA requires corrective action for releases of hazardous waste or hazardous waste constituents from Solid Waste Management Units (SWMUs) at hazardous waste Treatment, Storage and Disposal Facilities (TSDF) seeking an RCRA permit or approval of final closure. The owner or operator of a facility seeking a RCRA permit must:

- Institute corrective action as necessary to protect human health and the environment from all releases of hazardous waste and hazardous constituents from any SWMU at the facility.

- Comply with schedules of compliance for such corrective action.

- Implement corrective actions beyond the facility boundary.

The corrective action process has four main components: a RCRA Facility Assessment (RFA); a RCRA Facility Investigation (RFD; a Corrective Measures Study (CMS); and Corrective Measures Implementation (CMI).

- **RFA** - An RFA is designed to identify SWMUs which are, or are suspected to be, the source of a release to the environment. The RFA begins with a preliminary review of existing information on the facility, which may be followed by a visual site inspection. The RFA will result in one or more of these actions: (1) no further action is required: (2) an RFI is to be conducted to further investigate the documented

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[2] The nine criteria are (1) overall protection of human health and the environment, (2) compliance with applicable or relevant and appropriate requirements (ARARs), (3) long-term effectiveness permanence, (4) short-term effectiveness, (5) reduction of toxicity, mobility, or volume, (6) implementability, (7) cost, (8) state acceptance, and (9) community acceptance.

[3] If the RI shows no unacceptable risk, regulators may agree to eliminate the FS and proceed directly to a no-action proposed plan.

[4] OSWER has published several Directives for RODs. Further information on these can be found in the USACE (1995b) Technical Project Planning Guidance document.

or suspected releases; (3) interim measures are necessary to protect human health or the environment: and (4) referral to other authorities to address problems related to permitted releases.

- **RF1 -** An RFI may be required based on the outcome of the RFA. An RFI is accomplished through either a permit schedule of compliance or an enforcement order. The extent of this investigation can range widely from a small or specific SWMU study to an Area of Concern (AOC)**.** Results of the RFI will result in one or more of these actions: (1) no further action is required; (2) CMS is necessary: (3) interim corrective measures are necessary; or (4) referral to another authority to address problems related to permitted releases.

- **CMS** - A CMS is an "engineering evaluation" designed to evaluate and recommend the optimal corrective **measure(s) at each SWMU or CAMU where** contaminant levels are found in excess of screening "action levels" (developed during the RFI). Medium-specific cleanup levels protective of human health and ecological receptors are developed, and the boundaries or point(s) of compliance are set. At this project phase or before the CMI phase, RCRA provides the designation of a CAMU or TU in which remediation wastes **may be moved and managed** (according to the approved corrective measures) without triggering land disposal restriction regulations under 40 CFR Part 268. The remedy selected from all potential remedial alternatives, including the "no further action" alternative, should be based on four criteria:

  - Protection of human health and the environment

  - Attainment of media cleanup standards

  - Control of sources to eliminate harmful releases

  - Compliance with RCRA's waste management and disposal requirements

- **CMI** - A CMI includes the actual design, construction, operation, maintenance, and periodic evaluation of the selected corrective measures.

EPA can impose interim corrective measures on RCRA facilities under corrective action to protect human health and the environment. The interim corrective measures can be taken at any time during the corrective action process.

EPA is accelerating cleanups at RCRA corrective action sites by promoting the reduction of exposure and further releases of hazardous constituents until long-term remedies can be selected. These accelerated cleanup actions are known as "Stabilization Initiatives" and are similar in concept and application to the Super-fund Accelerated Cleanup Model (SACM) under CERCLA.

1.3.3 Functional Equivalency of CERCLA and RCRA Corrective Action Processes

The RCRA and CERCLA programs use different terminology but follow parallel procedures in responding to releases. In both programs. The fist step after discovery of a site is an examination of available data to identify releases needing further investigation. This step is called PA/S1 in the CERCLA process and RFA in the RCRA process. If imminent human health and/or environmental threats exist, a mitigating action is authorized. known as a removal action under CERCLA Section 106 or an interim measure under RCRA Section 7003 or 3005(c)(3). Both programs require an in-depth characterization of the nature, extent, and rate of contaminant releases, called an RI in the CERCLA process and an RFI in the RCRA process. This is followed by a formal evaluation and selection of potential remedies in the FS (CERCLA) or CMS (RCRA) project phase. The selected remedy is executed by an RD/RA under the CERCLA process or CMI under the RCRA process. A specific discussion of the functional equivalency of both programs is presented in the preamble discussion of the July 27, 1990, proposed rules for Corrective Action for SWMUs at Hazardous Waste Management Facilities. A diagram comparing the RCRA and CERCLA processes is presented **in** Figure i-l.

1.3.4 Role of Risk Assessment in the HTRW Process

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

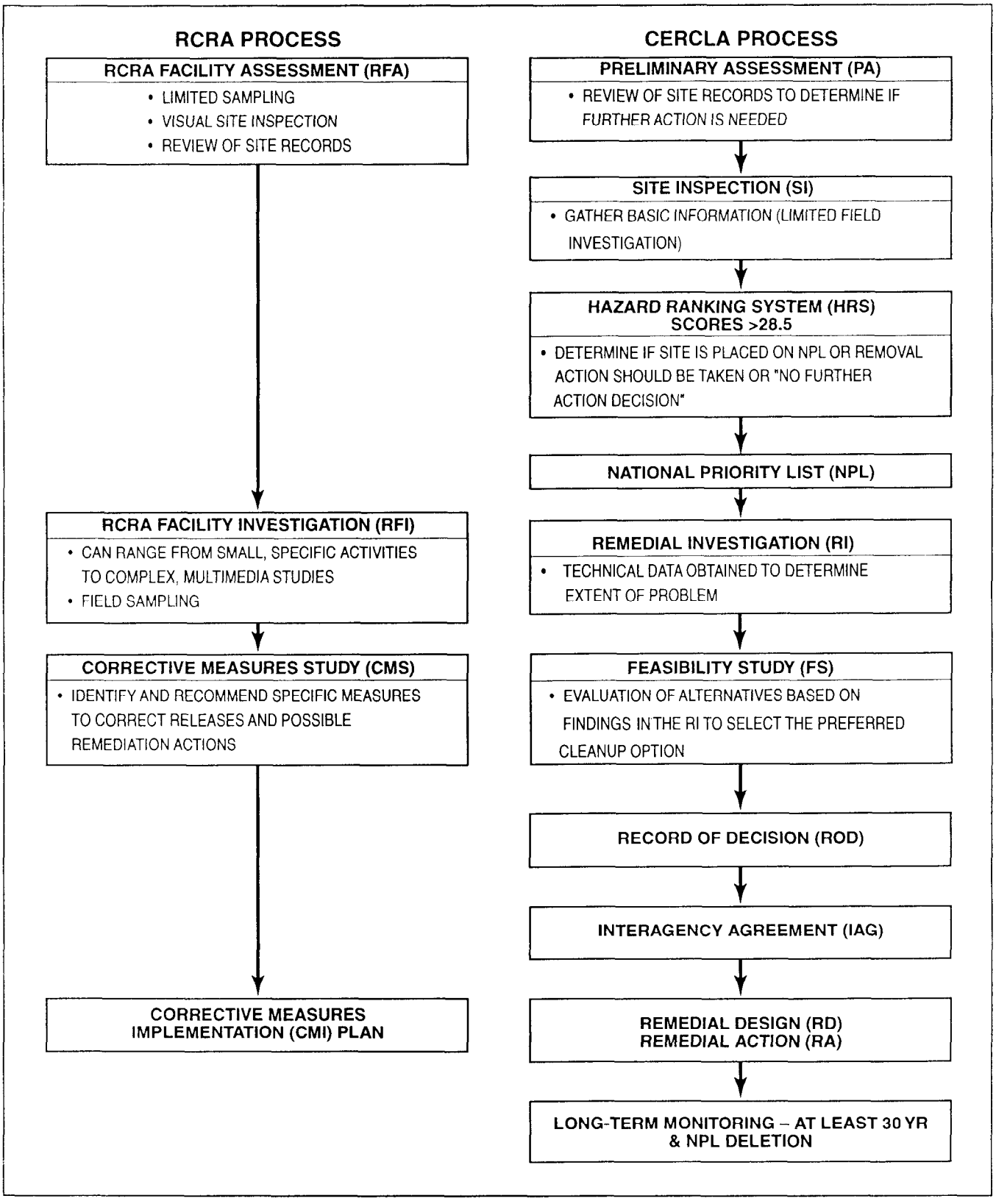


Figure 1-1. Comparison of RCRA and CERCLA processes

1.3.4.1 PA/SI, RFA, or Other Preliminary Site Investigation Activities

In this phase of the site investigation process, risk assessment information is used to: determine whether a site may be eliminated from further concern; identify emergency situations which may require immediate response actions/interim corrective measures: assess whether further site investigations are required; develop a data collection strategy; and set site priority, e.g., to rank sites.

The screening risk assessment developed during this phase should be conducted using conservative scenarios, as guided by the preliminary ECSM, to ensure that any closeout decision at the PA/SI stage is protective. The PA/SI ERA screening study is not to be confused with Preliminary Natural Resource Surveys (PNRSs), which are simple screening studies conducted by natural resource trustees in conjunction with an NRDA. If release of hazardous substances appears to have resulted in natural resource damage, then Section 122(j) of the amended CERCLA 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 in an ERA can be used by the trustees in carrying out their responsibilities.

1.3.4.2 RI, RFI, or Other Additional Site Investigation Activities

Data collected in this phase should comprise those media and pathways identified in the preliminary screening, including background data. If the data are useable and appropriate for the potential exposure pathways considered to be complete, a baseline ERA can be developed. The baseline ERA will identify whether unacceptable ecological risks are posed by existing conditions at the site.

For assessing 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 SWMUs or operable units (OUs) or developing a base-wide 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.

1.3.4.3 FS, RD/RA, CMS/CMI, or Other Remedial Design and Implementation Activities

The baseline ERA completed in the RI serves to identify the need for response actions and the relative degree of response required. The potential human/environmental impacts posed during remediation (short-term and long-term) and the residual risks after remediation are evaluated during remedy selection.

1.3.4.4 Use of Risk Assessment in Special Studies

The following are examples of ERAs used in special studies:

- ARAR Waiver - If a site-specific alternate remedial action objective developed from the ERA 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.

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

- 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 cleanup 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.

1.4 Concept of Risk Assessment and Good Science

Risk assessment can be qualitative or quantitative. It includes an integration of hazard (chemical or nonchemical), 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 judgement is needed to predict or infer certain outcomes under certain scientific principles (Federal Focus Inc. 1994). The application of such judgement requires that the risk assessor provide the rationale or basis for the judgement. This view is reflected by the recent *Policy for Risk Characterization* (EPA 1995a) and *NRC's* (1993) *Science and Judgement in Risk Assessment.* Both EPA and NRC recognize the inherent uncertainties in the risk assessment methodologies and the need for making risk assessments more transparent, clear, consistent, and reasonable.

This section highlights the principles, instructions, or recommendations for assessing ecological risks from potential COECs[5] in environmental media at HTRW sites. A more in-depth discussion of the various risk assessment components and issues relating to HTRW response actions is presented in Chapter 4.

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. This section concludes by identifying the minimum requirements for a risk assessment under the "good science" concept.

1.4.1 Basic Concepts

An open and unbiased ERA allows risk managers to make informed site decisions. The concept of "risk assessment" is presented in the following questions and answers:

What is a risk assessment?

- A risk assessment is an evaluation of the potential adverse impact of a given activity or a lack of activity upon the well being of an individual, a population, a community, or an organization. It is a process by which information or experience concerning the cause and effect under a set of circumstances (exposure) is integrated with the extent of exposure in order to assess risk. RAGS II (EPA 1989a) defines an ERA as a qualitative and/or quantitative appraisal of the actual or potential effects of a hazardous waste site on plants and animals other than people or domesticated species (EPA 1989a). EPA (1994a) further defines an ERA as an estimate of the likelihood that adverse ecological effects (e.g., mortality, reproductive failure) will occur as a result of a release of a hazardous substance at a Superfund site. EPA (1994a) states the purpose for conducting the ERA is to "(1) identify and characterize the current and potential threats to the environment from a hazardous substance release, (2) evaluate the ecological impacts of alternative remediation strategies, (3) establish clean-up levels in the selected remedy that will protect those natural resources at risk."

  Generally, an ERA consists of a three-step process:

  - **Problem Formulation** - specify objectives and scope; identify preliminary remediation goals; qualitatively evaluate contaminant release, migration, and fate; identify potential COECs, exposure pathways, receptors, and known effects: develop a preliminary ECSM: and select ecological endpoints.

  - **The Analysis Phase,** which is comprised of two major elements:

    - **Exposure Characterization** - quantify contaminant release, migration, and fate: characterize receptors: measure or estimate exposure point concentrations: and refine the ECSM regarding the relationships among trophic levels in the food web model.

    - **Effects Characterization Assessment** - review ecotoxicity information from

[5] Chemicals of potential ecological concern (COPEC) may also be used instead of potential COECs. The term "potential" should be used throughout the course of the ERA, until the chemicals are determined to be or not to be of concern. In this manual, the term potential is generally implied wherever COEC is used.

literature, toxicity testing, and field studies: and assess nonchemical impacts or potential adverse health impacts from remediation.

- **Risk Characterization** - present findings qualitatively or quantitatively with regard to the potential impacts to individuals, populations, communities, or other ecosystem components of concern from a single chemical or multiple chemicals from one or more site media, based upon the review of exposure assessment and exposure-response information. A candid discussion of the uncertainty associated with the risk characterization findings is an essential component of this step. This step focuses on the significance of the impact, causal association or weight-of-evidence, and sources of uncertainty.

Why use risk assessment in site decisions?

- Risk assessment can identify sites in the SI or RFA stage that warrant no further evaluation.

- Risk assessment provides a tool that enables risk managers to determine if remediation is warranted and to prioritize those sites requiring remediation.

- CERCL/SARA requires that remedial actions assure "protection of human health and the environment" against contaminants that "will, or may reasonably be anticipated to cause" certain adverse health effects, and must under certain circumstances meet standards set under other Acts..." The NCP provides for the use of risk assessment in removal actions, remedial actions, and remedy selection. Consistent with the NCP, the SACM at EPA requires site screening, risk assessment, and early action to reduce immediate risk for removal/immediate response actions.

- RCRA/HSWA establishes EPA programs to control disposal of solid wastes which "may cause, or significantly contribute to an increase in mortality or . . . serious irreversible, or incapacitating reversible, illness; or . . . pose a substantial present or potential hazard to human health or the environment" or which "endanger health [when present in excess of certain levels]." The RFI Guidance (EPA 1989b) provides general procedures for performing a health assessment and an environmental assessment. The Corrective Action Rule (RCRA Subpart S) also provides the use of a site-specific risk assessment to evaluate SWMUs or the CAMUs under enforcement actions or Part B permitting.

What are the minimum requirements of information **in the risk assessment?**

- Specification of which chemicals are of particular concern from an ecological perspective and what are the mechanisms for their release and transport (chemical abstract numbers should be provided).

- Environmental setting, and potential/reasonably anticipated land use.

- Potential receptors and populations, and the relationships of organisms/populations among different trophic levels in a community or ecosystem.

- Complete and significant exposure pathways.

- Reasonably assumed chemical uptake, bioaccumulation in the individual and biomagnification in the ecosystem under short-term and long-term exposure conditions.

- Adverse ecological effects for ecological receptors that are measurable and can be appropriately related back to the assessment endpoints.

- Uncertainties and limitations of the risk assessment, expressed either qualitatively or quantitatively.

- Chemicals and exposure pathways which contribute the most risk (pose the principal threat).

- Protectiveness of remediation goals and health impacts of the removal/remediation actions.

Throughout this manual, there are references to uncertainties in a risk assessment and the use of good science to plan and execute a site-specific baseline ERA. Clarifying the meaning of these terms will help readers who are responsible for scoping, planning, and reviewing a baseline risk assessment. The existence of uncertainties in a risk assessment and the importance of good science are explained in the following questions and answers:

How do "uncertainties" impact a risk assessment?

- The application of sound scientific principles is critical to assessing risks. Only rarely do sufficient data exist to accurately define the extent of exposure and the resulting ecological effects. Therefore, an ERA is frequently performed with assumptions, empirical models, extrapolations, test of hypotheses, and inferences of results which have a certain level of uncertainty. Many times, conservative assumptions are used in models relating to exposure and toxicity that characterize ecological risk. These assumptions add another degree of uncertainty to risk assessment. For these reasons, the predicted ecological effects experienced by the individuals, populations, and/or community could be higher than the current or future observed effects. This conservatism may unnecessarily result in environmental cleanup with little or no measurable environmental benefits and can divert resources from higher priority projects.

What is meant by "good science" in a risk assessment?

- Risk assessment as a "scientific" endeavor should be objective to assure that the assessment is specific to the site, is based on sound scientific principles, and is defensible. However, a risk assessment often requires use of "professional judgement" when data are lacking, lends itself to interpretation, often uses assumptions and generalities, and may easily become nonobjective. Bias or lack of scientific objectivity can cause the risk results to over- or under-estimate the true risks. This may result in costly delays or inappropriate inaction/action. Therefore, a peer review process should be incorporated in various phases of the risk assessment, and care should be given early in the scoping and planning process to collect data and specify requirements in performing a risk assessment under the HTRW program. Persons performing the risk assessment should have a good understanding of the site and should possess the basic skills needed to plan, collect, and interpret the information.

1.4.2 Risk Assessment as Decision Criteria in the HTRW Program

The role of a risk assessment in the site decision-making process at CERCLA and RCRA Corrective Action sites has been well defined by EPA 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 NPL, risk assessments should be similarly applied. Activities at these sites require the evaluation of potential 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 baseline risk assessment is an important decision tool for USACE customers. If cleanup is needed, the extent or level of cleanup required will be based on results of the baseline risk assessment, in addition to ARARs or other nonrisk factors. Therefore, risk assessment is used as a decision tool at all HTRW response action sites.

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 in the project planning phase to develop assessment strategies and preliminary remedial action objectives.

1.5 Policy Considerations and Risk Management

This section presents a general discussion of the influence of policy considerations in risk assessment and risk management. Because of the implications of policy considerations on the site decision process, the risk assessors and risk managers are encouraged to identify the policies early in the decision process.

Unlike regulations which are enforceable, policies or published guidelines are administrative procedures or requirements concerning certain environmental regulations. DoD has issued directives to components (Army, Navy, Air Force, Defense Logistic Agency, and Defense Nuclear Agency), reaffirming DoD's commitment to comply with specific environmental laws or executive orders. The respective components have also issued directives or orders expressing the same procedures or requirements. USACE will follow such policies or directives issued by DoD or its components regarding compliance with Federal environmental laws in the execution of HTRW response action at DoD installations or facilities. Some states or regional environmental control boards have also issued environmental policies or guidance. In the unlikely event that a policy is scientifically incongruent with site situations, early identification and

resolution are critical. HQUSACE or HTRW CX technical staff should be consulted in these instances. All major policies used in making site decisions should be identified in the ROD or site decision documents so that the USACE customers and other stakeholders can judge the merit of these policies in achieving protection of human health and the environment.

1.5.1 Relationship Between Policy Considerations and Risk

A risk assessment is the technical evaluation of the degree of hazard or risk associated with exposure of a receptor or receptor populations to contamination of an environmental medium or media. Risk management is oriented toward deciding whether remedial actions are warranted in light of the results of a risk assessment. The National Academy of Sciences (NAS) National Research Council (NRC) defines risk management as "the 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" (NRC 1983). NAS has identified four key components in managing risk and resources: public participation, risk assessment, risk management, and public policy decision-makers (NRC 1994).

In making risk management decisions, the risk manager considers the degree of risk, technical feasibility to address risk, costs and benefits, community acceptability, permanence of the proposed actions, and other similar factors which are subject to policy considerations or regulatory requirements. As such, risk management is an important part of the USACE HTRW site response process, as it combines results of the risk assessment, regulatory requirements, and applicable agency policies (e.g., applicable DoD policies for defense sites).

1.52 EPA Headquarters, Regional, and State Policies

To successfully complete a risk assessment for use in making site decisions, HTRW project managers and risk assessors generally work with Federal, regional, and state regulatory agencies to identify their specific policies or procedural requirements. HTRW risk assessors should identify and assist, where appropriate, in negotiations with the agencies on policies, procedures, and assumptions which are questionable.

All HTRW response actions should be in compliance with the Regulatory Policy Guideline issued under Executive Order 12498 (1985) Government Management, which states, "Regulations that seek to reduce health or safety risks should be based upon scientific risk assessment procedures, and should address risks that are real and significant rather than hypothetical or remote." USACE's HTRW position should be supported by scientific principles, site data, or literature values, whenever possible. USACE recognizes that at times, agencies have to set policies in the absence of scientific consensus: however, USACE, through the HTRW program, has the responsibility to apply such policies properly and objectively based on site-specific considerations.

1.5.3 Risk-Based Management Decisions for Site Actions

Risk managers select the most appropriate remedy by considering "trade-offs" among different remedial alternatives and evaluating the ability of the alternatives to accomplish the overall project objectives. To improve the quality of risk-based management site decisions, HTRW risk assessors should identify key information that can affect that decision-making. This information should include policy considerations, assumptions concerning the margins of safety, and the use of other relevant data not associated with the site in the risk assessment. The sources of such policies and data, as well as the qualifications of persons/organization recommending the policies or use of data, should be clearly identified. HTRW risk assessors can further help risk managers by providing an explanation of uncertainties in the risk assessment. When science deviates from policies or assumptions inherent in the risk assessment, it is the responsibility of HTRW risk assessors to clearly identify these instances as potential uncertainties as well.

1.6 Regulatory Directives and Guidance

This section highlights major executive orders, Federal statutes/regulations under which the HTRW programs operate, and EPA risk assessment guidelines which provide the basis for development of this manual. Irrespective of the procedures or mechanics for conducting risk assessments according to regulatory guidelines, all risk assessments performed under the HTRW response action must be based on "good science" and reasonable and unbiased scientific judgment. Although this section lists only major applicable executive orders and directives, others may be accessed through the appropriate agencies and databases on Internet (see Appendix B).

1.6.1 Executive Orders and Federal Statutes/ Regulations

Executive Order 12088 (1978). ***Federal Compliance with Pollution Control Standards,*** established the mechanism by which the Executive Branch assures that its facilities (in various departments) meet their compliance responsibilities by complying with substantive and procedural requirements of Federal environmental statutes. These statutes include: Endangered Species Act (ESA), the Clean Air Act (CAA); the Federal Water Pollution Control Act (Clean Water Act): the Solid Waste Disposal Act (as amended by RCRA); the Noise Control Act: the Marine Protection, Research and Sanctuaries Act (Ocean Dumping Act), the Safe Drinking Water Act (SDWA), the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the National Historic Preservation Act (NHPA), and the National Environmental Policy Act (NEPA).

Executive Order 12498 (1985), ***Government Management,*** incorporates by reference the regulatory principles contained in a Task Force report regarding future significant regulatory actions. Two principles of interest are:

- Regulations that seek to reduce health or safety risks should be based upon scientific risk-assessment procedures, and should address risks that are real and significant, rather than hypothetical or remote.

- To be useful in determining overall benefits and costs, risk assessments must be scientifically objective and include all relevant information. In particular, risk assessment must be unbiased best estimates, not hypothetical "worst cases" or "best cases." ... In addition, the distribution of probabilities for various possible results should be presented separately, so as to allow for an explicit "margin of safety" in final decisions.

Executive Order 12580 (1987). ***Superfund Implementation,*** requires all Federal agencies to comply with CERCLA/ SARA and NCP in the same manner as the private sector. This Order delegated to the Secretary of Defense the response authority of DoD, which includes removal/ remedial actions, site investigation and risk assessment, remedy selection, performance of PAs, and assuming natural resource trustee's responsibilities for current and former DoD facilities, and others. The Office of the Deputy Under Secretary of Defense for Environment Security (ODUSD [ES]) is responsible for carrying the Secretary's responsibilities and administering DERPs in compliance with this Order.

Executive Order 12777 (1991). ***Implementation of Section 311 of the Federal Water Pollution Control Act of October 18, I972 and the Oil Pollution Act of*** 1990. Delegates to the EPA and Coast Guard various responsibilities assigned to the President under Clean Water Act Section 311 and the Oil Pollution Act of 1990.

Other relevant Executive Orders include: Executive Order 11990 (1977), ***Protection of Wetlands,*** and Executive Order 11988 (1977), ***Floodplain Management.***

NEPA 1969 provides a national framework for the protection of the environment by requiring compliance with a wide variety of existing environmental statutes. It mandates the Federal agencies "utilize a systematic, interdisciplinary approach that will ensure the integrated use of the natural and social sciences and the environmental design arts in planning and in decision-making, which may have an impact on man's environment." The implementing regulations for NEPA am found in 40 CFR 1500-1508, as promulgated by the Council on Environmental Quality.

It is, in essence, a planning tool for nonemergency environmental actions, through either justifications for categorical exclusions or through preparation and approval of NEPA documents (i.e., environmental assessment [EA] and environmental impact statements [EISs]). The NEPA documents evaluate alternatives and provide analysis on alternatives regarding their impacts on health, safety, and welfare of humans and the environment, including environmental justice in minority and low income populations. HTRW response actions, specifically removal and remedial actions, could be subject to NEPA review for the selection of alternatives. The implementing guidance for DoD for NEPA includes:

- DoD Directive 6050.1 (July 30, 1979a), ***Environmental Effects in the United States of Department of Defense Actions.***

- DoD Directive 6060.7 (March 31, 1979b), ***Environmental Effects Abroad of Major Department of Defense Actions.***

- Army Regulation 200-2 (1988), ***Environmental Effects of Army Actions.***

RCRA 1976, as amended by the HSWA of 1984, has the objectives to protect human health and the environment,

reduce waste and conserve energy/natural resources, and reduce or eliminate generation of hazardous waste:

- Subtitle D - solid waste (encourages states to develop and implement solid waste management plans to provide capacity).

- Subtitle C - hazardous waste program (identifies hazardous wastes and regulates their generation, transportation, and treatment, storage, or disposal; authorizes states to implement the hazardous waste program in lieu of EPA: requires permits for TSDFs).

- Subtitle I - underground storage tanks (regulates petroleum products and hazardous substances stored in underground tanks: requires compliance with performance standards for new tanks: and requires leak detection, prevention, closure, financial responsibility, and corrective action).

CERCLA of 1980, as amended by the SARA of 1986 (42 U.S.C. 9601 et seq.) provides broad Federal authority to respond directly to releases or threatened releases of hazardous substances that may endanger public health or the environment. SARA defines the process Federal agencies must follow in undertaking remedial action, including a requirement that EPA make the final selection of remedy if there is a disagreement between the Federal agency and EPA.

The NCP (55 FR 8660, 9 March 1990) provides procedures and standards for how EPA, other Federal agencies, states, and private parties respond under CERCLA to releases of hazardous substances. The NCP authorizes the U.S. Department of the Interior (USDOI) and other agencies, states, or entities to be the "trustees" of natural resources to recover compensatory damages for "injury to, destruction of, or loss of natural resources resulting from a discharge of oil into navigable waters or a release of a hazardous substance."

Federal Facility Compliance Act (PL-102386. October 21, 1992) directs Federal agencies to comply with Federal and state environmental laws, and provides authority to EPA to impose penalties on other Federal agencies for noncompliance. Among others, it amended Section 6001 of RCRA to waive immunity of the United States (Federal department, agency, or instrumentality of the United States) to administrative orders and civil penalties or fines associated with Federal, state, interstate, and local solid and hazardous waste management requirements. Section 3004 of RCRA was also amended to require EPA, in consultation with DoD, to identify and regulate waste military munitions which are hazardous.

1.6.2 DoD Directives

DoD Directive 5100.50 (19731, ***Protection and Enhancement of Environmental Quality,*** establishes procedures and assigns responsibilities for use of DoD resources in the protection and enhancement of environmental quality and establishes the DoD Committee on Environmental Quality.

DoD Directive 5030.41 (1977a), *Oil and Hazardous Substances Pollution Prevention and Contingency Program,* sets forth DoD policy in support of the NCP.

DoD Directive 4120.14 (1977b) ***Environmental Pollution, Prevention, Control, and Abatement,*** implements within DoD new policies provided by Executive Order 12088 and Office of Management and Budget (OMB) Circular A-106, and establishes policies for developing and submitting plans for improvements needed to abate air and water pollution emanating from DoD facilities.

DoD Directive 6230.1 (1978). ***Safe Drinking Water, sets*** forth DoD policy for provision of safe drinking water and compliance with the SDWA.

DoD Directive 6050.1 (1979a), ***Environmental Effects in the United States of DoD Actions,*** implements the CEQ regulations and provides policies and procedures to take into account environmental considerations in DoD actions.

1.6.3 EPA Headquarters and Regional Guidance

CERCLA

Guidance documents (OSWER Directives) for conducting various phases of a CERCLA response action have been developed or are being finalized by EPA headquarters. Key CERCLA guidance documents are identified below (also see Appendix B):

- ***Guidance for Performing Preliminary Assessments Under CERCLA*** (EPA 199 la). This document provides the PA objectives, data requirements, the procedural steps to complete the PA, and develops a site score using PA scoresheets. It also provides guidelines for reviewing the site evaluation and score, including identification of sites for emergency response actions.

- ***Guidance for Performing Site Inspections Under CERCLA*** (EPA 1992b). This document provides the approaches, data acquisition planning needs, sampling strategies, data evaluations using the SI worksheets, and reporting requirements for the CERCLA SI. The document describes the approach of use of a focused SI to test the PA hypotheses, resulting in one of three recommendations: (1) site evaluation accomplished: (2) expanded SI to collect additional data: or (3) preparation of an FIRS package for placement of the site on the NPL if the HRS scoring data requirements have been met.

- ***Hazard Ranking System Guidance*** (EPA 1992c) provides guidance to individuals responsible for preparing HRS packages for sites for inclusion on the NPL.

- ***Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA, interim final*** (EPA 1988a). This guidance describes the CERCLA RI/FS process to characterize the nature and extent of contamination or risks posed by a site and to evaluate whether remedial action is needed. It describes the site characterization techniques, the role of a baseline risk assessment, feasibility studies, and development of screening and detailed analyses of remedial alternatives.

- ***Guidance for Data Useability in Risk Assessment (Part A)*** (EPA 1992d) and (Part B) (EPA 1992e). These guidance documents provide approaches and recommendations for defining, planning, and assessing analytical data for the baseline risk assessment.

- ***Risk Assessment Guidance for Superfund, Volume II, Environmental Evaluation Manual*** (RAGS II) (EPA 1989a) - The guidance consists of two parts: (1) a guidance manual that establishes a general framework for understanding the ecological principles of a Super-fund ERA and discusses the performance of the assessment, and (2) a compendium method handbook, *Ecological Assessment of Hazardous Waste Sites: A Field* ***and Laboratory Reference*** (EPA 1989c).

- ***Eco Update*** - Eco Update is a bulletin series on ecological assessments at Superfund sites. These bulletins serve as supplements to RAGS II and share information with the readers advisories involving the Biological and Ecological Technical Assistance Groups (Biological Technical Assistance Groups [BTAGs], Ecological Technical Assistance Groups [ETAGs]), and other ERA and natural resource issues. The bulletin series is written for both general and technical audiences.

- ***BTAG Forum*** - BTAG Forum is a bulletin series published by EPA/OERR primarily to foster communication among BTAGs/ETAGs in EPA Regional Offices. The Forum carries news from the Regions, information on publications and other potentially useful resources, requests for information, and other items of interest to BTAG members.

- ***Superfund Program Checklist for Ecological Assessment/Sampling*** (EPA 1993a) - This checklist provides guidance on making observations during an ecological assessment and is a screening tool for preliminary site evaluation. The checklist is not intended to be used for limited actions nor for purely industrial settings with no discharges, but may be useful in planning more extensive site investigations.

- EPA Regional guidances - A number of EPA Regions and states have developed ERA guidance and specific protocols or approaches. Risk assessors should consult with the individual EPA Regions or states to obtain their specific guidances. For example, EPA Regions V and VI have published regional ERA guidance (EPA 1992f; EPA 1991b); EPA (1994b) Region III has issued *Interim Ecological Risk Assessment Guidelines:* and EPA Region IX is developing protocols for the evaluation of terrestrial indicators.

RCRA

Limited guidance has been developed for conducting various phases of a RCRA facility response action to address current or past releases. The key RCRA guidance documents that are available are identified below:

- ***RCRA Facility Assessment Guidance*** (EPA/530-SW-86-053) (EPA 1986a). Provides guidance for conducting facility assessments to reflect developments of the RCRA corrective action programs. Also clarifies the definition of an SWMU.

- ***RCRA Corrective Action lnterim Measures Guidance*** (EPA/530-SW-88-029) (EPA 1988b). Assists EPA regions and states to perform corrective action interim measures to mitigate or remove an exposure threat presented by releases.

- ***RCRA Corrective Action Plan*** (EPA/530-SW-88-028) (EPA 1988c). Provides technical framework for development of Corrective Action Orders and corrective action permit requirements.

- ***RCRA Facility Investigation (RFI) Guidance*** (EPA 1989b). General guidelines for performing health and environmental evaluations are described in this four-volume guidance manual. With regard to performing environmental risk assessments, this guidance is substantively equivalent to RAGS and references the CERCLA methodology.

1.6.4 State Requirements/Guidance

HTRW risk assessors and project managers need to be aware of any risk assessment procedures, data needs, or programs specific to the state in which their site is located. Almost all states have been authorized for RCRA permitting: some have corrective action authorities. Many states have statutes and regulations that address uncontrolled hazardous waste sites and SWMUs associated with regulated RCRA facilities. Also, many states have primacy in the water pollution control program (under CWA) and have either adopted EPA criteria or developed their own water quality standards. Many states have adopted the use of risk assessment for corrective action, to demonstrate "how clean is clean," to develop site-specific cleanup goals, to evaluate facilities burning hazardous waste, or for other uses.

Some states have developed specific guidance for assessing environmental impacts. For example, the New York Department of Environmental Conservation (NYDEC 1991) has developed *Fish and Wildlife Impact Analysis for Inactive Hazardous Waste Sites. Environmental Risk Characterization Guidance* is available from the Massachusetts Department of Environmental Protection (MDEP 1994). California Environmental Protection Agency has also developed its own guidance entitled, *Guidance for Ecological Risk Assessment at Hazardous Waste Sites and Permitted Facilities* (CAL EPA 1994). Pennsylvania's Department of Environmental Resources (1991) has developed *Risk Assessment Guidelines for Facilities Burning Hazardous Waste.* Other states (Connecticut, Illinois, and Kentucky) have adopted RAGS II, and in some cases, EPA regional guidance, as a matter of policy.

In addition to state rules, regional initiatives may exist that may need to be considered when performing an ERA. For example, EPA (1995b). in coordination with the Great Lakes states, undertook the Great Lakes Water Quality Initiative (GLWQI) and published the *Final Water Quality Guidance for the Great Lakes Systems (60 FR* 15366). The guidance specifies water quality criteria for the Great Lakes as well as specific water program requirements. The purpose of the guidance is to establish consistent water quality criteria within waters of the Great Lakes basin.

1.6.5 Others

U.S. Army (USA)

Army Regulation 200-l. *Environmental Quality, Environmental Protection, and Enhancement* (USA 1990). implements the Federal environmental laws and regulations at the Department of the Army facilities. Chapter 12-5. Army Regulation 200-1 requires the performance of an Environmental Baseline Study for any property transaction. DA PAM 40-578 (USA 1991). entitled *Health Risk Assessment Guidance for the Installation Restoration Program and Formerly Used Defense Sites,* presents the methodology used by the Army when reviewing health risk assessments, and designates the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) to oversee and recommend approval or disapproval to the Army Surgeon General on all human health risk assessments prepared by executing agencies for Army IRP sites, BRAC sites, and FUDS.

The U.S. Army Edgewood Research, Development, and Engineering Center (USAERDEC) (formerly the U.S. Army Chemical Research, Development, and Engineering Center) has developed the *Procedural Guidelines for Ecological Risk Assessment at U.S. Army Sites* (USAERDEC 1994). This guidance develops a standardized ERA procedure and tiered approach for assessing ecological risks.

Army Regulation 420-74, *Natural Resources -- Land, Forest, and Wildlife Management, p*rovides Army policy for managing natural resources and attaining the goal of ensuring that Army actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of the critical habitat of such species.

U.S. Air Force (USAF)

The Office of the Air Force Surgeon General's Biomedical Engineering Service (BES) is responsible for providing technical support for all Air Force DERP CERCLA activities. The Air Force *Installation Restoration Program Management Guidance* (USAF 1989) and FY 93/94/95 *DERA Eligibility and Programming Guidance* (USAF 1992) provide guidance in this area. Work relating to hazardous waste management activities under RCRA is performed by the BES in accordance with Air Force Regulation 19-7 and *USAF Hazardous Waste Management Policy* (USAF 1991). Currently, the environmental service centers for USAF, such as USACE, or the risk assessors at respective Major Air Force Commands (MACOMs) review risk assessments in coordination with the Air Force Surgeon General.

The Human System Division IRP Office at Brooks Air Force Base, Texas, has developed the *General Guidance for Ecological Risk Assessment at Air Force Installations* (USAF 1990). The document provides an overview of the fundamentals of risk assessment and guidance for conducting an ERA. Guidance is provided for assessing the terrestrial, freshwater, and marine habitats.

U.S. Navy and Marine Corps

The Chief of Naval Operations directive OPNAVINST 5090.1B (DON 1994), Department of the Navy (DON), assigns command responsibilities and provides Navy policy to comply with environmental laws and regulations. The Navy and Marine Corps IRP Manual (DON/CNO 1992) describes the Navy organization/responsibilities in support of IRP, priority for funding, research, training, and reporting requirements including preparation of Pollution Control Report to satisfy the OMB Circular A-106 reports to EPA. The Naval Environmental Health Center, under the direction of the Bureau of Medicine and Surgery (BUMED), provides a wide range of medical consultative services to the Naval Facilities Engineering Command community in support of the IRP, the BRAC Program, and other related environmental projects. Consultative support services include but are not limited to review of IRP and BRAC program documents (e.g., work plans, sampling and analysis plans, quality assurance/ quality control plans: remedial investigation/feasibility studies, risk assessments, health and safety plans) from a risk assessment and public health perspective: conducting risk evaluations or quantitative risk assessments; training in risk assessment, public health assessment, health and safety plans, and risk communication: sponsoring the 3-day tri-service Environmental Risk Communication and Public Dialogue Workshop: negotiating with regulators regarding the use of realistic exposure assumptions; assisting in developing community relations plans: assisting in establishing Restoration Advisory Boards (RABs); assisting in preparing correspondence from a risk communication perspective; preparing posters for public exhibits and public meetings; and acting as the DON liaison for ATSDR issues.

U.S. Environmental Protection Agency (EPA)

EPA has published a number of enforcement policies and procedures for Federal facilities, e.g., *Federal Facilities Compliance Strategy* (EPA 1988d), *Enforcement Actions Under RCRA and CERCLA at Federal Facilities* (EPA 1988e), *Evaluation Process for Achieving Federal Facility Compliance* (EPA 1988f), *Federal Facilities Negotiations Policy* (EPA 1989d), and *Federal Facilities Hazardous Waste Compliance Manual* (EPA 1990c). All Federal agencies are required to comply with hazards waste regulations and the NCP in the same manner as the private sector. EPA has published numerous guidance and resource documents applicable to ERAs. Many of these references are presented in Appendix B.

U.S. Department of Energy

DOE has issued a number of orders (5400 series and others) addressing a variety of environmental statutes and requiring all DOE facilities to comply with applicable environmental laws and regulations. Some of the key DOE guidances are included in Appendix B.

U.S. Department of Commerce, National Oceanic and Atmospheric Administration (NOAA)

NOAA has published a manual entitled *The Coastal Resource Coordinator's Bioassessment Manual* (NOAA 1992). As a desk reference manual for coastal coordinators, this manual provides general guidelines on the application of bioassessment procedures to different stages of the hazardous waste site remedial process, the design of bioassessment studies, and use of specific bioassessment methodologies. In addition, a summary of recommended aquatic toxicity testing protocols is provided. NOAA (Long et al. 1995) has also published screening levels for chemical concentrations in marine sediments, based on studies at multiple sites in the marine and estuarine environments.

Canadian Council of Ministers of the Environment

Environment Canada (1994) has published a *Framework for ERA* and sediment screening values (CCME 1995). The Canadian province of Ontario has published sediment lower effect level (LEL) and severe effect level (SEL) values for the evaluation of marine and freshwater sediments (Persaud, Jaugumagi, and Hayton 1992, Long et al. 1995).

USFWS

USFWS published the Contaminant Hazard Review series between 1985 and 1994. This continuing series of reports reviews the hazards of specific toxic compounds to invertebrates and wildlife. Biological Report 90(2) summarizes data on soil toxicity for screening assessment for terrestriaI systems (Beyer 1990).

Water Environmental Research Foundation (WERE)

WERF (1994) has developed the *Methodology for Aquatic Ecological Risk Assessment* which embraces established methodologies developed by the Federal agencies, national laboratories, and private institutions, and contains new, original procedures. The guidance is intended to assist members of the regulated and regulatory communities who need to estimate the effects of toxic chemicals on aquatic communities from new point or nonpoint sources of chemicals, improved wastewater treatment, discharge changes from an existing wastewater treatment facility, and hazardous waste site cleanup or remediation.

USGS

The U.S. Geological Survey (USGS) offers numerous publications on topics relevant to ecological risk assessment (e.g., background water chemistry).

1.7 Federal Facility Agreement

Although there may be subtle differences between a Federal Facility Agreement (FFA) and an IAG, these terms are used interchangeably under CERCLA Section 120 which addresses both NPL and non-NPL sites. This section focuses on the need for early planning and negotiation of an FFA among the USACE customer (a Federal agency), EPA, and the state agency (as appropriate). To accomplish this objective, the HTRW project team member (i.e., the risk assessor) and others should work cooperatively to develop statements/languages or addenda to the FFA early in the HTRW project cycle to define a flexible framework or process for risk management decision-making and to facilitate a site closeout protective of human health and the environment.

Executive Order 12580 delegates DoD to conduct response action under Section 104 of CERCLA (as amended by SARA) to address releases on DoD facilities or originating from the facilities. The order requires that the response action be conducted in accordance with Section 120 of CERCLA. According to CERCLA Section 120(e)(l), DoD is directed to enter into an IAG with EPA for remedial action within 180 days of EPA's review of the RI/FS. The *Federal Facilities Hazardous Waste Compliance Manual* (EPA 199Oc) states, "At a minimum, the IAG must include a review of cleanup alternatives considered and the remedy selected, a schedule for cleanup accomplishment, and arrangements for operation and maintenance" (EPA 1990e).

To address noncompliance issues at a Federal facility (e.g., a DoD installation), EPA may issue a complaint known as Notice of Noncompliance (NON). After such an issuance, EPA and the Federal facility enter into negotiation for a Federal Facility Compliance Agreement (FFCA) which resolves compliance violations and stipulates agreed-upon remedy, compliance schedule, and reporting and recordkeeping requirements. The target date for concluding such an agreement is within 120 days from the date of NON issuance (EPA 1990c). Since RCRA corrective actions are generally required at the time of RCRA Part B permitting or permit renewal, the Federal facility may be issued a RCRA Section 3008(h) corrective action order rather than a NON.

In recent years, model language has been developed to facilitate agreement among the Federal agency, EPA, and the state agency (if applicable) to identify milestones, schedule, requirements, and dispute resolution procedures pertaining to investigation and cleanup at CERCLA and RCRA sites. In the Federal Facility Compliance Agreement (FFCA) of 1992, Federal agencies are no longer afforded with "sovereign immunity" from compliance with state and Federal environmental laws. In the opinion of the Department of Justice (DOJ). however, executive branch agencies may not sue each other nor may one issue an administrative order to another without providing a prior opportunity to contest the order within the executive branch. "Executive branch disputes of a legal nature are properly resolved by the President or his or her delegate..." (EPA 1990a). In view of the above, and for the purpose of this manual, the risk assessor should provide assistance to the USACE's project manager (PM), USACE's technical manager (TM), risk manager, and the USACE customer so that an FFA or IAG can be

successfully negotiated to provide a framework for risk management decision-making and to initiate actions to protect human health and the environment where these actions are needed. The risk assessor and the HTRW project team may consider the following areas for assistance to be provided to the USACE customer concerning the FFA negotiation: these areas have been identified in the DoD-EPA Model IAG Language (EPA 1989d):

1.7.1 Basis for Interim Remedial Action (IRA) Alternatives

For purposes of this guidance, IRA may be interpreted as interim corrective measure under RCRA or removal action under CERCLA. One purpose of the FFA is to identify IRA alternatives which are appropriate at the site prior to the implementation of final remedial action(s). To identify such alternatives, the exposure area (study area or the area of ecological concern), the exposure pathways which contribute to the principal threat at the site, and the receptors/resources must also be identified. For the purpose of the FFA, a statement may be entered which indicates the basis for identifying IRA alternatives. This statement should address the following:

- The approach for conducting a screening risk analysis of the exposure units (EUs) (EPA 1991c), SWMUs, or the AOCs.
- The evaluation method for the risk assessment/ analysis results (qualitative or quantitative).
- Risk management decision-making considerations (Chapter 9) for identifying and/or selecting the IRA alternatives.

1.7.2 Requirements for RI/RFI and FS/CMS

Another purpose of the FFA is to provide a framework for investigating, assessing the impact, and evaluating remedial options to protect public health and the environment. Such a framework, consistent with the NCP and the RI/FS guidance (EPA 1988a), may be modified and formally incorporated in the FFA to meet the site-specific and project requirements. Statements or languages or addenda to the FFA may be prepared by the risk assessor and the project team to serve as a basis for determining the extent of data collection, data evaluation, assessment of baseline risk, and evaluation of remedial alternatives. The HTRW data quality design process (USACE 1995b) and associated DQOs should be identified as the framework for determining data needs, data use, and data quality. The point of departure for no-further action and/or monitoring only based on acceptable risk should be identified in the FFA (EPA 1991d). The statement should indicate the phased approach recommended by this manual and other inputs from the expert ecologist, risk assessor(s), or advisory panels (e.g., BTAG/ETAG; Restoration Advisory Boards/Technical Review Committees [RABs/ TRCs]), including criteria used for assessment of uncertainties.

1.7.3 Expedited Cleanup Process

Both DoD and EPA are in agreement that early action or accelerated cleanup may be needed to stabilize the site and to facilitate implementation of the final remedies. However, the basis for such action is not well defined, except that the actions are intended to control contaminant migration, to reduce exposure, and to accelerate response. In addition to time-critical and emergency response actions where safety and acute hazards are involved, the risk assessor and the project team can provide valuable input to the USACE customer and risk manager for such expedited actions. This can be rather quickly accomplished by comparing the measured media concentrations with available human health and ecological risk-based protective criteria. This may be useful for relatively straightforward sites, such as drum removal, product removal, and containment. For response actions at a complex site, a baseline ERA may be more appropriate, however, and expedited cleanup would not be done. All decision criteria for eliciting response actions to protect environmental components should be well thought out, reasonable, and consistent with current EPA guidance.

1.7.4 Units Excluded from the Agreement

RCRA and CERCLA integration issues should be addressed in the FFA in unambiguous terms. This is particularly true for sites of which the state agency is also an interested party or natural resource trustee in the agreement. Some state agencies have their own risk assessment policies and guidances, and risk management decision-making criteria which may vary substantially from those of EPA (EPA's ERA procedures under RCRA and CERCLA are judged to be substantially equivalent at this time). The risk assessor should review state policies, guidance, and requirements, and identify any critical risk assessment/risk management issues for the PM, TM, and the customer for resolution. These issues should be addressed and resolved in the FFA negotiations. If not successful, separate FFAs may be needed to address RCRA and CERCLA units within the facility. The USACE and customer's legal counsels should be contacted for briefing on these issues early in the process.

Chapter 2
Ecological Risk Assessment Scoping Considerations

2.1 Introduction

This chapter introduces the conceptual and technical objectives for scoping an ERA and the elements that should be included in an ERA. The methodology for conducting the ERA is presented in greater detail in the following chapters. Chapters 2 through 8 are intended as a guide for enabling a risk assessor and risk manager to critically scope and evaluate ERAs, as well as appraise their quality for supporting potential site remedial responses at his or her site. These chapters present important components of the risk assessment, highlighting where planning and professional judgment are needed. They are not intended to present step-by-step instructions. Adequate guidance for preparing an ERA is provided in other resources as referenced throughout this manual.

The ERA is an integral component of the PA/SI, RFA, RI/FS, RFI/CMS, and emergency response processes. It serves multiple roles regarding the need for action at a site:

- The ERA provides an evaluation of the potential ecological risks under baseline (i.e., no action) conditions.
- The ERA helps to determine the need for remedial action at the site.
- The ERA provides a basis for determining remediation goals for chemicals in site media.
- The ERA can be used as a basis for comparing different remedial alternatives.
- The ERA provides a means for assessing potential ecological risks and for allowing comparison of potential ecological risks between sites.

The ERA is one component of overall site investigation and remedial activities. It should be developed with a recognition of how it is supported by preceding and concurrent components of site activities, such as sampling and analysis and the human health risk assessment effort, and how it supports and shapes the following components, such as remedial design. Although the ERA is performed to achieve several specific objectives (describing current and future ecological risks), it needs to be coordinated with other site activities (e.g., human health risk assessment) and needs to be responsive to other general site concerns (e.g., restoration, mitigation, litigation) and the resources (cost and schedule to be met) available.

Risk assessments have different applications in different regulatory programs.[1] The application of risk assessment is discussed in the following phases of site activity:

- PA/SI and RFA.
- RI and RFI.
- FS and CMS activities, including development of remediation levels and comparative risk assessments associated with selected remedial options followed by the evaluation of short-term risks associated with the implementation of the selected remedial option.
- RD/RA and CMI activities, including potential need to further evaluate short-term risks for the purpose of designing/implementing control measures.
- Assessment of residual risk after implementation of the selected remedial option.

Risk assessments developed for each of these activities will have slightly different scope or level-of-effort requirements. However, the technical basis for the risk assessment is essentially the same.

EPA's *Framework* (EPA 1992a) and *Risk Assessment Guidance for Superfund, Volume II (RAGS II),* (EPA 1989a) provide the general guiding principles and structure for the conduct of an ERA and the format of this manual. Forthcoming guidance from EPA Headquarters, Environmental Response Team (ERT), is expected to provide further details on an eight-step process for designing and conducting ERAs based on the *Framework* (M. Sprenger, EPA 1995c). Additionally, USAERDEC's (1994) *Procedural Guidelines for Ecological Risk Assessment at U.S. Army Sites* presents a similar framework

[1] Performance of an EBS under the BRAC program is not addressed in this guidance. However, the general concepts, particularly those for the Tier I ERA, are applicable to this program to meet the objectives of the Community Environmental Response and Facilitation Act (CERFA).

approach and a three-tier investigative process used to further enhance an understanding of the ERA requirements under CERCLA.

The framework for ERAs as presented in these references is conceptually similar to the approach used for human health, but is distinctive in its emphasis in three areas. First, the ERA can consider effects beyond those individuals of a single species and may examine a population, community, or ecosystem. Second, no single set of ecological values to be protected can generally be applied. 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).

2.2 Scoping Considerations

The consistent standardized approach presented in these guidance documents was devised to ensure consistent treatment among sites. For scoping purposes, it should be noted that most ERAs are highly site-specific and often require unique investigative plans and actions. Numerous other resource materials, guidance documents, bulletins, memoranda, technical manuals, and books that address the general ERA approach and scoping of site-specific data needs are available from EPA, other regulatory agencies, and scientific sources. A number of these resources are referenced in Appendix B. A copy of the Framework (EPA 1992a) is provided in Appendix C. The following chapters provide the USACE risk manager with more detailed guidance information on the ERA process, along with "how to" and "where to find" knowledge for evaluating the scope, design, and conduct of a site-specific ERA.

2.2.1 Objectives of the Ecological Risk Assessment

The goat of the ERA is to provide the necessary information to assist risk managers in making informed decisions. 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 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.

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 project to define decision data needs. 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:

- Generating a credible, objective, realistic, and scientifically balanced analysis.
- Presenting information on the problem, effects, exposure, and risk,
- Explaining confidence in each assessment by clearly delineating strengths, uncertainties, and assumptions, along with impacts of these factors (EPA 1995a).

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.

2.2.2 Definition of Ecological Risk Assessment

According to EPA's *Framework* (EPA 1992a). 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. Stressor is defined by EPA as 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 CFR 302.4) are the stressors of concern. 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).

No consensus definitions exist for many of the terms used in an ERA. Definitions herein are generally consistent with those used in the *Framework* (EPA 1992a) and *RAGS II* (EPA 1989a).

2.2.3 Planning for an ERA

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 risk management decisions, the risk assessor must always be mindful of the question, "Do the data and ERA approach support risk management decision-making?"

Planning for an ERA should be conducted concurrently with that for a human health assessment in that these two efforts often have similar data needs. ERA data needs are generally similar to those for human health risk assessments in the initial contamination characterization stages. Data needs for the ERA, however, eventually focus on developing remedial alternatives that are protective of ecosystem components, while the human health risk assessment focuses on developing remedial alternatives that are protective of a single species, humans.

Coordinated planning efforts for the ecological and human health risk assessment efforts, particularly where there is to be an expedited cleanup, should include consideration of the following:

- Overlaps in information needs with regard to human and ecological food chain issues.
- Benefits of the cleanup and the effectiveness of presumptive remedies.
- Ecological impacts from removal or remedial activities designed to protect human health.
- Identification of hot spots that may impact both human health and ecological receptors.
- Identification of the key assumptions and criteria common to the human health and eco-risk risk assessments that may drive cleanup decisions and focus the decision-making process.
- Early actions which may be taken at sites (i.e., OUs, CAMUs) that could quickly and at a relative lower cost reduce both ecological and human health risk.
- Identification of areas of greatest concern that may be addressed as discrete tasks in the ROD, thereby allowing priority to be given to those (removal/remedial) actions that achieve the greatest protection of the environment and human health for the capital (dollars) spent.
- 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.

ERAs employ a systematic planning format and process to ensure production of consistent and technically defensible ERAs. The ERA format and process, as described in the Framework, is designed to be flexible. Widely applicable regulatory protocols for formal site-specific ERAs are currently not available (in contrast to the approach used for human health). The flexible ERA process provides for coordination with the human health assessment in the chemical sampling program, determination of extent and degree of contamination, characterization of site risk. and the overall site management decision process.

In identifying data needs for the ERA, the risk assessor must fully understand the customer goals, regulatory programs driving the HTRW project execution and the associated project decision statements (PDs),[2] the study elements for the relevant project phase, and the type of ERA needed based on the study elements. The concept of technical project planning is fully explained in the USACE's (1995b) Technical Project Planning Guidance for HTRW Data Quality Design, which emphasizes the need for the data users (e.g., the risk assessor) to identify minimum data requirements for the tasks to be performed.[3] The concept of "minimum requirements" for

[2] PDs represent specific planning objectives of HTRW site investigations and evaluations. Selected PDs become the principal focus of the data quality design efforts (USACE 1995b).

[3] The HTRW technical project planning is a four-phased (Phase I through Phase IV) process that begins with the development of a site strategy and ends with the selection of data collection options. Throughout the process, USACE HTRW personnel of various disciplines and responsibilities (some of whom may assume multiple responsibilities) work closely together to identify data needs, develop data collection strategy, and propose data collection options for the customer. The HTRW data quality design process implements the EPA's DQO process, which is an iterative process applicable to all phases of the project life cycle.

the ERA is important in that it identifies certain minimum requirements for data collection activities preceding the ERA to ensure that critical data gaps or factors are addressed. Examples of minimum requirements for a risk assessment are presented in Exhibit 1.

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 screening techniques, 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 (EPA 1995a,d). The project planning process should produce an outline for a site-specific ERA that is credible, objective, realistic, and scientifically balanced. Since the ERA is conducted in an iterative, tiered approach, a decision diagram similar to that presented in Figures 2-l and 2-2[4] should be presented for discussion.

Throughout the planning discussions, the risk assessor should strive to point out potential setbacks, problems, or difficulties that may be encountered in a "'real world" situation. Biological sampling programs often entail scheduling constraints, e.g., surveys for endangered speties (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 nondetects 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[5]

[4] Details presented on the tiered ERA process in these figures are elaborated upon in succeeding chapters. See Section 2.4 for an introduction to USACE's four-tiered EPA approach.

[5] For example, if the RI data are skewed, it may be necessary to address site risk by evaluating hot spots separately. The risk assessor may wish to indicate this in the Work Plan, in order to characterize hot spot areas without delaying the assessment of risks for the non-hot-spot areas.

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 develop ment, identification of site media, 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. Coordination with an agency (EPA or DoD [USAEC]) BTAG/ETAG coordinator will also help ensure conduct of an effective and acceptable 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 onsite burrowing animals from being at risk), the risk assessor should provide the basis that will allow him or her to answer this question.

In the risk planning process and on Superfund sites in particular, it is also important for the risk assessor, risk managers, and decision-makers to coordinate with natural resource trustees (e.g., DoD, the State, NOAA[6] USFWS, USFS, and BLM) at the earliest possible stage. In this

[6] NOAA's Coastal Resource Coordination Branch (CRCB) works with EPA through all phases of the formal remedial process at Superfund waste sites. The CRC Branch acts for the Dept. of Commerce as trustee for natural resources such as anadromous and marine fish. Coastal Resource Coordinators (CRCs) and an advisory staff of environmental, marine, and fisheries biologists provide technical support and expertise to EPA, DoD, and other agencies during response and cleanup at coastal waste sites. The CRCs and supporting staff recommend appropriate environmental sampling, coordinate with other natural resource trustee agencies to build consensus on natural resource issues, and recommend appropriate cleanup levels. The CRCB works with EPA to gain cost-effective remedies that minimize residual resource injury without resorting to litigation. CRCs are in most EPA regions (not in Regions 7 and 8; coming soon to Region 5). See Appendix B for additional information on NOAA programs.

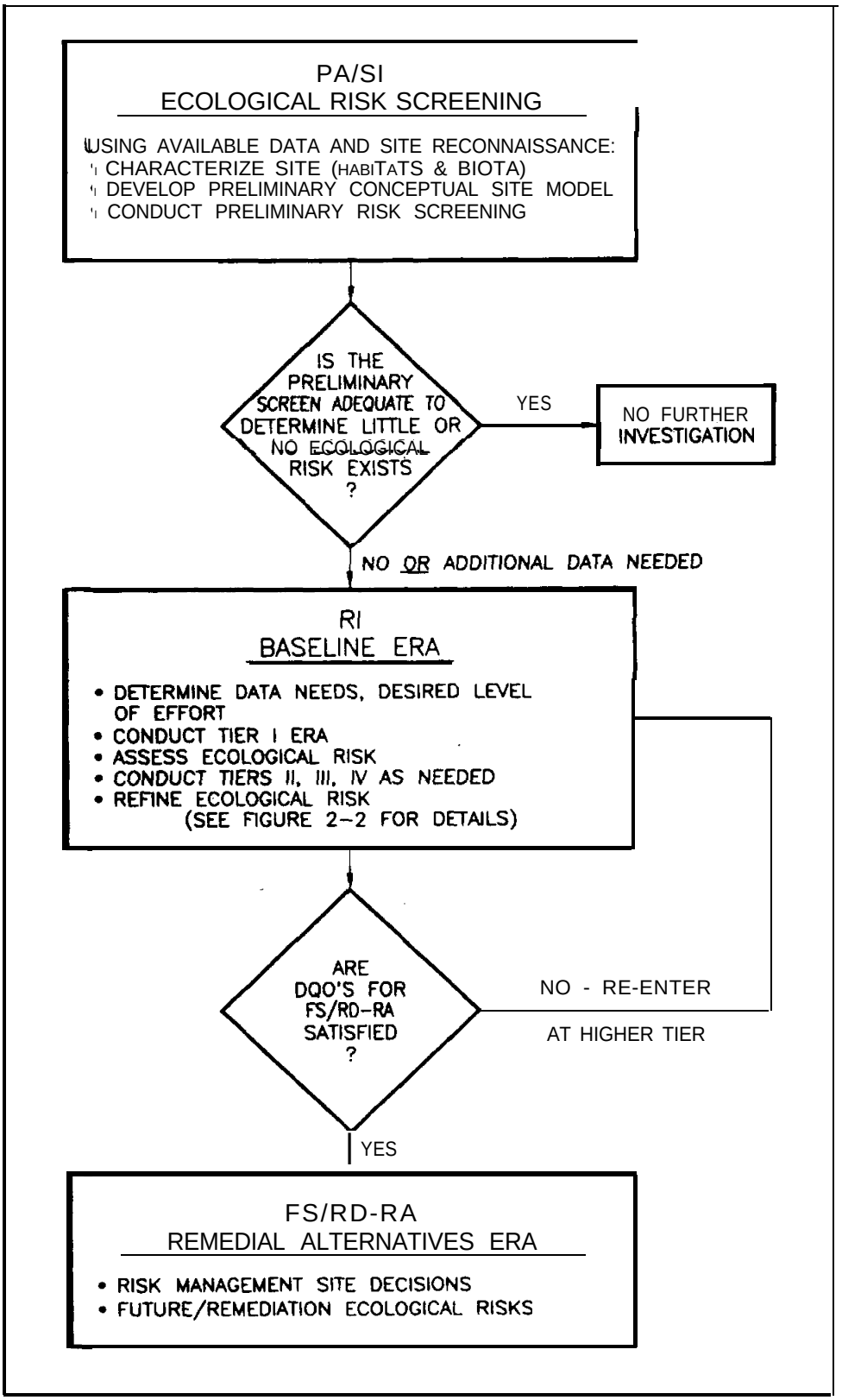


Figure 2-1. ERA flow chart

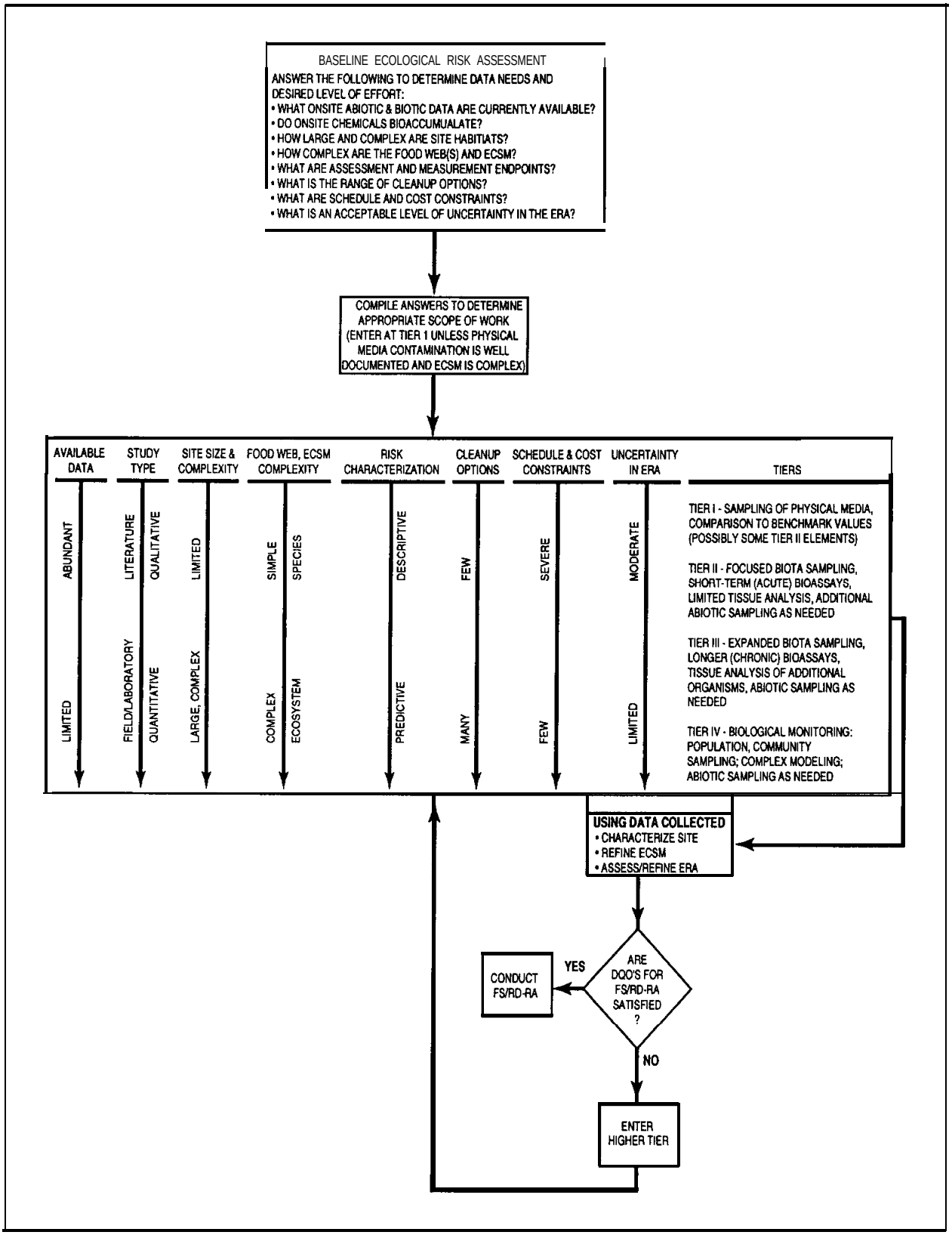


Figure 2-2. Baseline ERA flow chart

way, the trustee can be assured that potential environmental concerns are addressed and conclusion of action may be expedited (EPA 1989a). 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, to ensure the protectiveness of the selected remedy for trust resources, and to provide for proper restoration and mitigation for injured 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, PM/TM meetings, and public information meetings.

2.2.4 HTRW Policy and Technical Project Planning

The ERA process presented herein is consistent with DoD and EPA policy and guidance. Recent EPA (1995d) risk characterization guidance reaffirms the principles and guidance found in earlier EPA (1992g) policy, Guidance on Risk Characterization for Risk Managers and Risk Assessors. EPA's (1995a,d) risk characterization policy establishes the core values of clarity, transparency, reasonableness, and consistency in both ecological and human health risk assessments across Agency programs. Adherence to this policy is intended to:

- Ensure that risks are characterized fulIy, openly, and clearly.
- Promote full disclosure of scientific analyses, uncertainties, assumptions, science policies, and the rationale which underlie decisions as they are made throughout the risk assessment and risk management process.
- Improve the understanding of ERAs, to lead to more informed decisions, and to heighten the credibility of both the risk assessment and risk management decisions.

Risk management is an important aspect of USACE's HTRW program. To ensure the utility of the ERA in meeting risk management needs, the HTRW Technical Project Planning process laid out in EM 200-1-2 (USACE 1995b) should be followed. In accordance with this planning process, the USACE PM and/or TM provides the leadership to define a site strategy and to effectively communicate this strategy.

Risk assessment is based on a series of questions about scientific information that is relevant to the estimation of risk. Each question calls for analysis and interpretation of the available studies, selection of the concepts and data that are most scientifically reliable and most relevant to the problem, and scientific conclusions regarding the questions presented. The HTRW planning process is used to focus on data needs and to design quality data collection options. The HTRW planning process also encourages early refinements of the data collection options as a means of identifying cost-effective options for selection. By emphasizing the process, it is expected that the ERA will be useful as a site-decision-making tool.

2.2.5 The HTRW Technical Project Planning Process

USACE recognizes the need for cost-effective and efficient site investigation/response actions. The HTRW Engineer Manual 200-1-2, *Technical Project Planning Guidance for HTRW Data Quality Design* (USACE 1995b) provides guidance on data collection programs and defines DQOs for HTRW sites. The HTRW technical project planning process is a four-phased (Phase I through Phase IV) process that begins with the development of a site strategy and ends with the selection of data collection options.

DQOs define the project's data needs, data use, number of samples desired, the associated quality assurance 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 (Phase IV) of the HTRW data quality design process after the customer has selected the preferred data collection program (ER 1110-1-263, USACE 1995c). 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. 'Ibis 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.

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 HTRW data quality design process implements the EPA's DQO process, 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 (TQM) tool (EPA 1989e). Incorporating the HTRW data quality design and technical project planning process is key to ensuring successful planning and performance of the ERA.

Three basic questions related to the use of the HTRW technical project planning approach are:

- What decisions are the data intended to resolve? What are the primary and secondary regulatory programs that require data input? What are the customer's goals and concept of site closeout? Where is the project phase under such program(s)? What are the PDs for the project phase?

- Why does the customer (or the data user) need a specific type and quality of data? What are the study elements for the project phase? What are the minimum data requirements for the study elements? What am the data quality requirements to satisfy PDs? (For example, to eliminate sites early in the project phase based on the lack of ecological resources of concern, the study element could be an environmental survey and assessment to identify the presence or lack [unrelated to contamination] of ecological resources of concern. The data quality associated with the survey and assessment will need to be specified. Involved parties would also have to agree on the finding that ecological resources of concern [potential assessment endpoints] are absent.)

- How will data be used to defend site decisions? How will the results of the study be used to satisfy PDs? What are the data collection options and anticipated removal/remedial options, if applicable? What is the customer's preference or choice for the options? How should the selected option(s) be implemented? (If sensitive receptors are identified at a site, the customer may choose to further evaluate the impact by collecting data to support a baseline ERA. Alternatively, the customer may chose to negotiate with the regulatory agencies on various interim measures or remedial actions to mitigate the release or rehabilitate the site).

Phases I through IV (described below) of the HTRW technical project planning elements address the above questions methodically and should be incorporated or used in the entire HTRW project life cycle. Using this technical project planning process, the risk assessor will be able to define minimum information requirements for risk evaluations in support of site decisions. Further explanation of the HTRW data quality design approach as it relates to the conduct of the ERA is provided in Appendix D. The utilization of key information identified in the ERA for risk management decision-making is described in Chapter 9.

2.2.5.1 Phase I - Develop Project Strategy

This phase of the project planning process involves identifying site decision requirements and developing an approach to address these requirements. Site strategy is broadly defined in the beginning of a project at this stage. As the project progresses into subsequent phases, the strategy is refined based on an improved understanding of the site. The risk assessor is crucial to the development of appropriate site strategy in this phase and the identification of data needs/quality to support risk management decisions. In this planning phase, site conditions am reviewed qualitatively, and a preliminary ECSM is developed to help define the study elements for the current and subsequent project planning phases. In terms of project execution, key inputs required for decision-making can be more readily defined after site-specific conditions are generally understood.

2.2.5.2 Phase II - Identify Potential Data Needs to Support Decisions

This phase of the project planning process focuses on identifying data needs and minimum data quality requirements to support site decisions identified in the PDs. Data users identify potential data needs and their respective proposed quality assurance/quality control requirements based on site background, regulatory information, and the customer's goal. At this phase, the compliance specialist, remedy-design engineer, and responsibility-legal data users, who have specific data needs, present their data requirements along with the data needs identified by the risk assessor. The objective is to scope out data needs and quality requirements by ah project team members. Data requirements are documented so that the data implementors, chemists, geologists, and/or statisticians may recommend potential optimum sampling design and data collection options for selection and implementation.

At most sites it is unusual for massive, adverse, ecological effects impacting sensitive species or valued resources (assessment endpoints) to be readily observed in a field survey. Consequently, multiple data or measurement

endpoints are needed to infer or link the collected data with the assessment endpoints. The likelihood or tendency to overscope data needs at this project planning phase is high, if an iterative approach is not followed. The danger of falling into a trap of endless research studies without added benefits can readily occur if the risk assessor attempts to address all uncertainties in a single study.

Contaminants found on many CERCLA/RCRA sites are commonly localized to small areas. In these cases, perturbations on the overall structure and function of valued (societal and ecological) populations (excluding threatened and endangered species), communities, or ecosystems are often found to be negligible. Depending on the specific site conditions (or presence of protected receptors), simple screening methods and limited field studies or bioassays (e.g., Tier I or Tier II approach as described in Chapters 4 and 5, respectively), are frequently adequate for risk management decision-making.

To select the proper risk assessment approach, given time and resource constraints, it is important that the risk assessor has the proper training and experience to scope and manage the ERA. To the extent feasible, the experience and skill of expert ecologist(s) and advisory groups (BTAG/ETAG) should be leveraged when identifying the data needs for the ERA. Data needs consistent with customer's goals and concept of site closeout, time/budget, site and project strategy, PDs, and the project study element requirements are documented as part of the Phase II requirements. This information in turn is communicated to the data implementors for developing sampling strategies and data collection options under Phase III.

2.2.5.3 Phase III - Identify Data Collection Options

This phase of the technical project planning process incorporates previously identified data needs and project constraints in designing a data acquisition approach. Various sampling approaches can be used, ranging from purposive (judgmental or biased) to representative sampling methods. Data may also be obtained from single-step to multi-step abiotic (media) investigations, from single species and microcosm (multitrophic levels) laboratory toxicity tests to mesocosm, sentinel and field surveys, or to long-term (multiseasons and multiyear) modeling and monitoring studies of ecological community function and reference areas to satisfy data needs critical for the site decisions.

This phase of project planning also involves identifying the optimum sampling/data collection scheme so as to minimize mobilization, field sampling, and demobilization efforts and costs. The objective of Phase III is to identify options (preferably two or three options, out of which one is an optimum option) for presentation in Phase IV.

2.2.5.4 Phase IV - Select Data Collection Options and Assign DQOs

This is the most important phase of the project planning/ execution process, because this is where data collection options are selected. To properly execute Phase IV, the proposed options should be clearly explained and characterized. The discussion should include data uncertainties, cost/benefits, schedule, and other constraints. Based on feedback from the customer or decision-maker, the project team may have to refine the preferred option(s). Prior to the presentation of options, it is recommended that the PM or TM review the options to determine if they are consistent with site strategy and meet the requirements of the PDs.

The project team critically reviews the output from Phase I through Phase III of the project planning process to recommend an array of options. Specifically, the project team reviews the army of data collection options and reexamines the PDs, data needs (including critical samples, i.e., samples necessary for the site decision at that project execution phase) and their quality assurance requirements, budget/tie constraints, the customer's goals, and regulatory/compliance requirements. The team reexamines whether the options meet the project strategy and whether the options are cost-effective in terms of meeting minimum data requirements of the data users and the site decision-makers for the current phase. as well as subsequent phases of the project.

Because ERAs typically have limited budget and time for completion, data requested for the ERA should be action-oriented, i.e., they should assist the customer to make informed decisions. It is critical that sufficient data are collected to address uncertainties associated with the ERA. Although such uncertainties can often be addressed via long-term research projects or studies, these are generally not appropriate under RCRA and CERCLA. The purpose of an ERA is not to prove an ecological effect or accurately predict such effect, but to reasonably determine the degree to which hazardous constituents or wastes have impacted or could impact the structure. function. and dynamics of the ecosystems (i.e., biological diversity,

functional integrity, energy and nutrient dynamics). If the impact is judged to be significant, further action will be warranted.

The products of this phase of the project planning process are the Statement of Work (SOW) for USACE work acquisition (either internal or the architectural-engineering [A-E] contractor), a detailed cost estimate for the selected option, and DQOs for the data collection program. The DQOs explain the objectives of the data gathering activity, the data type/location, data collection and analytical methods, rationale for requiring certain data quantity and quality, and how the data are to be used in making site decisions. If the acquisition strategy in Phase I technical project planning was to seek assistance of an A-E contractor, the DQOs and the appropriate information from Phases I through III will also be provided to the contractor to develop the Sampling and Analysis Plan (SAP) (synonymous with Chemical Data Acquisition Plan. USACE 1995a,b), in order to meet the goals and objectives of the next executable phase of the project life cycle. Caution should be taken at this point about the integration and coordination between the human health assessment and ERA as to how they influence DQOs. RAs may require lower media-specific detection limits than human health assessments for certain COECs and vice versa. The ultimate DQOs should be the lower of either for dual purpose samples, or the appropriate concentration for specific purpose samples.

Depending on the level of expertise and familiarity of the contractor with the project, the USACE HTRW PM may elect to allow the contractor to assume some responsibilities to complete Phases II through IV, with input from USACE. In terms of technical project planning for ERAs, it is critical that the contractors are trained and understand the Corps ERA approach, the customer's objectives and site strategy, and have the required experience.

The Phase IV project planning process involves the selection and documentation of the data collection program in support of an ERA or risk analysis. Such documentation will provide a historical knowledge which justifies and guides the data review and data use.

2.2.6 Approaches to the Conduct of an ERA

The approach and level of effort for an ERA are based on DQOs developed under the HTRW technical project planning process. DQOs address data quality and quantity requirements and data use. DQOs am integral to the design and conduct of cost-effective and efficient ERAs under current and future land-use scenarios.[7] While the overall framework for the conduct of the risk assessment should remain consistent with the Framework 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.

A preliminary ERA screen is generally based on the criteria or chemical concentration-based approach. Chemical criteria, such as state and Federal ambient water quality criteria (AWQC) or naturally occurring background concentrations, are routinely screened against in the initial investigation stage of an ERA. Ecotoxicological risk-based screening concentrations (RBCs), similar to human health RBCs, are being developed in some EPA regions. These chemical screening concentrations represent conservative values that are designed to be protective of specific ecosystems (aquatic, terrestrial, wetland) and can serve as a technical basis for the development of site-specific cleanup objectives. Numeric screening concentrations, however, are not available for a great many chemical contaminants.

The ecological effects-based approach is more commonly applied in the baseline ERA. 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

[7] For example, if the intended use of the site after site closeout is a park/recreation area, the data to be collected to support the ERA will be quite different from the future land use of an industrial park. The former may involve identifying the potential ecological receptors of concern (based on a reference park/recreational area), availability of food sources, and assessing the potential effects of the potential COECs, under the no-further-action scenario. The data needs and DQOs for the latter land use may only include collecting data to ensure that the current site condition and its conversion to an industrial park will not impact potential ecological receptors in the vicinity of the site, including those in surface water bodies. EPA's land use guidance, *Land Use in CERCLA Remedy Selection Process* (EPA 1995e) and other land use information should be reviewed as part of the HTRW technical planning process.

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 co augment the risk assessment. Criteria for evaluating causal associations have been suggested by Hill (1965) and are provided in EPA's (1992a) *Framework.*

Both of these approaches are part of the overall strategy of the Framework approach for establishing site-specific remediation objectives (see Section 2.3). The following chapters are directed more toward the former approach in their presentation of the quotient methodology and discussion of risk-based screening concentrations. The toxicity test approach is described in much greater detail in two recent documents: *Procedural Guidelines for Ecological Risk Assessment at U.S. Army Sites* (USAERDEC 1994) and *Methodology for Aquatic Ecological Risk Assessment* (WERF 1994).

ERAs also entail the use of various classification schemes such as: qualitative versus quantitative, predictive versus retrospective, empirical versus theoretical, and top-down versus bottom-up methods. These schemes have been described in publications by Parkhurst et al. (1990), Norton et al. (1988). and Pastorok and Sampson (1990) 'and in Environment Canada's (1994) *Framework for ERAs.* Use of a particular classification scheme rests on site-specific objectives and, to a great degree, the knowledge and experience of the risk assessor.

2.2.7 Establishing the Level of Effort

The preliminary level of effort and nature of the ERA are directly related to the PDs 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 preliminary assessment and the site-specific nature of the potential risk.

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. Project 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. The methodology for conducting an ERA, as described in this manual, is based on a four-tiered approach. The four-tiered approach is introduced in Section 2.4 and presented in detail in Chapters 4 through 8.

2.3 Introduction to the ERA Process

This ERA process presented herein is based on EPA's *Framework* and its risk paradigm for ecological assessments. The framework consists of three major phases or parts: (1) problem formulation, (2) analysis, and (3) risk characterization. Problem formulation is a planning and scoping process that establishes the goals, breadth, and focus of the risk assessment. Its end product is a conceptual model that identifies the environmental values to be protected (assessment endpoints), the data needed (measurement endpoints), and the analysis to be used. The analysis phase develops profiles of environmental exposure and ecological effects of the COECs on the receptors of concern. The exposure profile characterizes the ecosystem, in which the COECs 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 COECs on the receptors of concern and relates them to the assessment and measurement endpoints. Risk characterization integrates the exposure and effects profiles. 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. Risk can be expressed as a qualitative or quantitative estimate. depending on the available data.

Most ERAs include an initial risk screening assessment to provide an initial delineation of the problem and to help structure the baseline ERA should one be needed. The screening ERA is a streamlined version of the complete *Framework* process and is intended to allow a rapid determination by the risk assessor and risk manager if the site poses no or negligible risk. The basis of the screening level assessment is the ecological site characterization and

the comparison of site abiotic media concentrations with existing environmental criteria and guideline values (i.e., ARARs), such as Federal and state[8] AWQC: marine sediment effects levels (Long et al. 1995); freshwater sediment effects levels (Persaud, Jaugumagi, and Hayton 1992); or other readily available screening-level ecotoxicity values. The basis for applying the existing environmental criteria and guidelines draws on factors introduced later and presumes an understanding of the risk assessment methodology.

Environmental criteria such as Long et al.'s (1995) sediment criteria, EPA's (1993b) proposed sediment criteria, or EPA AWQC are not the same as remediation levels discussed in Chapter 8. In general, environmental screening criteria should be highly conservative and should not necessarily be applied as cleanup objectives at a site. The sediment criteria and AWQC may be used as a screening tool prior to the performance of an RI or RFI. Remedial levels are developed later from the site-specific baseline ERA and are tailored to site ecology as well as management objectives. The biological/ecological basis for each screening criterion should be carefully considered if used for more than screening, since it is entirely possible that such criteria could be overprotective or underprotective of the potentially exposed receptors, depending on site-specific biological, physical, and chemical characteristics.

A screening ERA may be performed for a PA/SI (RFA), or as the initial step in the RI (RFI) baseline ERA. In addition to environmental criteria, other factors that should be considered in the screening ERA include habitat suitability (e.g., absence of suitable habitat because location is an industrial area) and exposure pathways (e.g., absence of complete exposure pathways to ecological receptors). If the initial risk screen suggests the site cannot be eliminated based on environmental criteria or suitable habitat and exposure pathway considerations, project planning may occur to review the screening results and define the scope and critical aspects of performing a baseline ERA. Spatial boundaries such as the size of the impacted areas or potential threats to important ecosystem components (e.g., threatened and endangered species and their habitat) greatly determine the potential scope and design of the baseline ERA. Data deficiencies may be determined early on as part of the risk screen. Recognizing these planning elements and articulating specific objectives early in the risk screening stage will determine the need and drive the design and focus of the baseline ERA. The decision to continue beyond the preliminary ecological risk screen 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 risk and accompanying uncertainty is needed.

The baseline ERA is a process that combines data from biotic and abiotic media along with exposure and toxicity information to provide a determination of environmental risk. The methodology presented in this chapter for performing the baseline ERA has largely been developed by EPA for activities undertaken under CERCLA. This methodology is appropriate for ERAs performed as part of CERCLA RIs or RCRA RFIs. as well as many other situations. The two primary guidance documents that form the basis for the discussion on ERA methodology include:

- *Risk Assessment Guidance for Superfund - Volume II: Environmental Evaluation Manual (RAGS II).* Interim Final. (EPA 1989a).

- *Framework for Ecological Risk Assessment (Framework).* Risk Assessment Forum. (EPA 1992a).

Supporting Federal and state guidance documents, methods documents, and information sources are provided in Appendix B.

The baseline ERA provides an objective, technical evaluation of the potential ecological impacts posed by a site. The baseline ERA 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 baseline ERA is used by the risk manager, in conjunction with regulatory and policy considerations, to determine the appropriate response actions at the site.

While the methodology for conducting the ERA is presented in detail in the following chapters, this manual is not intended to be a step-by-step instruction manual. Rather, it is intended to be a guide for scoping and critically evaluating the screening and baseline ERAs. Adequate guidance is provided in other resources for performing and preparing an ERA, and is referred to throughout the remainder of the manual. This and the following chapters discuss the important components of the screening and baseline ERAs, highlighting where up-front planning and professional judgment are needed. The

[8] Both state and Federal AWQC should be reviewed as state AWQC can be more stringent than the Federal criteria.

goal in providing the following detailed description of the baseline ERA process is to enable a risk manager to critically appraise the scope, conduct, and quality of an ERA for his or her site.

2.4 Introduction to the Four-Tiered Approach

A four-tiered approach is incorporated in the conduct of a baseline ERA and the evaluation of potential adverse effects on ecological receptors. The four tiers are:

- Tier I - Preliminary Ecological Risk Assessment: The Tier I ERA is characterized by relatively simple, quantitative wherever possible, desk-top methods that rely heavily on literature information, previously collected data, and a chemical-concentration based approach.

- Tier II - Focused Biological Evaluation and Sampling: The Tier II ERA is recommended where there is a need to reduce uncertainty or verify Tier I findings by using a biological effects-based, sampling approach.

- Tier III - Expanded Sampling Program: The Tier III ERA is recommended where longer term or more extensive biological or chemical sampling programs are needed to resolve issues presented by larger sites having complex ecosystems.

- Tier IV - Monitoring Program: The Tier IV ERA is reserved for the largest and most complex sites and is only appropriate where multiple year, biological monitoring or sampling programs are needed, and an ERA with the highest degree of certainty is required.

The tiered approach to the baseline ERA is composed of sequentially more sophisticated and complex evaluations. Therefore, scoping of the ERA for different tiers will require various data needs to be satisfied. Sequential evaluation, feedback, and flexibility allow for sound scientific judgments and efficient use of resources by minimizing unnecessary data collection, focusing major efforts, and optimizing benefits. Each tier has a similar three-part framework and builds upon knowledge. data, information, and decisions from the preceding tier, with each becoming progressively more focused. Although each tier is, in essence, a stand-alone evaluation, consistency and continuity are needed to keep the focus on assessment endpoints intact as the baseline ERA proceeds to higher tiers.

Within each tier, the baseline ERA, like the screening ERA, consists of the three major parts described in EPA's Framework:

- Problem Formulation.
- Analysis.
  - Exposure Characterization
  - Ecological Effects Characterization
- Preliminary Risk Characterization and Summary.

The tiered approach to the baseline ERA is an iterative process, with each subsequent tier including the same three parts, but building on information provided in the previous tier. Within each tier, new biological, toxicological, and abiotic chemical data are collected or evaluated. in order to revise and focus the ERA effort (see Figure 2-2). Also, within each higher tier, the data collection effort generally shifts from direct chemical analyses of abiotic media to short-term biotic sampling to longer term biotic sampling. The tiered approach is designed to address a series of questions regarding ecological conditions and effects at a site. Decisions are made in each tier as whether to proceed to the next tier and what specific sampling analyses should be conducted, based on the adequacy of data collected up to that point. While proceeding to the next tier may entail an expansion of time and effort, use of the iterative tiered approach provides a way to focus the ERA on specific decisions and DQOs throughout the process. The tiered approach offers an opportunity for decision-making at a variety of steps and thereby eliminates unnecessary testing and focuses resources on the important problems.

Tiering of a site-specific ERA is intended to provide a flexible, cost-effective management mechanism for the site investigation. While the baseline ERA process follows the simplified Framework structure, the actual level of effort within and between tiers may be both nonsequential and iterative. The order of actions taken depends on site status, RI/FS or RFI/CMS stage, amount and types of site information available, the necessity of multiple sampling events, and other factors. While the tiered approach is intended to maximize efficiency of data collection, there are cases where the tiered approach may require multiple field programs or time delays. In some cases, logistics and cost considerations outweigh the benefits of tiered testing. The scope of the effort and cost/benefit of applying the tiered approach are determined

through project planning, DQO evaluation, and through risk management decisions based in part on the results of the screening ERA.

Overall, the tiered approach is designed to ensure that all procedures to be performed are appropriate, necessary, and sufficient to characterize the nature and extent of effects to biota under the current and future land (or resource) use scenarios. To evaluate the relationship between contamination and ecological effects, the tiered approach requires iterative reevaluation of strategy objectives and data needs throughout the process, based upon the integration of three types of information:

- Chemical: Chemical analyses of appropriate media to establish the presence, concentrations, and variabilities of specific toxic compounds.
- 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.
- Toxicological: Toxicological and ecotoxicological information or testing to establish the link between adverse ecological effects and known contamination.

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. Use of the tiered approach is intended to maximize the efficiency of data collection in each of these three areas, using the information obtained at each tier to focus on the problem, and optimize the design of the next tier, if needed.

The four tiers and their interrelationship are shown on the flow charts in Figures 2-1 and 2-2. Figure 2-1 shows the overall relationship of the baseline ERA to the screening ERA and the Remedial Alternatives ERA (FS/RD-RA). Figure 2-2 shows the interrelationship of the four tiers within the baseline ERA. As shown in Figure 2-2, the number of tiers likely to be included in the baseline ERA depends on the PA/SI screening ERA results, specific project planning objectives and determination of data needs (see USACE's [1995b] HTRW Technical Project Planning document), and potential constraints such as schedule and cost, or cleanup options. Whether or not to proceed from the Tier I ERA to a focused biological field sampling program (Tier II), or an expanded biological sampling program (Tier III), or a multiple-year sampling program (Tier IV) will depend on how decision data needs are satisfied during the Tier I effort.

Chapter 3
Evaluating the Screening Ecological Risk Assessment

3.1 Introduction

The screening ERA follows general EPA guidance as presented in the Framework (EPA 1992a) and RAGS II (EPA 1989a). The screening ERA is a generalized, simplified assessment that is conducted by assuming conservative values for parameters where data are lacking. A screening ERA assessment may be performed as part of the PA/SI or RFA effort or as the initial Tier I effort during the CERCLA RI or RCRA RFI. The screening ERA consists of the following elements:

- Problem Formulation.
- Analysis.
  - Exposure Characterization
  - Ecological Effects Characterization
- Preliminary Risk Characterization and Summary.

3.2 Problem Formulation

Problem formulation begins with a compilation of readily available information on the environmental setting and potential contamination problem. EPA suggests use of their environmental checklist (EPA 1993a) 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., 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 assessment endpoints. Ecological information on potentially impacted environments and components can be derived from installation natural resource personnel, state natural heritage reports, and Federal agencies such as the USFWS.

3.2.1 Chemical Data Collection and Review

Appropriate data must be used for the screening level assessment to meet its objectives. Data available from PA/SI and RFA activities are usually limited in number but should be broad in scope of chemical analysis and in the number/type of abiotic media sampled.

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 screening ERA 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 ERA will be limited and cannot be used to eliminate the site from further consideration,

The following are examples of minimum requirements for data applied to a PA/SI or an RFA screening level assessment:

- Chemical-specific analyses of appropriate abiotic media of potential concern (soil, sediments, surface water).
- Data of good quality according to the analytical methodology applied.

3.2.2 Ecological Conceptual Site Model

A preliminary ECSM may 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.

3.2.3 Problem Formulation Summary

A problem formulation summary typically includes the following:

- The environmental setting: contaminants expected, and maximum (or 95% upper confidence limit [VCL]) concentrations on a medium-by-medium basis.
- Contaminants and likely categories of ecological resources and receptors that could be affected.
- The complete exposure pathways that may exist within the impacted area.

Assessment and measurement endpoints are generally identified in the screening BRA. For the screening ERA, assessment endpoints include any likely adverse ecological effects on ecological resources of concern, for which exposure pathways are complete, as determined from the information listed above. Measurement endpoints are based on available toxicity values from the literature (i.e., toxicological endpoints). Through the exposure-response evaluation, exposure at or above levels at which adverse ecological effects might be expected are established from the contaminants and exposure pathways of concern.

3.3 Exposure and Effects Analysis

The analysis process consists of two interrelated efforts: exposure characterization and effects characterization.

3.3.1 Exposure Characterization

The two primary objectives of the exposure characterization are (1) identification of the important ecological receptor(s) or receptor group(s) in relation to the assessment endpoint(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 or receptor species are typically chosen for evaluation in the screening assessment, Ecological receptors with the highest potential for exposure and/or high sensitivity to exposure should be identified. Development of a preliminary ECSM (see Section 4.2.6) in conjunction with the preliminary ecological site characterization can be used to identify these receptors. In some cases, site-specific information on receptors may be lacking, for example, due to seasonal field survey constraints. Where site-specific information on receptors present at the site is limited, generic or surrogate receptors may be used. These receptors are selected using professional judgment in a manner consistent with EPA guidance (EPA 1992a) and consideration of the following:

- Ecological relevance and the assessment endpoints.
- Regulatory significance.
- Relative species sensitivities to the contaminants.
- Mensurability and predictability.

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

The screening assessment should specify which contaminants are of particular concern from an ecological perspective. This is generally done by comparing the screening criteria to the highest detected chemical concentrations (if enough data are available, the 95% UCL on the mean may be used).[1] The range of chemical concentrations detected, as well as the number of samples collected, should be reviewed to evaluate which approach

[1] The maximum is not necessarily the most conservative approach. For exposure areas with limited amounts of data or extreme variability in measured or modeled data, the 95th UCL can be greater than the highest measured or modeled concentration (EPA 1992h. *Supplemental Guidance to RAGs: Calculating the Concentration Term).* In these cases, if additional data cannot practicably be obtained, the highest measured or modeled value can be used as the concentration term. 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 (i.e., there is a large difference between the sample mean and the 95% UCL), 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 (i.e., the 95% UCL is close to the sample mean).

is most appropriate. Environmental criteria only exist for a few of the many chemicals that may be found at a site. In some cases, chemicals for which criteria have been established may be used as surrogates or analogues for other chemicals at the site. EPA (19888). for example, provides guidance for using structure-activity relationships (SARs) as an analogue method for estimating toxicity to aquatic organisms. Where criteria do not exist for the contaminants and receptors in question, analysis of known toxic effects and possible threshold levels may be used to develop site-specific screening criteria against which field exposure data may be compared

To appropriately use. a screening criterion, the assessor must be aware of the assumed receptors, exposure pathways, and exposure factors used to derive the exposure concentration, as well as the nature of the screening criterion. If other exposure pathways are anticipated to be significant at a given site, use of the screening criterion is limited. If the screening criterion is based on acute toxicity and chemical concentrations in site media approach (but don't exceed) the criterion, that would be interpreted as evidence that chronic impacts could or are likely to occur.

For the screening exposure estimate, the highest estimated contaminant concentrations are used to estimate exposures to ensure that potential ecological threats will not be missed. Areas of maximum potential exposure are designated for each ecosystem (terrestrial, aquatic, wetland) or habitat. In the absence of sound site-specific information, preliminary exposure estimates are usually based on conservative assumptions such as:

- Area use is 100 percent (for a particular habitat).
- Bioavailability is 100 percent.
- The most sensitive life stage is present,
- Minimum body weight and maximum ingestion rate are used.

3.3.2 Effects Characterization

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 no observed adverse effects levels (NOAELs) arc not available, NOAELs may be conservatively estimated from the lowest observed adverse effects level (LOAEL) or other available toxicity values. 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.

Sources for obtaining ecotoxicity benchmarks in a screening assessment are generally limited to published literature and readily available criteria and information such as:

- State and Federal AWQC.
- EPA, NOAA, and Ontario sediment criteria.
- EPA on-line databases.
- ECOTOX, includes the Aquatic Information Retrieval Database (AQUIRE).
- Hazardous Substances Data Bank (HSDB) (National Library of Medicine database].
- Registry of Toxic Effects of Chemical Substances (RTECS) (National Institute for Occupational Safety and Health NOSH] database).
- Oak Ridge National Laboratory (ORNL) benchmarks.
- USAEC toxicity profiles (military compounds).
- USACHPPM information databases (military compounds).

A list of environmental resources for obtaining ecotoxicity information and values is provided in Appendix B.

3.4 Preliminary Risk and Uncertainty Characterization

Risk characterization is the screening, summarizing step of the risk assessment. 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 (EPA 19954). The preliminary risk (screen) characterization is used to document a decision about whether or not there is negligible potential for ecological impacts, based on the available information at this stage.

EPA has two requirements for the full characterization of risk (EPA 1995a,d). 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 process in the ERA process provides:

- Integration of the individual characterizations from the ecological effects and exposure characterizations.
- Evaluation of the overall quality of the assessment and the degree of confidence in estimates of risk and conclusions drawn.
- Description of risks in terms of extent, severity, and probable harm.
- Communication of risk assessment results to the risk manager.

Although several approaches can be used to assess risk, for the preliminary risk screen, comparisons of available criteria and/or screening ecotoxicity values to maximum conservative exposure estimates is considered adequate by EPA, where a quantitative approach is called for. The preliminary risk screen employs a conservative approach to ensure that potential ecological threats are not overlooked. In general, if the 95% UCL or maximum chemical concentration exceeds the screening criterion, further assessment of the site is probably indicated.

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 1995d). In the screening ERA, 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.

In the risk characterization and 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. As a minimum requirement, the potential effect of the following uncertainty factors should be discussed:

- Uncertainties associated with the (limited) chemical database for the site (availability of site-specific data for medium of concern).
- Use of the 95% UCL or maximum chemical concentration for representing the site.
- Use of surrogate or generic receptors and worst-case exposure scenarios.
- Use of screening criteria and the associated assumptions.

The need for additional risk clarification beyond that of the screening ERA is based on project planning and scoping discussions by the risk assessors and risk managers. The baseline ERA process described in Chapters 4 through 7 includes the same elements as the screening ERA described above, but is more focused, detailed, and quantitative in its characterization of receptors, chemicals of concern, exposure pathways, effects, and uncertainty.

Chapter 4
Evaluating the Tier I Baseline Ecological Risk Assessment

4.1 Introduction

This chapter introduces the conceptual and technical objectives for evaluating a Tier I baseline ERA. The Tier I ERA is characterized by relatively simple, quantitative wherever possible, desk-top methods that rely heavily on literature information, previously collected data, and a chemical concentration-based approach. The Tier I ERA emphasizes adverse effects to the individual based on literature-cited toxicity values with extrapolations to potential impacts at the population, community, or ecosystem level. The Tier I ERA provides quantitative chemical information for the exposure point media (e.g., soils, sediments, surface water) and possibly qualitative biological data to fill gaps in the available data set. Field or laboratory bioassays are typically not part of a Tier I effort. Any biological samples collected are co-located to the extent possible with abiotic media samples. The Tier I ERA includes the establishment of appropriate ecological endpoints (ecological components affected by chemical exposure) for the chemicals of potential concern. Tier I activities are essentially a more advanced form of screening with emphasis on the following:

- Compiling and evaluating available data and information.
- Identifying critical information gaps.
- Determining the need for design and implementation of remedial activities.
- Ascertaining the need for detailed field studies prior to design and implementation of remedial activities.

Development of a site-specific ECSM, selection of potential COECs, and a description of exposure pathways are major activities in this tier. Qualitative and quantitative data from a site reconnaissance or field survey of flora and fauna are summarized in an ecological site description. This field visit coupled with site-specific information provides for documentation of obvious adverse effects, identification of potentially important receptors, and development of simplified food web models to evaluate the potential for COECs to bioaccumulate in receptors of concern.

Abiotic concentration data are used to establish exposure concentrations for the receptors of concern. Preliminary effects estimates are based on regulatory and literature values. Quotient calculations in conjunction with available toxicity information, exposure concentrations, and reasonable, conservative assumptions are used to provide initial risk estimates.

The main output from Tier I is a detailed, site-specific technical report, If the information provided by the Tier I ERA is adequate to support decisions in the FS/RD-RA, no further ERA sampling or analyses are needed. If, however, there are insufficient data (i.e., too much uncertainty in the ERA) to reach FS/RD-RA decisions, additional biotic and abiotic data needs will be identified, the data collected, and a more definitive assessment performed within Tier II, III, or IV.

In the following sections of this chapter, the individual steps required to prepare a Tier I ERA are introduced and discussed. Exhibits and a case study (CS) are also provided to illustrate the performance of these various steps (see CS 1). Exhibits are located after Chapter 9. The steps to perform a Tier I ERA are grouped as follows, in general accordance with EPA's *Framework:*

- PROBLEM FORMULATION:
  Ecological site description
  Chemical data collection and review
  Selection of preliminary COECs
  Selection of key receptors
  Ecological endpoint (assessment and measurement) identification
  ECSM
- ANALYSIS PHASE -

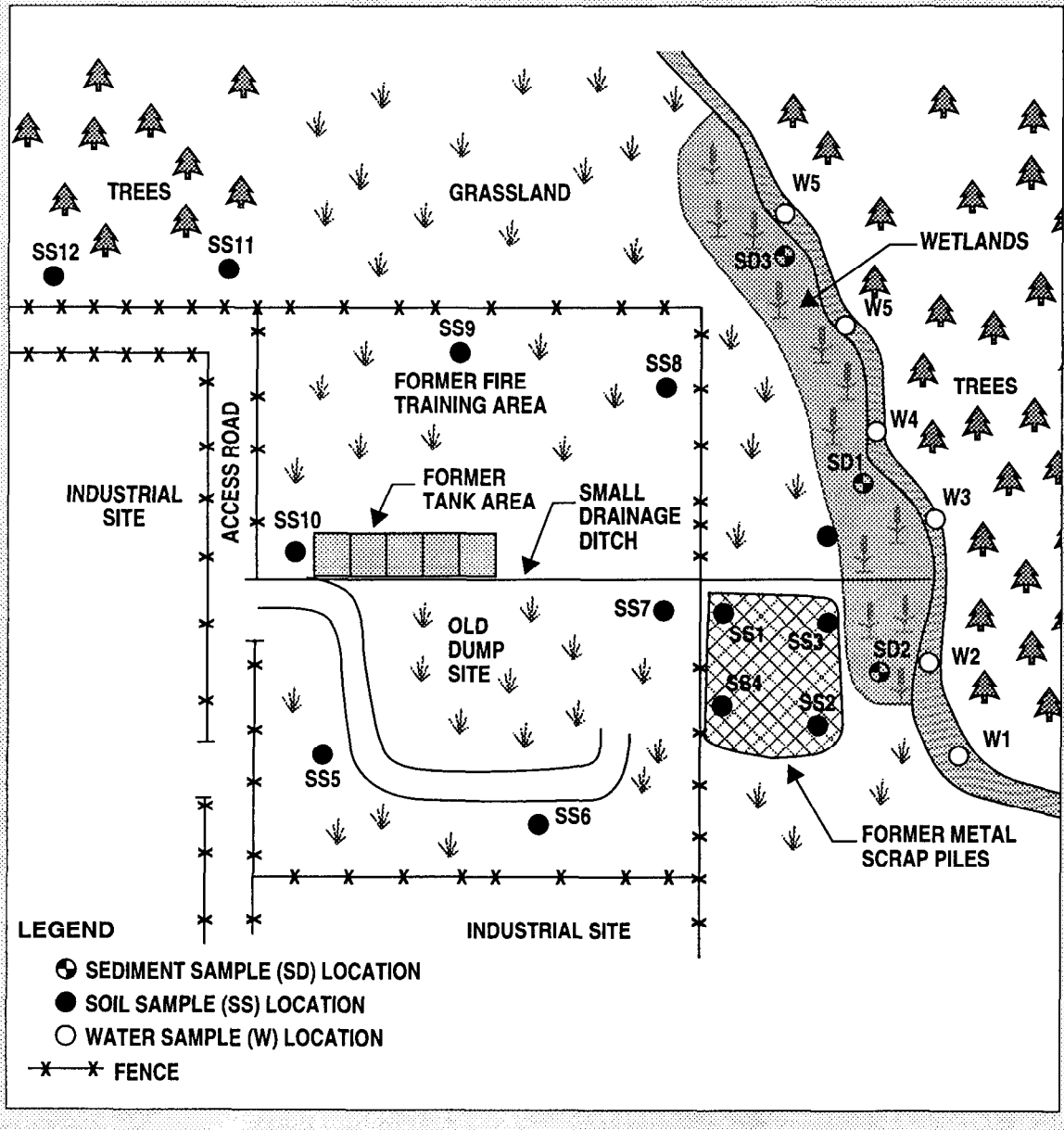
  EXPOSURE CHARACTERIZATION:
  Exposure analysis
  Exposure profiles

  ECOLOGICAL EFFECTS CHARACTERIZATION:
  Selection of literature benchmark values
  Development of reference toxicity values
- RISK CHARACTERIZATION:
  Risk estimation
  Risk summary
  Uncertainty characterization

CASE STUDY 1

SITE SETTING

For the purposes of demonstrating performance of a baseline ERA, a case study is provided throughout this section. Major steps in the ERA process are demonstrated in the following pages.



Our case study site is a former fire training area of a formerly used defense (FUD) site. The site contained a gasoline storage area near an old dump site. It is believed that only gasoline was stored in the tanks but the old records have been lost, and storage of other petroleum products or solvents may have occurred. Records on materials placed in the old dump site were also not available. There is some anecdotal information suggesting that chlorinated solvents were also dumped or burned. The gasoline storage tanks have been removed. A portion of the old dump contained some metal scrap piles that have been removed. The site is being investigated for possible chemical releases to the surrounding environment. As part of the site investigation, a baseline ERA is being performed to determine whether the chemical releases, if any, pose adverse ecological risks.

The setting of the site is shown above in this case study. The area east and north of the site is a mixture of undeveloped grassland and woodland. A small drainage ditch between the old dump site and fire training area leads to a small stream and wetland area of about 5 acres.

A preliminary investigation/site assessment (PA/SI) was performed by the state, providing the following information:

- When tanks were removed, they were found to contain holes;
- Soils in the tank excavation pits were tainted and had a petroleum odor;
- Surface soils were sampled at two locations (SS1 and SS2) during the PA/SI and analyzed for metals only. Soils were found to contain arsenic, barium, cadmium, nickel, and lead. No information on background soil quality is available.

As the risk assessor for the site, you have been asked to provide input into the development of the sampling and analysis plan (SAP), the quality assurance project plan (QAPP), and subsequent investigations.

The sequence of steps presented above is similar to the format used in most ERA documents. The actual sequence of events followed in the conduct of an ERA, however, can be quite variable and is frequently dependent on data availability, time availability, and the individual nature of the site and project. While the steps listed above are generally the same in each of Tiers I through IV, each may receive different emphasis depending on the tier and hence level of complexity of the baseline ERA.

4.2 Problem Formulation

Problem formulation is used to establish the goal, scope, and focus of the Tier I ERA. This systematic planning phase identifies the major factors to be considered in evaluating ecological risks associated with a given site and its linkage to the regulatory and policy context of the assessment. Problem formulation provides an early identification of key factors to be considered in the Tier I ERA. The problem formulation stage thereby encompasses the creation of PD statements to represent the specific planning objectives of the Tier I effort.

Once triggered, the problem formulation process begins a preliminary (largely conceptual) characterization of exposure and effects. This involves evaluating the potential COECs present, the ecosystems and receptors potentially at risk, the ecotoxicology of the contaminants known or suspected to be present, and observed or anticipated ecological effects. Then, ecological endpoints to be addressed and/or measured are identified (see Section 4.2.5). The process culminates in a preliminary ECSM that identifies potential exposure pathways, environmental values (receptors) to be protected, impacts or adverse effects to be evaluated, data needed, and analyses to be used (see Section 4.2.6).

4.2.1 Ecological Site Description

An initial site description is needed to orient the technical specialists. This information should be assembled from existing sources of information, without conducting formal field studies. Initially, base or facility natural resource personnel should be contacted as they often have relevant data or useful ecological information. Many state and Federal agencies can provide information on sensitive areas or regional data on ecology, especially threatened and endangered species, checklists of biota, endemic species, and other pertinent ecological information. These agencies include USFWS, local and state planning agencies, 404 staffs in EPA regions, state fish and wildlife agencies, and perhaps the new USDOI National Biological Survey in the near future. Surveys conducted by the Nature Conservancy or state Natural Heritage Programs may also be available.

Much information may be available from published sources such as soil survey and topographic maps, National Wetlands Inventory Maps (NWI), and information from natural history or heritage program databases or from previous assessments of the site. In addition, experts at local or regional universities often can provide information on wetland species, bird checklists, mollusks, plants, or other specialties. Local, regional, or university museums or state biological surveys may be other sources of information.

Presence of wetlands, threatened or endangered species, endemic species, or lands or waters containing species considered as or classified as having a “high” value will significantly impact problem formulation and planning for conduct of the ERA. Where waters of the state are involved, the National Pollutant Discharge Elimination System (NPDES) permitting agency may be a good source of information especially if they have conducted use attainability studies for the purpose of classifying the uses or have permitted discharges to the waters.

4.2.1.1 Reconnaissance (Biota Checklist)

Much of the information sought during a site reconnaissance is commonly available information. However, it is essential that a site reconnaissance and ecological site characterization be conducted in this stage by an ecologist.

Prior to arrival at the site, the ecologist should be provided with information on the site, including topographic maps; township, county or other appropriate maps: location of potential ecological units such as streams, lakes, forest, grasslands, floodplain and wetlands on or near the site: soil types: and local land uses. Much of this information may already have been obtained and documented as part of the PA/SI effort. A checklist with information similar to that on EPA’s (1993a) ***Checklist for Ecological Assessment/Sampling*** should be completed, if it was not completed as part of the PA/SI.

The location of known or potential contaminant sources affecting the site and the probable gradient or pathway by which contaminants may be released from the site to the surrounding environment should be determined to the extent possible based on observations and available information from earlier studies (i.e., PA/SI or RFA). If waters of the state or the U.S. are potentially involved, their designated uses should be determined, so that the

ecologist can make a preliminary qualitative determination as to whether such uses are apparently being achieved.

Ecologists can use the reconnaissance to evaluate the site for more subtle clues of potential effects from contaminant release. For example, the noticeable absence of flora or fauna where otherwise expected may be a clue to potential contaminant effects or other stressors. Absence of the flora understory from a forest may be an indication of soil contamination and the inability of shorter lived forbs and shrubs to reestablish themselves. On the other hand, unusually high numbers of a particular species or unusually thick accumulation of litter may indicate the absence of predators or disruption of nutrient cycling processes. Such ecological observations are important clues to DQO development, the data interpretation effort, and the weight-of-evidence presented in the subsequent risk characterization.

4.2.1.2 Documentation of Potential Receptors of Special Concern and Critical Habitat

The site reconnaissance, in combination with published resources, and information obtained from state and Federal fisheries and wildlife agency experts, should be used to determine if the site or nearby site areas have designated wetlands or critical or sensitive habitats for threatened or endangered species. If such species or entities are present, they must receive special protection during all aspects of the project planning and implementation following consultation with appropriate regulatory authorities.

During the reconnaissance, a checklist of biological species should be developed. From this list, receptors of special concern will be identified. Depending on the 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.

Receptors am the components of ecosystems that are or may be adversely affected by a chemical or stressor. In the Tier I investigation, 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) is used to assess potential harm to all components of the system. In the Tier I ERA, specific organisms or groups (e.g., small herbivores) are usually selected as key receptors.

4.2.1.3 Significant Ecological Threats

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.

4.2.2 Chemical Data Collection and Review

Planning, collection, and review of chemical data constitute the initial and often the most substantial level of effort in a Tier I ERA. Because of the importance for obtaining useable data to the end goal of an acceptable ERA, the following sections describe the data collection and review process in detail (including elements as described in the HTRW technical project planning guidance document).

4.2.2.1 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.

To plan and provide input to the data collection effort, the risk assessor should follow the three DQO steps recommended by EPA (1989c) ***in*** the ***Field and Laboratory Reference Document.*** Step I of the process includes preparing definitions of the problem and concise (as possible) statements of the questions to be answered. Examples of Step I DQOs include the following:

- Identify potential and appropriate site-specific receptors, potential COECs, and potential exposure pathways to assess the potential for adverse effects to occur to biological resources as a result of contamination.

- Evaluate the potential for impacts to occur to biological resources outside the current site boundaries.

- Evaluate the need for remediation to protect the environment.

Steps II and III of the DQO process include identification of data needed to answer questions identified in Step I and design of the data collection program (i.e., the data quality design process). Products of Step II include proposed statements of the type and quality of environmental data required to support the DQOs, along with other technical constraints on the data collection program. The objective of Step III is to develop data collection plans that will meet the criteria and constraints established in Steps I and II. Step III results in the specification of methods by which data of acceptable quality and quantity will be obtained (ER 1110-l-263). The DQO development process is flexible and may continue throughout the baseline ERA.

Data needs for the ERA are likely to overlap with those for the human health risk assessment or other data users in specific physical areas of a site. The potential for data need overlaps should be identified early on. Nearby surface waterbodies that are potentially linked to the source through chemical fate and transport are typically sampled for human health purposes. Sediment samples may also be desired 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.

Development of a preliminary ECSM is useful in planning for identifying data that will be needed (i.e., sampling and analysis plan) in the ERA (see Section 4.2.6) (see CS 2 and CS 3). An ECSM identifies the likely source(s) of chemicals, the chemical release mechanisms, fate and transport potential, and the resultant secondary and tertiary media that may be impacted. The ECSM also (1) identifies plausible food webs at the site, (2) identifies all potential pathways from chemicals at the source to receptors of concern, and (3) evaluates the completeness of potential exposure pathways, based on known nature and extent of contamination and ecology of species and communities potentially occurring at the site. In essence, the ECSM describes the exposure pathways or routes a chemical takes from point of release from the chemical source to receptors of potential concern. The ECSM is thus a summary of some portions of the exposure characterization. By identifying the potential abiotic media that may need to be assessed in the ERA, and the potential exposure routes by which ecological receptors may be exposed, the ECSM can identify the type of data needed in the ERA. Section 4.2.6 discusses the ECSM in more detail.

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 (QA/QC) procedures, or scope of analyses. Data from historical sources, therefore, may not be appropriate to use in the quantitative ERA; however, they often can be used in a supportive, qualitative role. When evaluating historical or purposely collected data, a number of factors need to be evaluated. Some factors that should be considered are presented in Exhibit 2.

On the other hand, unique data needs may also be identified early on in the PA/SI or Tier I ERAs that would require purposive (biased) sampling in order to collect abiotic samples from specific areas of contaminant or ecological concern. Onsite animal activity should be initially observed to best evaluate obvious activity patterns relative to the contaminant source areas. For example, if

CASE STUDY 2

DEVELOPMENT OF A PRELIMINARY ECOLOGICAL CONCEPTUAL SITE MODEL

The first step in developing a credible sampling design to support the risk assessment is to formulate an ecological conceptual site model (ECSM). Development of an ECSM is discussed in Section 4.2.6, which should be consulted in conjunction with this case study step. First, some hypothesis of chemicals potentially present on site is needed.

The existence of gasoline or petroleum tanks and possible disposal of solvents suggest the following chemicals may be present:

- Benzene, toluene, ethylbenzene, xylenes (BTEX)
- Polycyclic aromatic hydrocarbons (PAHs)
- Trichloroethylene and other chlorinated solvents

The surface soil analyses detected the following metals:

- Arsenic
- Barium
- Cadmium
- Nickel
- Lead

In order to evaluate how and where chemicals may migrate from the site, and in what media the chemicals may be located, the following information is needed for each chemical:

- Water solubility (S);
- Tendency to bind to soil (K_{oc});
- Tendency to accumulate into animal tissue (BCF); and
- Volatility (vapor pressure or Henry's Law Constant).

Obtain these chemical and physical parameters, and anticipate how the potential chemicals may be released and migrate from the site. Then, develop a preliminary ECSM, starting with the primary source areas and progressing to secondary and tertiary sources, and through specific release and migration mechanisms.

CASE STUDY 3

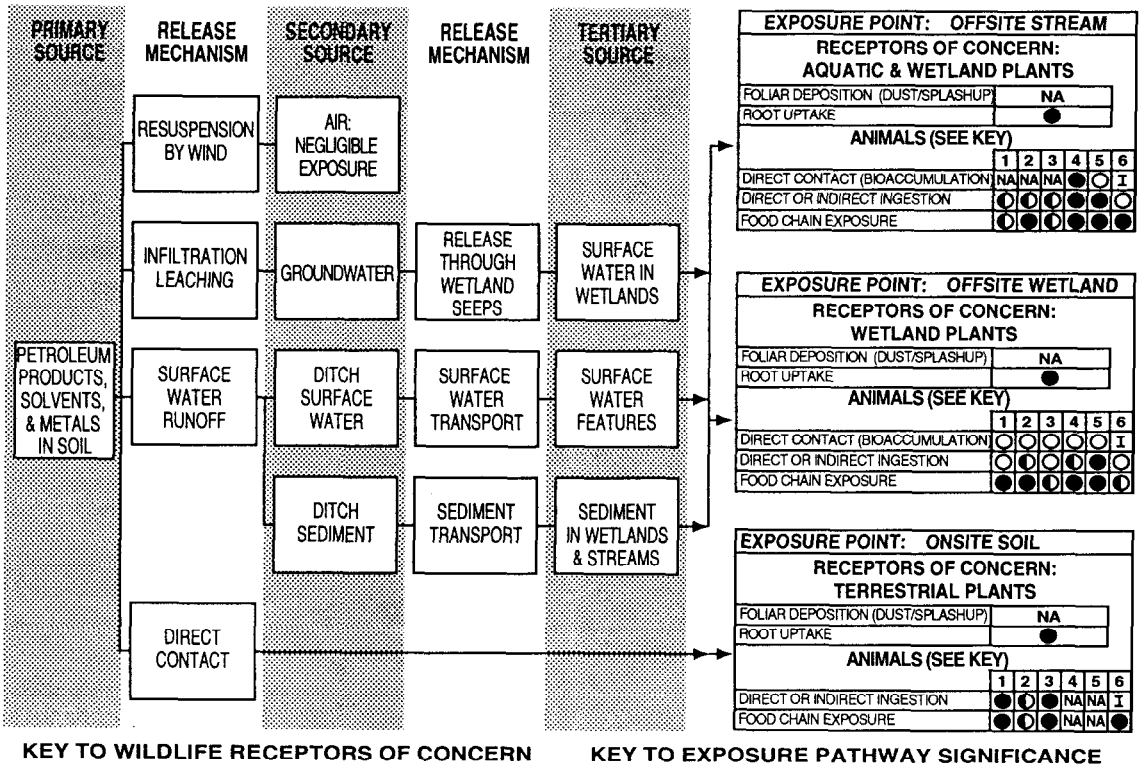
DIAGRAMMING THE ECSM

The ECSM is developed and diagrammed by examining the sources of chemicals and possible release mechanisms, based on an understanding of the fate and transport characteristics of chemicals potentially present on site. A diagram of the ECSM is shown in Example 1 ECSM.

Primary Sources

Preliminary information suggests four possible sources of chemical release to the environment: (1) the former tanks, (2) the old site, (3) the old burn pit, and (4) scrap metal piles. Release at each of these sources may have contaminated soils at the site. Because the original sources have been removed and operations have ceased, soil is considered the primary source of potential contaminant release to the environment.

Example 1 ECSM



KEY TO WILDLIFE RECEPTORS OF CONCERN

① MAMMALIAN HERBIVORES
② MAMMALIAN OMNIVORES AND CARNIVORES
③ AVIAN OMNIVORES
④ AQUATIC INVERTEBRATES AND INFAUNA (ANIMALS)
⑤ WADING BIRDS
⑥ PREDATORY RAPTORS

KEY TO EXPOSURE PATHWAY SIGNIFICANCE

NA NOT APPLICABLE
I INCOMPLETE
○ EXPOSURE POTENTIAL RELATIVELY LOW
◐ EXPOSURE POTENTIAL INTERMEDIATE
● EXPOSURE POTENTIAL RELATIVELY HIGH

Primary Release Mechanisms

Preliminary information suggests the following release mechanisms:

- Resuspension by wind;
- Infiltration and leaching to groundwater from the burn pit, tank area, and scrap piles;
- Surface water runoff from the tank area and scrap piles; and
- Direct contact with site soils.

Secondary Sources

Primary releases from contaminated soils may have resulted in secondary contamination of the following environmental media:

- Groundwater beneath the site;
- Surface water in the ditch;
- Sediments in the ditch or adjacent stream and wetlands; and
- Air.

Due to ecological and climatic conditions, exposure to airborne contaminants is usually considered negligible with respect to the other primary exposure pathways. Lichens, however, are one example of a receptor group that is exceptionally sensitive to airborne contamination.

Secondary Release Mechanisms

Fate and transport information suggests the following secondary release mechanisms:

- BTEX and solvents in groundwater may be released to surface water at the wetland seeps;
- Metals and organic contaminants in ditch surface water may be transported in surface water to the wetland and stream;
- Metals, PAHs, and other organic contaminants in sediment may be transported to the wetland and stream; and,
- BTEX and solvents in soil or groundwater may volatilize to air (not shown in ECSM).

Tertiary Sources

From the above secondary release mechanisms, the potential tertiary sources are:

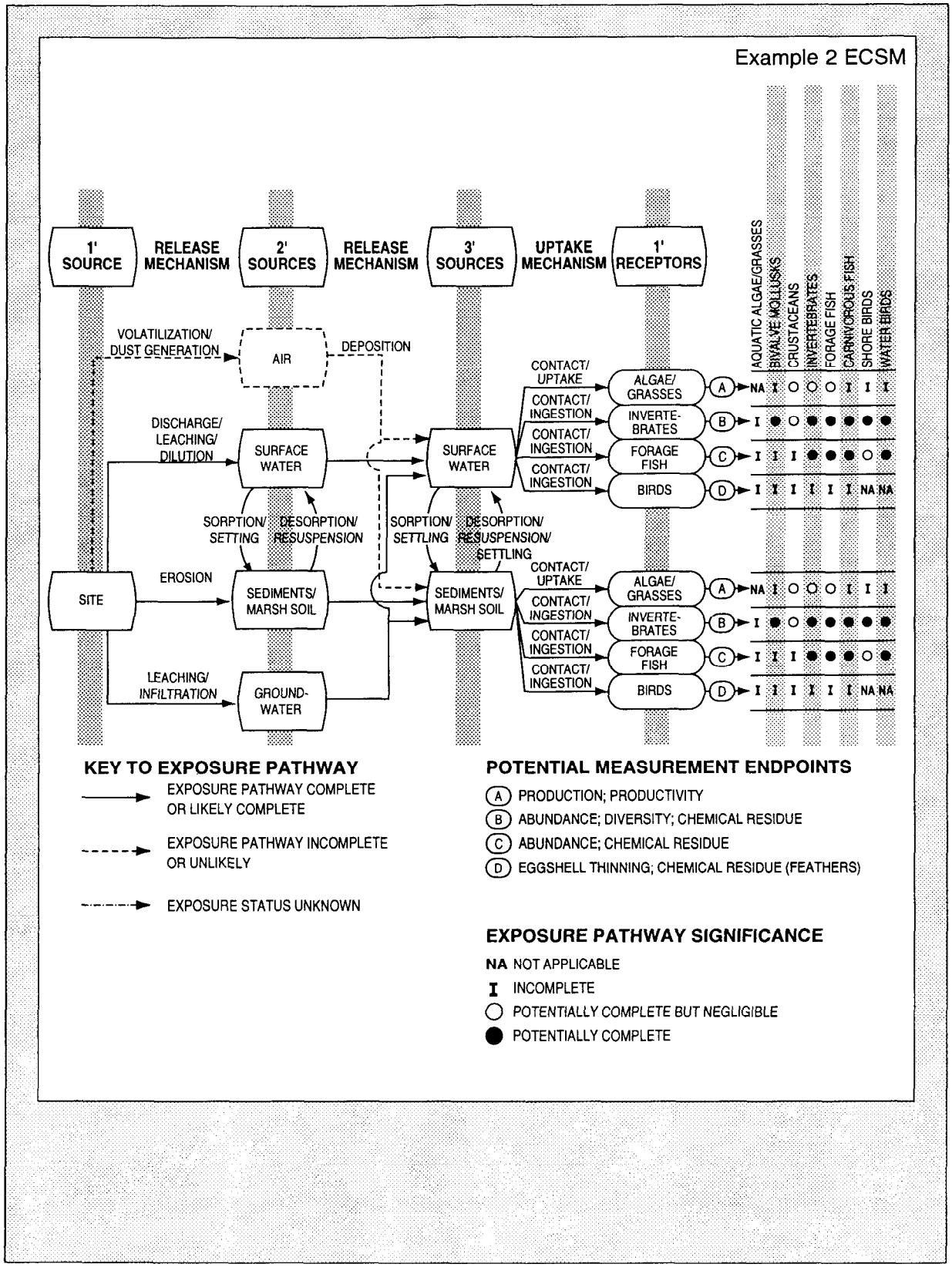
- Surface water in wetlands and the stream; and
- Sediments in wetlands and the stream.

Primary Potential Exposure Pathways

The primary potential exposure pathways for ecological receptors include the following:

- Ingestion of surface soils (on-site);
- Root uptake from soil by terrestrial plants;
- Root uptake from water or sediment by aquatic and wetland plants;
- Direct contact/bioaccumulation from surface water by aquatic animals;
- Ingestion of surface water;
- Ingestion of sediments; and
- Food chain exposure.

This completes the preliminary ECSM. An additional ECSM diagram is shown in Example 2 ECSM.


Example 2 ECSM
1' SOURCE
RELEASE MECHANISM
2' SOURCES
RELEASE MECHANISM
3' SOURCES
UPTAKE MECHANISM
1' RECEPTORS
AQUATIC ALGAE/GRASSES
BIVALVE MOLLUSKS
CRUSTACEANS
INVERTEBRATES
FORAGE FISH
CARNIVOROUS FISH
SHORE BIRDS
WATER BIRDS
VOLATILIZATION/ DUST GENERATION
AIR
DEPOSITION
DISCHARGE/ LEACHING/ DILUTION
SURFACE WATER
SURFACE WATER
SORPTION/ SETTING
DESORPTION/ RESUSPENSION
SORPTION/ SETTLING
DESORPTION/ RESUSPENSION/ SETTLING
EROSION
SITE
SEDIMENTS/ MARSH SOIL
SEDIMENTS/ MARSH SOIL
LEACHING/ INFILTRATION
GROUND-WATER
CONTACT/ UPTAKE
CONTACT/ INGESTION
ALGAE/ GRASSES
INVERTE-BRATES
FORAGE FISH
BIRDS
A
B
C
D
NA I ○ ○ ○ I I I
I ● ○ ● ● ● ● ●
I I I ● ● ● ○ ●
I I I I I I NA NA
KEY TO EXPOSURE PATHWAY
EXPOSURE PATHWAY COMPLETE OR LIKELY COMPLETE
EXPOSURE PATHWAY INCOMPLETE OR UNLIKELY
EXPOSURE STATUS UNKNOWN
POTENTIAL MEASUREMENT ENDPOINTS
(A) PRODUCTION; PRODUCTIVITY
(B) ABUNDANCE; DIVERSITY; CHEMICAL RESIDUE
(C) ABUNDANCE; CHEMICAL RESIDUE
(D) EGGSHELL THINNING; CHEMICAL RESIDUE (FEATHERS)
EXPOSURE PATHWAY SIGNIFICANCE
NA NOT APPLICABLE
I INCOMPLETE
○ POTENTIALLY COMPLETE BUT NEGLIGIBLE
● POTENTIALLY COMPLETE

receptors of special concern are observed on site, it may be advisable to collect chemical sample(s) from their specific habitat.

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 certified reporting limits (CRLs) for these chemicals. Also, matrix effects interference in soil and sediment sampling often results in detection limits well above ecological effects levels. While it may be desirable, it is not always possible to have the CRLs 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.

The risk assessor's data needs definition for a site is the culmination of the assessor's effort to conceptualize and develop a strategy for conducting the baseline ERAs, 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. 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. Further details on technical project planning and designing a data collection program for an ERA are presented in the following section and in EM 200-1-2 HTRW ***Technical Project Planning*** document USACE (1995b).

4.2.2.2 Evaluation of Available PA/SI Chemical Data

Quality chemical data from the PA/SI data collection effort should be available for use during problem formulation and conduct of the Tier I ERA. Knowledge about historical use of the site should provide information about potentially present contaminants. Available PA/SI chemical data and physicochemical data (organic carbon content, pH, etc.) for abiotic media are used in the screening process to compare measured values with selected toxicity benchmarks for those media. This information in concert with observations made during the reconnaissance and professional judgment are used to characterize risk and evaluate the potential need for a Tier II, III, or IV ERA.

The need to proceed to Tier II 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 log K_{ow} (logarithm of the n-octanol water partition coefficient, log P) values greater than 3.5 are of greatest concern (EPA 1991e) due to their potential to biomagnify in ecological systems. 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 if the residue is toxic (EPA 1989a). 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 in Tier I or in the need to proceed to Tier II biological sampling.

Care should be taken where data collected during the PA/SI are largely intended for use in the human health risk assessment, 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 $CaC0_3$ hardness is much lower (12 pg/L). Conversely, some of the listed carcinogenic organic compounds are relatively nontoxic 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 (see CS 4).

4.2.2.3 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 Tier I ERA are performed, if data quality is poor or data do not accurately reflect site contamination or the types of exposures assessed, the Tier I 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.

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 DQQ process. These and

CASE STUDY 4

DEVELOPMENT OF A SAMPLING AND ANALYSIS PLAN

Evaluation of the existing data for our site has concluded the following:

- Releases of metals to surface soils, surface water, and sediments have potentially occurred;
- Petrolcum/solvent releases to surface and subsurface soils have occurred; and
- Volatile organic compound releases to groundwater and subsequent release to wetland and creek sediments and surface water may have occurred.

The ECSM suggests the following:

- Volatile and semivolatile organic compounds may be present in the soil; and
- Semivolatile organic compounds and metals may be present in the soils, sediments, and surface water over a greater area than expected.

The following data gaps are identified:

- There are no data on volatile or semivolatile organic compounds in surface or subsurface soils and metals data in soils are limited;
- There are no surface water or sediment data for organic compounds or metals; and
- Information on groundwater flow direction is not available.

Data quality objectives for additional sampling include:

- Collection of additional soil samples for metals, volatile and semivolatile organic compounds;
- Collection of sediment and surface water samples for metals, volatile and semivolatile organic compounds;
- Collection of groundwater samples for metals, volatile and semivolatile organic compounds and for water table levels; and
- Collection of background surface soil, groundwater, surface water and sediment samples.

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.

Numerous factors may potentially have to be considered when identifying minimum data collection requirements for an ERA, or when reviewing existing data to determine useability in an ERA. Relevant guidance on data useability in ERAS is published in the following EPA documents (also see Appendix B):

- *Guidance for Data Useability in Risk Assessments* (Parts A and B) (EPA 1992d,e)
- *Laboratory Data Validation Functional Guidelines for Evaluating Inorganics Analysis* (EPA 1994c)
- *Laboratory Data Validation Functional Guidelines for Evaluating Organics Analysis* (EPA 1994d)

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

- Data Collection Objectives (discussed above).
- Documentation.
- Analytical Methods/Quantitation Limits (see Exhibit 3).
- Data Quality Indicators (see Exhibit 4).
- Data Review/Validation (see Exhibit 5).

Each of these categories contain other factors that should be considered, as well. In some cases, portions of the evaluation are performed by practitioners 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. Further discussion of the data quality evaluation process is presented in Appendix D (HTRW *Technical Project Planning Process).*

4.2.2.4 Data Presentation and Summary

Data that have been identified as acceptable for use in the Tier I ERA should be summarized in a manner that presents the pertinent information to be applied in the ERA (see CS 5). 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.

At this point in the Tier I 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 COECs for the site, as discussed in the next section. 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.

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 and the habitats potentially exposed to contamination. An exposure area may be the entire site if chemical contamination is widely dispersed, or it may be a small subsection 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 a real 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 nondetected 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.

CASE STUDY 5

SAMPLING RESULTS (TERRESTRIAL ECOSYSTEM)

The following soils data were obtained from site sampling.

Soil Sample Location	Acetone (ug/kg)	Arsenic (mg/kg)	Cadmium (mg/kg)	Nickel (mg/kg)	Lead (mg/kg)	Barium (mg/kg)
SS1	5 B	7.8	100	20	4	302
SS2	2 BJ	6.2	92	16	17	314
SS3	5 U	5 U (2.5)	78	19	16	356
SS4	5 B	10.3	75	15	19	396
SS5	5 U	4.9 J	42	12	13	377
SS6	2 BJ	11.4	51	19	15	342
SS7	6 B	5 U (2.5)	33	21	18	309
SS8	3 BJ	7.9	29	17	18	433
SS9	5 U	9.4	53	18	14	395
SS10	3 BJ	5 U (2.5)	48	14	16	302
SS11 (background)	7 B	8.4	32	19	19	392
SS12 (background)	4 BJ	6.2	56	16	13	376

B = Analyte found in associated blank as well as in sample
U = Compound analyzed, but not detected
J = Value is estimated
( ) = Value is 1/2 the sample 9 detection limit

Reference area locations should not be included with site samples when defining an exposure area. Reference locations are selected to represent offsite conditions and to help distinguish 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 unimpacted 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. Further discussion on use of background determinations is presented in Section 4.2.3.3.

4.2.3 Selection of Preliminary Chemicals of Ecological Concern

COECs 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 COECs. COECs 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 those found at background or reference sites, (3) chemicats 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 COECs parallels that for the human health risk assessment, the lists may differ somewhat based on chemical fate and transport characteristics and species-specific toxicities.

4.2.3.1 Objectives

The objective of selecting preliminary COECs for the Tier I 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 nonsite sources, and are present at sufficient frequency, concentration, and location to pose a potential risk to ecological receptors. The selection of COECs is a process that considers site-specific chemical data in conjunction with the preliminary ECSM (see Section 4.2.6) that describes potential exposure pathways from chemical sources to ecological receptors. This selection process is needed for several reasons:

- 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 offsite areas.
- Some chemicals may be a result of inadvertent introduction during sampling or laboratory analysis.
- Disparities as well as similarities exist in the selection process for COECs and chemicals of concern to human health.
- Not all chemicals detected at a site are present at concentrations high enough to pose a potential exposure or ecological threat. Additionally there may be trace elements present at nutritionally required or ecologically protective concentrations.

The chemical selection process is performed by evaluating the data that have been identified as useable by the data evaluation process (described previously). Chemical selection involves evaluation of these data using criteria to identify those chemicals that are not appropriate to retain as COECs (see Section 4.2.3.3). Through an exclusion process, the COECs 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.

4.2.3.2 General Considerations

Two 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?

- Not all chemical data collected from site media represent those to which ecological receptors are necessarily exposed. When selecting COECs, 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 COECs need to be identified.

- A distributional analysis of the chemicals present at a site should be conducted. This examination would differentiate between impacted areas and nonimpacted 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 subunits of the site as the exposure area.

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).' 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 (EPA 1993c).

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 am not relevant to exposures for animals with a small home range or specific habitat preferences.

[1] EPA 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 [EPA 1995f]).

4.2.3.3 Selection Criteria/Methodology

Criteria that can be applied to determine whether a chemical should be removed as a potential COEC must be fitting to the selected or anticipated ecological endpoints and the overall adequacy of the sampling program. The process for selecting COECs 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? Were groundwater wells screened at appropriate locations to detect nonaqueous phase liquids (NAPLs; e.g., coal tars)? Could site-related COECs potentially exert similar toxic action as background "contaminants" or exacerbate the toxicity of the background "contaminants"?[2] The decision to carry forward all detected compounds into the exposure and effects characterization portions of the screening or baseline ERA 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 application of screening criteria. Through this elimination process, the risk assessor assumes 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:

- Nondetection (use of appropriate detection limits).
- Limited chemical distribution and limited presence in environmental media.
- Comparability with screening criteria (AWQC, effects range-low (ER-Ls), LELs, etc.).
- Comparability with background concentrations (consideration of site-relatedness).
- Non-site-relatedness.
- Role as an ecologically essential nutrient at site concentrations.
- Low toxicity/bioconcentration screen.

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

- Low potential for bioaccumulation and biomagnification.

These criteria, which generally follow *RAGS I and II* (EPA 1989a,f). are typically applied sequentially to the available data Once a chemical is eliminated based on a screening criterion, it is not considered in subsequent screening. Each of the above criterion is discussed further in the following sections. Further explanation of the COEC selection process is provided in CS 6 and CS 7.

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 COEC selection process is branched: one branch focuses on aquatic receptors, the other branch focuses on terrestrial receptors. Within the terrestrial COEC 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 COECs 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).

4.2.3.3.1 Nondetection. Chemicals analyzed for but not detected in any sample of a site medium should not be included as COECs for that medium. To be selected, a chemical must be found in at least one sample of the environmental medium at a reported concentration (i.e., the results are not reported as nondetect and qualified with a "U"). To be included, a chemical must have concentrations above the sample quantitation limit (SQL), which is the lowest level that a chemical may be accurately and reproducibly quantified (EPA 1989c), or have concentrations that are quantified but estimated (i.e., less than the SQL and labeled with a "J" qualifier). Where samples have an associated duplicate analysis, the higher of the sample or the duplicate results (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 SQLs is presented; if one result is detected and the other is ND, then the detected concentration is reported.

Care must be taken when evaluating analytical results in which a very high detection limit is attained, since a nondetection may mask the presence of a chemical at a concentration less than the quantitation 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

Detection levels also need to be evaluated with respect to ARARs and toxicity screening levels. For some PAHs and dioxins, detection 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 pg/L) is barely below the AWQC (0.012 pg/L).

4.2.3.3.2 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 COEC. 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.

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 COEC (assuming an appropriate sampling design was used), or to select the chemical as a COEC 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.

The following factors should be considered when applying this criterion:

- 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.

- The quantitation limit achieved. If the quantitation limit achieved in one or more of the analyses is high relative to other detected concentrations, the high quantitation limit may mask the presence of chemicals.

- The sampling scheme. Biased sampling plans, intended to identify "hot spots," may over-represent the occurrence of chemicals (however... see the next point).

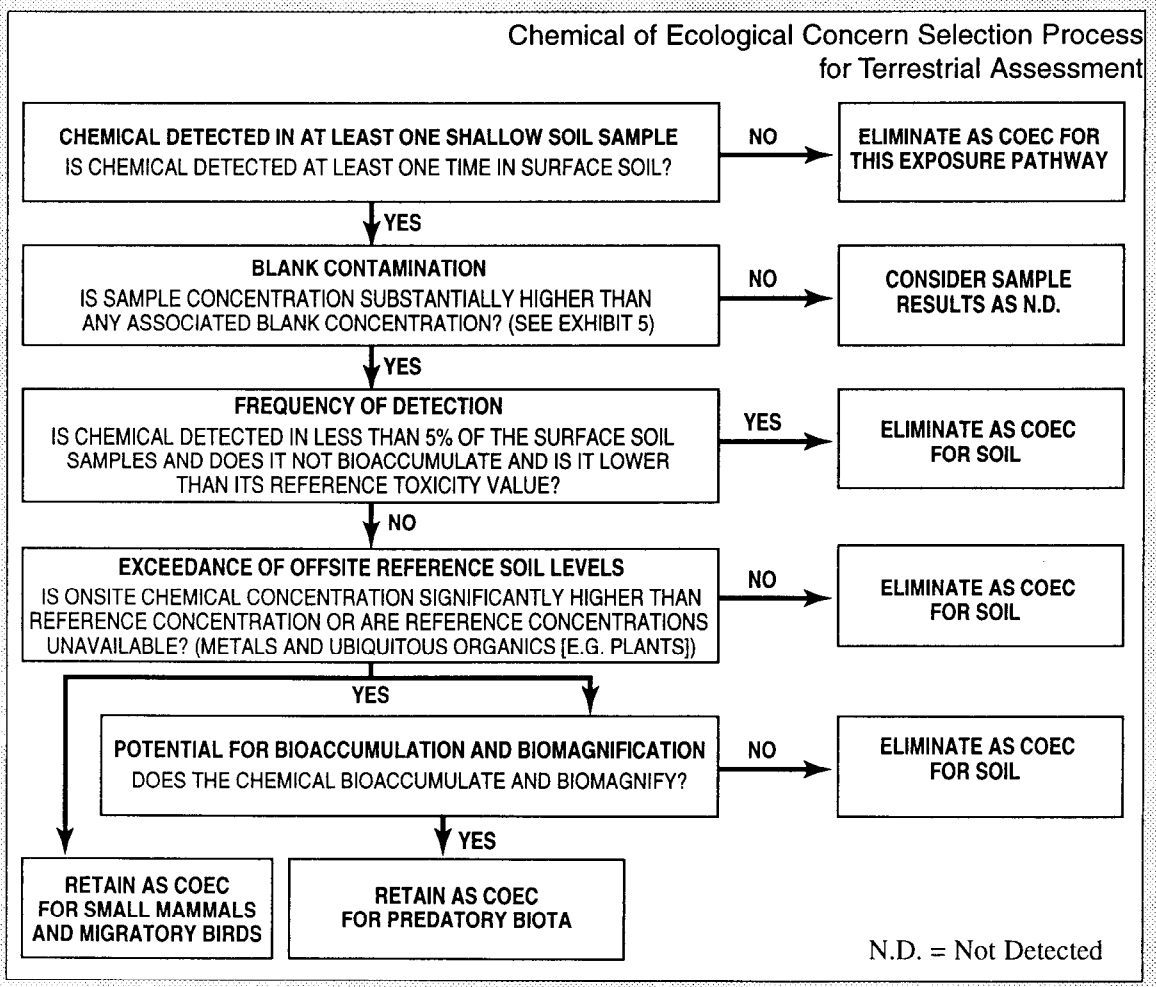
CASE STUDY 6

SELECTION OF COECS - I (TERRESTRIAL ECOSYSTEM)

The chemical data for soil need to be examined to select chemicals of ecological concern, or COECs, for the assessment. Examine the data for soil with respect to the provided information and the following factors:

- Nondetection,
- Comparison with laboratory blanks,
- Limited presence,
- Comparability with background concentrations,
- Non-site-relatedness,
- Role as an essential nutrient,
- Toxicity screen, and
- Potential for bioaccumulation and biomagnification.

Then select the COECs. A flow diagram similar to that shown below may be developed to depict the COEC selection process that is used.



CASE STUDY 7

SELECTION OF COECS - II (TERRESTRIAL ECOSYSTEM)

Now examine the soil data and select soil COECs for the ERA:

Comparison with Laboratory Blanks - Soils

Acetone was detected in several soil samples. There are no field blanks associated with the soil samples, so no direct comparison with field blanks can be made. However, three factors suggest that acetone is not site-related. First, the B qualifier indicates that acetone was detected in the laboratory method blanks and is therefore a laboratory contaminant. Second, acetone was found in background soil samples at concentrations comparable to those in site samples. Third, acetone is volatile and would not be retained in surface soil, suggesting its presence as a laboratory contaminant. For these reasons, acetone is not retained as a COEC (although it is treated as a COEC for the purpose of developing a Reference Toxicity Value [RTV] in CS 12).

Comparison with Background - Soils

A statistical evaluation or a numerical comparison can be used to make background comparisons. In this example, a numerical comparison is used due to the limited number of background samples. Three factors are examined: the range of concentrations detected, the arithmetic mean, and the 95% upper confidence limit (UCL) of the mean concentration (assuming a lognormal distribution). The 95% UCL is calculated only for site data because the background sample size (n = 2) is too small to support statistical estimation of the mean.

	Arsenic	Barium	Cadmium	Nickel	Lead
Site Samples					
Range (mg/kg)	5U-11.4	302-433	2.9-100	12-21	4-19
Arithmetic Mean	6.3	352.6	60.1	17.1	15
95% UCL	10.5	390	81.8	19.2	18
Sample Size	10	10	10	10	10
Background Samples					
Range (mg/kg)	6.2-8.4	376-392	32-56	16-19	13-19
Arithmetic Mean	7.3	384	44	17.5	16
Sample Size	2	2	2	2	2

When ranges of concentrations are compared and mean and 95% UCL site concentrations are compared to background means, arsenic, barium, nickel, and lead appear to be comparable to background; cadmium does not. From this numerical comparison, concentrations of arsenic, nickel, barium, and lead are considered comparable to background concentrations and these metals are therefore not selected as COECs. Cadmium is retained as a COEC for this site.

Examination of Role as Essential Nutrient - Soils

None of the metals detected in surface soils, with the possible exception of arsenic, are essential micronutrients for ecological receptors.

- The concentrations detected. Presence of a chemical at relatively high concentrations, even at a low frequency, may indicate the occurrence of a localized area of contamination (i.e., a hot spot) that may need to be examined as a discrete exposure area, and may require further sampling. What constitutes a "high" or a "low" concentration depends upon the toxicity and other properties of the chemical, the medium in which it was detected, and the site history (whether the chemical was used at the site), and requires some degree of professional judgment to identify.

4.2.3.3.3 Comparability with Background Concentrations. In conducting a risk assessment, it may be important to distinguish site contamination from background levels due to anthropogenic or naturally occurring contamination in order to determine the presence or absence of contamination and to compare with background risk (EPA 1992d,e). Some chemicals detected in site media may be naturally occurring or present as a result of ubiquitous or offsite chemical use. Therefore, it is appropriate to exclude them from the risk assessment. Exhibit 6 presents some chemicals that should be examined for presence in background samples. Background samples are kept discrete from the site data for the purposes of assessing exposures, and are used exclusively to identify non-site-related chemicals.

The most appropriate measure of background quality is obtained by the collection of background data from unaffected onsite areas or nearby, offsite 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 COECs, 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?

. 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 offsite sources of contamination that would not impact the site, such as other sites, roadways, etc.

- If offsite 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 offsite 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?

- 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 actual number of samples with data available should be examined to determine if the minimum requirements have been met. For historical data, professional judgment must be used to determine whether adequate background samples are available, or if additional samples are required.

- 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 (i.e., there is a large difference between sample mean and the 95% UCL), 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 (i.e., the 95% UCL is close to the sample mean) (EPA 1992h). In general, the UCL approaches the true mean as more samples are included in the calculation.

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 exclusion of a chemical as a COEC. If historical data include NPDES data, they may be used in addition to any other regulatory-required data acquisition.

Determination of comparability with background can be accomplished in several ways, depending on the amount of data available. Two methods that are available are statistical evaluation and numerical comparison.

A statistical evaluation is best when enough site and background samples are available 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 can be used when the risk assessor has defined the minimum requirements for background and site sample numbers and sampling design.

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. Test selection depends upon data distribution (normal, non-normal), whether nondetected values are included, if appropriate proxy values are used, number of samples, and other factors. This is the most rigorous method of determining comparability. An example of one type of statistical comparison that assumes a normal distribution of data with two unequal variances is shown in CS 8.

Numerical comparisons can be made when background data are more limited in number, making a statistical comparison less meaningful. This approach may be useful when historical data with limited background samples are being used, or when minimum requirements for ERA data collection have not been met and less than optimal numbers of background sample results are available. The following comparisons can be made:

- Comparison of site and background arithmetic mean concentrations.
- Comparison of site and background 95% UCL concentrations.
- Comparison of range of detected concentrations in both data sets.

For the most thorough comparison, all three of these factors should be examined. In a numerical comparison, the definition of "comparability" is arbitrary. Selecting a factor, such as a factor of two, while arbitrary, provides a benchmark against which to define comparability. As an example of this approach, site samples could be defined as comparable if the mean concentration were less than or equal to two times the mean background concentration.

4.2.3.3.4 Determination of Site-Relatedness. Background sampling is conducted to distinguish site-related contamination from naturally occurring or other non-site-related levels of chemicals (EPA 1989f). 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 in the ERA, although this decision requires professional judgment for reasons noted earlier (Section 4.2.3.3) and policy[3] considerations. 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 COEC. The supporting information must be conclusive and presented in the report.

4.2.3.3.5 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:

[3] Recent court cases, plus policies adopted by some states, suggest that "non-site-relatedness" is not an appropriate criterion: mere presence of a potential COEC 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.

CASE STUDY 8

EXAMPLE OF APPLYING A STATISTICAL TEST TO DETERMINE COMPARABILITY WITH BACKGROUND

Data Set:

Site Samples	Background Samples
$x_1 = 125$	$x_2 = 97$
$s_1 = 50.6$	$s_2 = 26.9$
$n_1 = 40$	$n_2 = 8$

Assumptions: If the data for the analyte are normally distributed or can be log-transformed to become normal, the Student's t-test is used. If the data are neither normal nor log-normal, then a nonparametric test such as the Mann-Whitney U test is used.

The distribution of the results suggested that both the site and background data are normally distributed. The population variances are unknown but assumed to be unequal.

Hypothesis: The null hypothesis is

$$H_0: \mu_1 \leq \mu_2$$

The alternative hypothesis is

$$H_a: \mu_1 > \mu_2$$

Procedure: The calculations are conducted assuming unequal variances between the two data sets. This assumption generally holds true for environmental data sets but will not impact the results if the variances are equal. The test results include a calculated t parameter and degrees of freedom (df). The calculated t is compared to the critical t (assuming a significance level of a = 0.01) to assess if the null hypothesis is rejected. The nondetects may be treated as follows: (1) for those data sets with more than 85 percent of detects, the nondetects are replaced by 1/2 of the SQL, and (2) for those data sets with 30 to 85 percent detects, Aichison's Adjustment may be performed before the t parameter is calculated to account for the nondetects in the data sets. The Aichison's adjustment procedure is explained in greater detail in the *Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities* (EPA 1989g). If 30 percent or fewer of the samples have detectable concentrations, then tests such as the Poisson Tolerance Limits (PTL) are used.

Statistic:

$$t = \frac{(x_1 - x_2) - (\mu_1 - \mu_2)}{(s_p^2/n_1 + s_p^2/n_2)^{0.5}}$$

x = mean concentration of the sample set (mg/kg)
s = standard deviation (mg/kg)
n = sample size
μ = true mean of the population
s_p^2 = pooled sample variance

Using this method, the sample variances are pooled by the following equation:

$$s_p^2 = \frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}$$

$$s_p^2 = \frac{(40 - 1)(50.6)^2 + (8 - 1)(26.9)^2}{40 + 8 - 2}$$

$$s_p^2 = 2{,}281$$

Distribution of Test Statistic: If the null hypothesis is true, the test statistic follows the Student's t distribution with v′ degrees of freedom.

$$v' = \frac{\left[\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}\right]^2}{\frac{(s_1^2/n_1)^2}{n_1 - 1} + \frac{(s_2^2/n_2)^2}{n_1 - 2}} = \frac{\left[\frac{(50.6)^2}{40} + \frac{(26.9)^2}{8}\right]}{\frac{(50.6^2/40)^2}{40 - 1} + \frac{(26.9^2/8)^2}{8 - 1}}$$

v′ = the adjusted degrees of freedom and the standard t distribution table can be used.

$$s_p^2 = \frac{\sqrt{s^2}(n_1 + n_2)}{n_1 * n_2}$$

Decision Rule: Fail to reject (accept) the null hypothesis if $t > 1.684$.

Accept (or fail to reject) the alternative hypothesis if t does not exceed 1.684.

Calculation:

$$t = \frac{(125 - 97) - (0)}{\left[\frac{2281}{40} + \frac{2281}{8}\right]^{\frac{1}{2}}} = 1.51$$

Decision: The calculated t value does not exceed 1.684. Therefore the null hypothesis must be rejected, and the alternative hypothesis is not rejected (i .e., that site concentrations exceed background concentrations).

- Calcium.
- Copper.
- . Chromium (trivalent).
- . Magnesium.
- [illegible]
- Iron.
- Potassium.
- Selenium.
- Sodium.
- [illegible]

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 onsite receptors. Nutritional requirements and limits for livestock and experimental laboratory animals (e.g., small mammals, birds, fish) are well-established.

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 COECs, 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 COECs.

4.2.3.3.6 Preliminary Toxicity Screen

A toxicity screen to determine which chemical concentrations exceed applicable regulatory standards (toxicity benchmarks) is performed for the selection of COECs. Various reference toxicity values for water and sediment developed by EPA (1986b, 1993b, 1994e, 1995b,f) can be used. ORNL (1994) has also developed screening benchmark preliminary values for aquatic and terrestrial ecosystems.[4] Guidance values from NOAA (Long and Morgan 1990), Washington State Department of Ecology (1991) Florida Dept. of Environmental Protection (MacDonald 1994), and Canada (Long et al. 1995, Persaud, Jangumagi, and Hayton 1992, CCME 1995) for marine and freshwater sediment threshold environmental effects levels can be used directly in Tier I screening for COECs in aquatic ecosystems with few or no modifications (see Exhibit 7). Additional toxicity benchmarks for aquatic ecosystems may be developed using information provided in EPA databases such as ECOTOX and ASTER (see Appendix B, Information Sources).

Standardized values to perform a toxicity screen of chemicals in terrestrial ecosystems are generally not available, although ORNL (1994) has recently published toxicity benchmarks for a variety of benchmarks that can be used in a Tier I terrestrial toxicity screen. Standardized values for screening terrestrial wildlife are currently under development by EPA. 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 (EPA 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 COEC selection. A cautious approach should be used in COEC screening as toxicity can differ among similar receptor species due to differences in either physiology or exposure. For example, some songbirds seem to be more sensitive to organophosphorus compounds than other songbirds (personal communication, Dr. J. Whaley, USACHPPM, 1995).

[4] The ORNL (1994) benchmark values are a useful preliminary screening tool. However, these documents do contain errors, have yet to be widely peer-reviewed, and should not be considered standardized benchmarks. ORNL will be updating these benchmarks and posting them on the Internet (www.ornl.gov).

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 5 percent or fewer samples and tend not to bioaccumulate, the lethal concentration for 50 percent of the population (LC_{50}) values (for plants or soil-dwelling organisms) may be compiled from available ecotoxicological literature and compared to the 95th UCL 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 (see Section 4.3.3).

Chemicals that have the potential to bioaccumulate or biomagnify through the food web should be retained for consideration as COECs, 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) (EPA 1995b). By definition, chemicals that tend to biomagnify also bioaccumulate. Chemicals with a log K_{ow} of less than 3.0 or a K_{oc} of less than 500 (i.e., log K_{oc} 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 (EPA 1995b)[5] (see Table 4-l).

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,l,1-trichloroethane, and xylenes are unlikely to bioaccumulate and biomagnify (Van Leeuwen et al. 1992; EPA 1982). Semivolatiles, including PAHs, tend not to bioaccumulate and show little tendency to biomagnify because they are readily metabolized (Eisler 1987, Beyer and Stafford 1993).

4.2.3.4 Presentation of Chemicals of Ecological Concern

The chemical selection process results in a select list of preliminary COECs that will be quantitatively assessed in the ERA. Tables should be developed identifying the COECs 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 COEC selection process should be included to clearly illustrate the decision process used (CS 6).

4.2.4 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) (EPA 1992a). 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 (see Section 4.2.5) to represent potential harm to all components of the system.

4.2.4.1 Objectives

Grouping of species, organisms, habitats, or ecosystem components under the heading of key receptors helps focus the exposure characterization portion of the Tier I ERA 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 the 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 input 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 error of uncertainty, this error might be offset by the use

[5] 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 am not accumulated in most vertebrates which have such enzyme systems.

Table 4-I
Chemicals of Ecological Concern According to Final Water Quality Guidance for the Great Lakes System (EPA 1995b)

Pollutanta that an bioaccumulative chemical of concern (BCCs)
Chlordane
p,p'-dichlorodiphenyl-trichloroethane (DDT) and metabolites
4,4'-DDD; p,p'-DDD; 4,4'-TDE; p,p'-TDE
4,4'-DDE; p,p'-DDE
4,4'-DDT; p,p'-DDT
Dieldrin
Hexachlorobenzene
Hexachlorobutadiene; hexachloro-1,3-butadiene
Hexachlorocyclohexanes (HCH); BHCs (benzene hexachloride; synonym for HCH)
alpha-Hexachlorocyclohexane
beta-Hexachlorocyclohexane
delta-Hexachlorocyclohexane
Lindane; gamma-BHC; gamma-hexachlorocyclohexane
Mercury
Methoxychlor
Mirex; dechlorane
Octachlorostyrene
PCBs; polychlorinated biphenyls
Pentachlorobenzene
Photomirex
2,3,7,8-TCDD; dioxin
1,2,3,4-Tetrachlorobenzene
1,2,4,5-Tetrachlorobenzene
Toxaphene
Pollutants that are not bioaccumulative chemicals of concern*
Acenaphthene
Acenaphthylene
Acrolein; 2-propenal
Acrylonitrile
Al&in
Aluminum
Anthracene
Antimony
Arsenic
Asbestos
1,2-Benzanthracene; benz[a]anthracene
Benzene
Benzidine
Benzo[a]pyrene; 3,4-benzopyrene
3,4-Benzofluoranthene; benzo[b]fluoranthene
11,12-Benzofluoranthene; benzo[k]fluoranthene
1,2-Benzoperylene; benro[ghi)perylene
Beryllium
Bis(2-chloroethoxy)methane
Bis(2-chloroethyl) ether
Bis(2-chloroisopropyl) ether
Bromoform; tribromomethane
4-Bromophenyl phenyl ether
Butyl benzyl phthalate
Cadmium

Table 4-1 (Continued)

Pollutants that are not bioaccumulative chemicals of concern*

Carbon tetrachloride; tetrachloromethane
Chlorobenzene
p-Chloro-m-cresol; 4-chloro-3-methylphenol
Chlorodibromomethane
Chloroethane
P-Chloroethyl vinyl ether
Chloroform; trichloromethane
P-Chloronaphthalene
2-Chlorophenol
4-Chlorophenol phenyl ether
Chlorpyrifos
Chromium
Chrysene
Copper
Cyanide
2,4-D; 2,4-Dichlorophenoxyacetic acid
DEHP; di(2-ethylhexyl) phthalate
Diazinon
1,2:5,6-Dibenzanthracene; dibenz[a,h)anihracene
Dibutyl phthalate; di-n-butyl phthalate
1,2-Dichlorobenzene
1,3-Dichlorobenzene
1,4-Dichlorobenzene
3,3'-Dichlorobenzidine
Dichlorobromomethan; bromodichloromethane
1,1-Dichloroethane
1,2-Dichloroethane
1,1-Dichloroethylene; vinylidene chloride
1,2-trans-Dichloroethylene
2,4-Dichlorophenol
1,2-Dichloropropane
1,3-Dichloropropene; 1,3-dichloropropylene
Diethyl phthalate
2,4-Dimethylphenol; 2.4-xylenol
Dimethyl phthalate
4,6-Dinitro-o-cresol; 2-methyl-4,6-dinitrophenol
2,4-Dinitrophenol
2,4-Dinitrotoluene
2,6-Dinitrotoluene
Dioctyl phthalate; di-n-octyl phthalate
1,2-Diphenylhydrazine
Endosulfan; thiodan
alpha-Endosulfan
beta-Endosulfan
Endosulfan sulfate
Endrin
Endrin aldehyde
Ethylbenzene
Fluoranthene
Fluorene; 9H-fluorene
Fluoride
Guthion
Heptachlor

Table 4-1 (Concluded)

Pollutants that are not bioaccumulative chemicals of concern*
Heptachlor epoxide
Hexachlorocyclopentadiene
Hexachloroethane
Indeno[1,2,3-cd]pyrene; 2,3-o-phenylene pyrene
Iron
Isophorone
Lead
Malathion
Methoxychlor
Methyl bromide; bromomethane
Methyl chloride; chloromethane
Methylene chloride; dichloromethane
Naphthalene
Nickel
Nitrobenzene
2-Nitrophenol
4-Nitrophenol
N-Nitrosodimethylamine
N-Nitrosodiphenylamine
N-Nitrosodipropylamine; N-nitrosodi-n-propylamine
Parathion
Pentachlorophenol
Phenanthrene
Phenol
Pyrene
Selenium
Silver
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
Thallium
Toluene; methylbenzene
1,2,4-Trichlorobenzene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichloroethylene; trichloroethene
2,4,6-Trichlorophenol
Vinyl chloride; chloroethylene; chloroethene
Zinc

Source: EPA. 1995b. Great Lakes Water Quality Initiative Methodology for Development of Bioaccumulation Factors. Final Rule. Federal Register. Vol. 60. No. 56. March 23.

* Pollutants that are not bioaccumulative (or biomagnifying) chemicals of concern may still be COECs.

of conservative criteria to select key receptors with the greatest sensitivity (highest trophic level receptor or chemically sensitive) or greatest opportunity for exposure.

4.2.4.2 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 assessment endpoints 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. A list of these statutes and the ecological receptors they are designed to protect is presented in Table 4-2. 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 Exhibit 8). These laws may also be applied to risk management decision-making during the FS/CMS 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.

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

- Likelihood of contacting chemicals.
- A key component of ecosystem structure or function (e.g., importance in the food web, ecological relevance).
- Listing as rare, threatened, or endangered by a governmental organization; or critical habitat for such.
- Sensitivity to chemicals.
- Recreational or commercially valued species (e.g., game and livestock).

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 nonmigratory 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.

4.2.4.2.1 Likelihood of Contacting Chemicals. Data 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.

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 potential COEC 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.

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 COECs). 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 COECs.

4.2.4.2.2 Sensitivity to Chemicals. Species differ in the ways that they take in, accumulate, metabolize, distribute, and excrete contaminants. Susceptibility of an organism also varies with the manner in which organisms am exposed to chemicals in their environment. When possible, key receptors and endpoints arc selected by identifying those that are known to be susceptible to chemicals at the site based on published literature This process

Table 4-2
List of Environmental Laws and Ecological Receptors (Adopted from the revised Hazard Ranking System (rHRS), 55 FR 51624, December 14,1990)

Ecological Receptors to be Protected	Statutory/Regulatory References
Critical habitat for Federal designated endangered or threatened species	Critical habitat as defined in 50 CFR 424.02; The Endangered Species Act Amendments of 1978
Marine Sanctuary	Marine Mammal Protection Act of 1972; Marine Protection, Research, and Sanctuary Act of 1972
National Park	National Park and Recreation Act of 1978
Designated Federal Wilderness Area	Endangered American Wilderness Act of 1978
Areas identified under Coastal Zone Management Act	Areas identified in State Coastal Zone Management plans as requiring protection because of ecological value; Coastal Zone Management Act Amendments of 1976
Sensitive Areas identified under National Estuary Program or Near Coastal Waters Program	National Estuary Program study areas (subareas within estuaries) identified in Comprehensive Conservation and Management Plans as requiring protection because they support critical life stages of key estuaries species under Section 320 of the Clean Water Act; near Coastal Waters as defined in Section 104(b)(3), 304(1), 319, and 320 of the Clean Water Act of 1977
Critical areas identified under the Clean Lakes Program	Clean Lakes Program critical areas (subareas within lakes, or in some cases entire small lakes) identified by State Clean Lake Plans as critical habitat (Section 314 of the Clean Water Act of 1977)
National Monument	Use only for migration pathway
National Seashore Recreational Areas	
National or State Wildlife Refuge	National Wildlife Refuge System Administration Act of 1966
Unit of Coastal Barrier Resource System	
Coastal Barrier (undeveloped)	
Federal land designated for natural ecosystems	National Forest Management Act of 1976
Administratively Proposed Federal Wilderness Area	
Spawning areas critical for the maintenance of fish/shellfish species within river, lake, or coastal tidal waters; Fishery Conservation and Management Act of 1976;	Limited to areas described as being used for intense or concentrated spawning by a given species
Migratory pathways and feeding areas critical for maintenance of anadromous fish species within river reaches or areas in lakes or coastal tidal waters in which fish spend extended periods of time	Anadromous Fish Conservation Act of 1965
Terrestrial areas utilized for breeding by large or dense aggregations of animals	For the air migration pathway, limited to terrestrial vertebrate species. For the surface water migration pathway, limited to terrestrial vertebrate species with aquatic or semiaquatic foraging habitats; Tule Elk Preservation Act of 1965;
National river reach designated as recreational	National Wild and Scenic River System of 1968
Bald and Golden Eagle	Bald Eagle Act of 1940

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.

4.2.4.2.3 **Threatened and Endangered Species.** By definition, endangered and threatened 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. 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 (see Exhibit 8).

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 COECs. 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.

4.2.4.2.4 **Importance of the Food Web. The** putpose 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 COECs bioaccumulate or if the direct effects on organisms from COECs 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 reasonable nor necessary. Based on the preliminary list of important species at the site, a preliminary simplified food web can be drawn (see **Section 4.2.6).**

4.2.4.2.5 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.

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 community food web includes the feeding relations of the entire community. 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). 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.

4.2.4.2.6 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 for predators, 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 ERA.

4.2.4.2.7 Reptiles and Amphibians. The selection of reptiles and amphibians as key receptors should be considered, particularly for installations where there are state or Federally protected species. Consideration of reptiles and amphibians has generally been avoided in ERAs due to limited knowledge about contaminant effects on these taxa. Information on contaminant toxicity and population modeling techniques, particularly for frogs and turtles, however, is becoming more prevalent in the published literature and accessible databases. USACHPPM is currently doing extensive exposure and toxicity modeling for

amphibians.[6] Where scope is limited in an ERA, EPA (1986c) 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 same 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 ERA.

Reptiles and amphibians should not be ignored in constructing food webs, particularly where chemicals are known to bioaccumulate. Amphibians and reptiles may carry substantial organochlorine residue burdens due to life history factors, particularly feeding habits. Toads, for example, feed primarily upon insects and other invertebrates, while garter snakes use mainly earthworms, salamanders, toads, and mice (Jorschgen 1970). Amphibians and reptiles in turn are a vital dietary component for a highly visible ecosystem component, the raptors (Ross 1989). Snapping turtles were selected as a key receptor in both the ERA and Human Health Risk Assessments at Aberdeen Proving Ground, Maryland.

4.2.4.2.8 Recreationally and Commercially Valued Species. EPA (1989a) 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.

[6] Mr. Mark Johnson at USACHPPM is specifically conducting research on the effects of munitions on salamanders. He may be contacted at (410)-671-5081 for further information. Mr. Keith Williams at (410)-671-2953 and Mr. John Paul at (410)-6714567, also of USACHPPM, may be contacted regarding their research on munitions and snapping turtles at Aberdeen Proving Ground.

4.2.5 Ecological Endpoints Identification

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:

- Assessment Endpoints. Explicit expressions of the environmental values that are to be protected (EPA 1992a).
- Measurement Endpoints. Measurable responses related to the valued characteristics chosen as assessment endpoints (EPA 1992a).

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 (EPA 1992a). Assessment endpoints most often describe the environmental effects that drive decision-making, such as reduction of key populations or disruption of biological community structure (EPA 1989a).

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 COECs and receptors. As in the PA/SI, measurement endpoints in the Tier I ERA are frequently based on toxicity values from the available literature. In higher tiers, measurement endpoints are more often expressed as the statistical or arithmetic summaries of the actual field or laboratory observations or measurements (EPA 1992a).

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. COECs for those receptors and endpoints are identified by &awing 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.

4.2.5.1 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.

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. 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.' 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.

4.2.5.2 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 (EPA 1989c):

. 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

Population-level assessment endpoints are generally recognized in ERAs because: (1) responses at lower levels (i.e., organismal and suborganismal) may be perceived as

[7] 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 COEC 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.

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 (EPA 1989a). 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.

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.

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.

Indirect effects of chemicals are often cited as justification for testing at higher level of organization (Tiers III and IV). Implementation of such testing, however, tends to be expensive, time-consuming, presents great uncertainty, and may have limited relevance to the risk management decisions. If ecological endpoints are not appropriate and compelling, they will not contribute to decisions regarding site remediation (EPA 1989a).

4.2.5.3 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 (EPA 1989c). Measurement endpoints should be selected so as to provide insights related to the specific assessment endpoint. In Tier I, reference toxicity values (e.g., LD_{50}, LOAEL, 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 (Tier II activities). 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 (a Tier II, III, or IV effort), the DQO process and guidance provided in the HTBW Tech***nical Project Planning*** document (USACE 1995b) should be followed.

4.2.6 Ecological Conceptual Site Model

The ECSM is a representation, often pictorial, of certain portions of the exposure characterization (CS 3). The ECSM traces the contaminant pathways through both abiotic components of the environment and biotic, food web components of the system (see CS 9). The ECSM, which may have been established in the PA/SI or RFA 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 PDs requirements. At this time, data concerning potential existence and locations of

sensitive environments, endangered species, or valued resources should already have been collected.

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

Initial formulation of the ECSM in the screening ERA is based upon existing information and assumptions regarding chemical presence and migration, which now should be verified and refined with data collected during the Tier I site investigation. Exhibit 9 discusses the components of the ECSM and identifies some specific factors that should be re-examined as part of the exposure characterization (also see CS 10). Exhibit 10 discusses the role of chemical and physical properties in developing an ECSM.

The ECSM is refined in greater detail throughout the Exposure Characterization portion of the ERA. The risk assessor and project team members should review site data and information collected in earlier project efforts (PA/SI or RFA) to establish or refine the ECSM (based on more complete background information or nonchemical data) and assess potential early/immediate response actions, as appropriate. All existing data should be reviewed for quality, useability, 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, AOCs, or CAMUs/TUs (if appropriate). This information should include:

- COECs (information concerning the source characteristics, medium contamination, and background chemicals, including those of anthropogenic origin, is needed to identify COECs).
- Potential target media (groundwater, surface water, soil/sediment, and air).
- Media parameters and characteristics.
- Potential receptors in the target media.
- 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).
- 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).
- Exposure areas or units with common COECs which also pose common exposure pathways and threats to ecological receptors.
- Potential secondary, tertiary, and quatemary sources of contaminants, and their release/transport mechanisms.
- Level of contamination when compared to available ARARs or benchmark values, and relevancy of sample location/matrix.
- Removal actions or interim corrective measures taken.
- Data useability 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.

4.3 Analysis Phase - Exposure Characterization

This section discusses the development of the exposure characterization portion of a Tier I ERA. The purpose of the exposure characterization is to estimate the nature, extent, and magnitude of potential exposure of receptors to COECs that are present at or migrating from a site, considering both current and plausible future use of the site. Several components of the exposure characterization have previously been evaluated during earlier stages of the SI and ERA for the purposes of developing the ECSM and focusing investigative activities. These components include identification of COECs, key receptors and food webs, exposure media, and preliminary exposure pathways and areas. These preliminary characterizations were based upon early and often incomplete information that now must be clarified in light of the information obtained during site investigative activities.

The steps required to perform an exposure characterization are:

- Refinement of the preliminary chemical fate and transport model developed during the PA/SI and the preliminary ECSM.
- Characterization of the exposure setting.
- Identification of potential exposure pathways and intake routes.
- Quantitation of exposure.
- Assessment of exposure uncertainties.

Each of the above components is discussed in detail in following sections.

4.3.1 Exposure Setting Characterization

The objective of describing the exposure setting is to identify the site physical features that may influence exposure for both current and future scenarios. 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.

- 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.
- 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 of aquatic ecosystems.
- 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).
- Meteorology. Wind speed and direction influence the entrainment of soil particles and the extent of transport and dilution of air contaminants.
- Vegetation. The nature and extent of vegetation influence the fauna that are present and their potential for exposure through the food chain.
- Soil Type. The type of soil (e.g., grain size, organic carbon, clay content) influences 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.
- Land Use. The types of receptors likely to have contact with site media and COECs depend, in part, on current and planned future land use. The appropriate current and future land uses should be identified, as is discussed above (see Exhibit 11).

Description of the site setting in the exposure characterization should involve obtaining more specific, in-depth information than was obtained during the preliminary ECSM development. The description should be supplemented by data collected during the site investigation. Description of portions of the exposure setting may have been discussed in other portions of the site report, and need only be referenced in this section. However, characteristics of the exposure setting that are specific to potential exposures should be presented.

4.3.2 Exposure Analysis

Exposure analysis combines the spatial and temporal distributions of the ecological receptors with those of the COECs 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.

4.3.2.1 Exposure Pathways identification

An exposure pathway is the physical course a chemical takes from the source to the exposed receptor (EPA 1989f).

A complete exposure pathway typically consists of the following four elements:

(1) A source and mechanism of chemical release.

(2) A transport medium such as water, soil, or forage (if the exposure point differs from the source).

(3) An exposure point or area where receptors may contact the chemicals.

(4) An exposure (intake) route through which chemical uptake by the receptor occurs (e.g., direct contact, ingestion, inhalation, or dermal absorption).

When all four elements are present, the exposure pathway is considered complete. If one or more of the components are missing (with the possible exception of the second element, transport medium), the exposure pathway is incomplete and there is no exposure and therefore no risk. It should be noted that the exposure point may be at the source itself, or the exposure point may be some distance from the source due to movement of the chemicals through the release and transport mechanisms. Circumstances should also be acknowledged where currently incomplete exposure pathways may present some future risk.'

Exposure pathways should be identified for both current land use and potential 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:

- **What is the current and future land use?** 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 are appropriate. Risk managers and decision makers should be included at this point so that future scenario assessments only include "real world" scenarios and thereby minimize wasted assessment efforts.

- **What is the exposure area?** If relevant, specific portions of the site or offsite 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.

- **In which media are COECs presently contained?** If COECs 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.

- **Into which media are the COECs anticipated to enter within the exposure period for current and future exposure scenarios (for example, accumulation of chemicals into animal and plant species over time)?** Is predictive modeling needed?

- **For what period of time are the COECs 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.

- **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 result in dermal contact being a negligible exposure pathway for the most part.

Exhibit 12 identifies a generic list of potential exposure pathways and mutes. A brief discussion on pertinent factors for generic exposure routes is presented below. When performing the exposure characterization, these potential exposure routes should each be examined and a decision made regarding the exposure route and pathway completeness of each for the site. Consideration of exposure routes and pathways for aquatic, versus terrestrial receptors requires somewhat different perspectives. Methods for quantifying exposure for these receptors are also

[8] Examples of this include: (1) a contaminated groundwater plume moving toward, but not yet at, discharge points to surface water bodies: (2) sediment contamination buried below the active zone of contamination that may become exposed at some future date due to natural (e.g., hurricane) or anthropogenic causes (e.g., dredging, elimination, or diversion of particulate inputs).

quite different. The approaches for assessing exposure in aquatic and terrestrial receptors are thus presented separately in the following text.

4.3.2.2 Exposure Routes for Aquatic Receptors

As discussed in the preceding section, a complete exposure pathway typically consists of four elements -- a source and release of COECs, 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 COECs am 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 Section 4.3.2.4.

Some common exposure pathways for aquatic receptors are illustrated in CS 3 (aquatic ECSM). The aquatic ECSM serves a very useful purpose -- it enables the risk assessor to visualize where and how COECs 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 also shows which pathways may be significant and what measurement endpoints should be considered.

From the primary source of COECs, 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 is a primary pathway to surface water, where chemical concentrations are rapidly diluted, and to sediment. Volatilization of organic COECs 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.

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 of COECs. Sediments are critical factors in aquatic ERAs because many COECs accumulate to elevated concentrations in sediments, and therefore act as sources of chemicals to the interstitial (i.e., pore) water and overlying surface waters.

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 COECs, sediment type, sediment and water movements, organism life stage and location in the water column, migratory movements, and feeding strategies.

Aquatic receptors can also be exposed to COECs 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 COECs 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 (see Chapter 5). Sediment contaminant concentrations can be compared to sediment standards, guidelines, or COEC sediment levels that are back-calculated from water criteria using chemical-specific K_p 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 to COECs 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 COECs, bioavailability of the COECs, and the toxicity of the COECs.

4.3.2.3.1 Physical Factors. Physical factors affect the release mechanisms that move COECs 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 COEC exposure point. Referring to the aquatic ECSM in CS 3, these physical factors include discharge, leaching, infiltration, erosion, dilution, settling, and resuspension on the physical media.

An example can serve to illustrate the physical factors that influence the presence and concentration of COECs at the exposure point. COECs 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 COEC concentration in groundwater, results in a loading rate to the surface water. Groundwater typically moves through the interstices of the sediment where the COECs 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 COECs to adsorb onto the sediment, thereby reducing their mobility in the aquatic environment. Throughout the pathway, 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 COECs at the exposure points (sediment and surface water).

Physical factors can also influence the movement and location of aquatic receptors, thus affecting their exposure to COECs. 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 COEC concentrations.

4.3.2.3.2 Chemical Factors. Chemical factors can affect the chemical and physical form of the COECs, their bioavailability, and ultimately, their 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 COEC when tested in a dilution series using laboratory water versus the same COEC tested using upstream natural water as dilution water.

In sediments, some of the same chemical factors influencing exposure of receptors to COECs in water also affect exposure to COECs in sediments. Two other chemical factors, total organic carbon (TOC) and acid volatile sulfide (AVS), strongly affect exposure of receptors to COECs in sediments. Increased levels of organic carbon in sediments tend to bind nonpolar organics to the sediment. This effect is reflected in the chemical-specific organic carbon-water partition coefficient, K_{oc}.

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 simultaneous extraction procedure referred to as SEM (i.e., SEM/AVS ratio is greater than l.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.

4.3.2.3.3 Biological Factors. Several biological factors affect the co-occurrence and exposure of aquatic receptors to COECs in the water and sediment exposure media. Similar factors also affect the exposure of prey organisms to COECs that can bioaccumulate in the prey tissues, thus contributing to the overall exposure of receptors to bioaccumulative COECs.

Some of the more important biological factors affecting exposure to COECs are life stage, feeding strategy, and migratory movements of the receptors. In a typical exposure scenario, COECs 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 and adult life stages that are sessile (i.e., attached to a substrate). If that substrate or the surrounding sediment has elevated COEC concentrations, the adult is likely to be exposed to COECs, whereas the larval stage is less likely to be exposed since it is not directly associated with the sediment.

Feeding strategy can also directly influence exposure to COECs. If a receptor feeds in or along the sediment and COECs are at elevated levels in the sediment, the receptor is apt to be exposed to COECs through ingestion of prey organisms that have accumulated COECs and incidental ingestion of sediment. If a receptor feeds higher in the water column, it is less likely to be exposed to COECs in

sediments and sediment-related prey. If a receptor is an upper-level predator (e.g., black drum), it is apt to be exposed to bioaccumulative COECs through ingestion of primary or secondary consumers that have elevated levels of COECs in their tissues. In contrast, a primary consumer that eats plant material is less apt to be exposed to COECs since chemicals are not apt to be accumulated to elevated levels in the vegetation.

Migratory movements of receptors can directly affect exposure to COECs. 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 COECs, 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 COECs only while it is in the vicinity of the contaminated sediment or other exposure medium.

The manner in which several of these biological factors may affect the exposure characteristics of receptors to COECs 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.

4.3.2.4 Exposure Routes for Terrestrial Receptors

Typical exposure pathways and routes for terrestrial (and wetland) receptors are illustrated in CS 3. Similar to the aquatic ECSM, the terrestrial ECSM enables the risk assessor to visualize where and how COECs 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.

4.3.2.4.1 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 surfacecontaminated 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 dermal exposure route is presented in Section 4.4.5.3.

4.3.2.4.2 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 inhalation exposure route is presented in Section 4.4.5.2.

4.3.2.4.3 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.

4.3.2.4.4 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 (EPA 1990d). Similar estimates of soil ingestion rates for grazing wildlife may also be used.

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). 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, Connor, and Gerould 1994). Soil ingestion rates for small rodents are reported at less than 2 percent (Beyer, Connor, and Gerould 1994).

4.3.2.4.5 Ingestion from Diet. Exposure of high trophic level receptors to lower trophic level plant or animal species into which chemicals have accumulated should be considered in cases where COECs have the potential to biomagnify. Organic chemicals with high log KOW (>3.0, EPA 1994f) or high molecular weights (i.e., pesticides and PCBs) are more likely to be transferred through the food web than those with low molecular weights. Plants can take up chemicals with low log K,, values by way of their roots, but cannot transport significant amounts of chemicals with high molecular weights and high low K_{ow} values in the same manner (EPA 1989c). Such chemicals can, however, be transported via the air pathway and deposited and adsorbed to plant surfaces (leaves, etc.). 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 COECs than the animals on which the birds prey. For terrestrial species, BCFs as little as 0.03 can be significant if the residue is toxic (EPA 1989a).

4.3.2.4.6 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 (Alloway 1990). Factors affecting the contaminant amounts absorbed by a plant are those controlling: (1) concentration and speciation of the contaminant in the soil solution, (2) movement of the contaminant from the bulk soil to the root surface, (3) transport of the contaminant from the root surface into the root, and (4) translocation from the root to the shoot (Alloway 1990). 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 and mesophytic plants which have more shallow root systems and depend on surface water from rainfall.

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 COECs. 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.

4.3.2.5 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 exposure characterization. Normalizing factors (e.g., body weight, growth rate) for the various receptors am also to be considered during exposure quantitation.

4.3.2.5.1 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.

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. 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 home range, or feeding/foraging range, to the area of contamination or the site area under investigation.

4.3.2.5.2 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.

4.3.2.5.3 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.

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. 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 15year study (Keith 1983). and it took 12 years for a relationship between conifer seed crop and red squirrel abundance to be repeated (Halvorson 1984).

4.3.2.5.4 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.

4.3.2.5.5 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.

4.3.2.5.6 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 COECs serve as input to the risk characterization.

4.3.3.1 Quantitation of Exposure

For soil-dependent organisms (plants, soil invertebrates, soil microbes), soil exposure concentrations are directly evaluated against soil criteria, similar to AWQC for aquatic organisms. Standard soil criteria like the AWQC are not currently available, but are under development by EPA. ORNL (1994) has recently published toxicological benchmarks for terrestrial plants and soil/litter invertebrates.

For wildlife, chemical intakes am 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.

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 than direct soil exposure for large herbivores. General factors to consider when deriving exposure concentrations are identified in Exhibit 13.

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. 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 is used[9] (see CS 11). It is worth noting that use of the central tendency value may not adequately address chemicals that are highly bioaccumulative or biomagnify.

EPA has recommended that the approach presented in Gilbert (1987) be used to calculate the exposure point concentration term (EPA 1992h). This approach derives the 95% UCL of the arithmetic mean, using log-transformed data. EPA recommends assuming a log-normal distribution unless an alternate distribution can be demonstrated to be appropriate. If a normal distribution is appropriate for the data the Student's t test can be applied. Exhibit 14 presents methods to calculate the 95% UCL concentration by these two distributions.

Often in data sets, a number of data points for a given chemical in a given medium will be reported as undetected or less than some quantitation limit.[10] Common errors in reporting and handling these data can occur and include: (1) omission of detection limits, (2) failure to define detection limits which am reported, and (3) unjustified treatment of nondetects as zero. In calculating the sample mean (x) and sample standard deviation(s), some method of handling these "less than" values is needed. Also, the uncertainties in statistical comparisons and variance biasing that can ensue when nondetection samples are assumed to be a single value should be addressed.

Four options for the treatment of nondetect values are discussed in Gilbert (1987):

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[9] 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.

[10] Analytical laboratories frequently code samples as "below detection" when the actual concentration was detectable with the method employed but fell below the Contract Laboratory Program (CLP) contract reporting limit. This situation is easy to spot because all "below detection" samples will have the same value. Sample specific (not generic) practical quantitation limits (PQLs) or method detection limits (MDLs) should also be reported.

CASE STUDY 11

CALCULATION OF EXPOSURE POINT CONCENTRATIONS (TERRESTRIAL ECOSYSTEM)

The exposure area for a small mammal is defined as the area of the former metal scrap piles. Therefore, data from locations SS-1 through SS-4 describe the exposure area and are combined to derive the exposure point concentrations. Assuming a log-normal distribution and applying the statistical approach for calculating the 95% UCL on the arithmetic mean for a log-normally distributed population (as recommended by EPA), the following exposure point concentrations are derived:

Chemical	Mean Conc	95% UCL	Max Conc
Cadmium (mg/kg)	85.6	104.3	100

Note that the 95% UCL concentration is greater than the maximum detected concentration. This occurred because the small sample size resulted in a high "H" statistic value and an artificially high 95% UCL. Since the 95% UCL exceeds the maximum detected value, the maximum value is used as the exposure point concentration. This concentration will be used as the exposure point concentrations for soil ingestion by wildlife and soil contact by soil-dependent organisms.

- Use only the quantified values
- Assume the nondetected values are equal to the quantitation limit.
- Assume the nondetected values are equal to zero.
- Assume the nondetected values are some value between zero and the quantitation limit, such as one-half of the quantitation limit.

The first three methods are biased for both the population mean (μ) and the population variance (σ^2); the fourth is unbiased for p if all measurements between zero and the quantitation limit have a uniform distribution. EPA discusses use of these approaches and recommends using one-half of the sample quantitation limit (SQL) if there is reason to believe that the chemical is present in the sample (such as being detected in other similar samples), or using the full SQL if there is reason to believe that concentrations are closer to the SQL than one-half of the SQL (EPA 1989f). The assumption of a value of zero for nondetects should be made only if site-specific information indicates that a chemical is not likely to be present in a sample. In *RAGS I*, EPA (1989f) indicates that omission of nondetected results is not appropriate. Additional discussion can be found in EPA Region III's (1991f) *Technical Guidance on Chemical Concentration Data Near the Detection Limit.*

In certain situations, an unusually high quantitation limit may be assigned to a nondetected result due to matrix interferences, high concentrations of other chemicals in the sample, presence of blank contamination, or other factors. When one-half (or all) of this quantitation limit is used to derive summary statistics, the mean concentration may exceed the maximum detected value. When the 95% UCL concentration is calculated, it, too, will be above the maximum detected value. In these situations, guidance recommends using the maximum detected value in place of the 95% UCL concentration. It should be noted, however, that if many of the undetected results have unusually high detection limits, these high limits may be masking the presence of the chemical. In this case, the utility of the data set and the need for additional analysis should be examined.

As an option, to obtain a more representative mean and UCL concentration, the sample with the unusually high quantitation limit can be removed from the calculation of the mean concentration, reducing the sample number ("n") by one. If the resultant mean concentration still exceeds the maximum detected value, the next highest quantitation limit should be removed, and the mean recalculated. This process can continue until a mean concentration less than the maximum concentration is attained. The 95% UCL concentration then can be recalculated, as well.

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.

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:

- When the potential exposure point is at a location other than those for which monitoring data are available (e.g., in offsite areas or locations in-between those which have been described).
- When the potential exposure is anticipated to occur in the future (e.g., proposed incinerator emissions).
- When the chemical concentrations are anticipated to change with time.
- 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).
- When the potential exposure point concentration is anticipated to increase with time (as with bioaccumulation into animal or plant species).
- When the bioavailable portion of the chemical concentrations is anticipated to change with time (e.g., seasonal AVS fluctuations, fluctuations

between fresh and saline water either with migration downstream or tidal influence).

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, including the following:

- *Superfund Exposure Assessment Manual* (EPA/ 540/l-88/001,4/88) (EPA 1988h).
- *AirlSuperfund National Technical Guidance Study Series* (Volumes I - V) (EPA 1989h,i; 1992i, 1993d: 1995g).
- *A Workbook of Screening Techniques for Assessing Impacts of Toxic Air Pollutants* (EPA-450/4-88-009, 9/88) (EPA 1988i).
- *Selection Criteria for Mathematical Models Used in Exposure Assessments: Ground-water Models* (EPA/600/8-88/075, 5/88) (EPA 1988j).
- *Selection Criteria for Mathematical Models Used in Exposure Assessments: Surface Water Models* (EPA/600/8-87/042, 7/87) (EPA 1987a).
- *Rapid Assessment of Exposure to Particulate Emissions from Surface Contamination Sites* (EPA/600/8-85/002, 2/85) (EPA 1985).
- *Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions* (EPA/600/6-90/003, 1/90) (EPA 1990d).
- *Assessment and Control of Bioconcentratable Contaminants in Surface Water* (EPA 1991e).

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.

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 concentration results tends to result in an overestimation of the exposure concentration (and risk) for larger mobile animals (deer, antelope) that don't 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 areawide intake concentration. Where the receptor's home range lies within the contaminated area, alternate methods of removing the bias from the areawide exposure concentration (e.g., weighted average, Theissen polygons) data set can be used, but may result in an over- or underestimate of exposure. Probability analysis techniques (Monte Carlo) and programs (e.g., Crystal Ball@) are also gaining greater acceptance as a means to provide a more realistic estimate of actual exposure conditions by generating a distribution of probable exposure concentrations (See Appendix E).

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 Tier I 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 (or livestock) are generally lacking: limited guidance on these intake routes are provided by EPA (1990d, 1993e) and USDOI (1991).

For each receptor, the following four exposure factors are considered in the calculation:

- Food Intake (FI) - These rates can vary by age, size, and sex and by seasonal changes in 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 in EPA's (1993e) *Wildlife*

Exposure Factors Handbook (see Exhibit 15). 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).

- 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.

- 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 published by EPA (1993e; see Exhibit 15).

- 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* (EPA 1993e). 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. Estimating contaminant exposure for wildlife consists of summing the exposure received from each separate source. Total exposure intake for terrestrial wildlife is represented by the following generalized equation (ORNL 1994):

$$E_{total} = E_{food} + E_{water} + E_{soil}$$

where

E_{total} = exposure from all sources

E_{food} = exposure from food consumption

E_{water} = exposure from water consumption

E_{soil} = exposure through consumption of soil and sediment (incidental or deliberate)

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. The following equations for chemical intake exemplify the simplified assumption models commonly used in a baseline ERA. More complex assumption models can be found in the *Wildlife Exposure Factors Handbook* (EPA 1993e).

Chemical intake is estimated by applying the following generic equation to each exposure source (e.g., food):

$$\text{Daily Intake}_{food}\ (\text{mg-chem/kg-bw/d}) = \frac{C \times FI \times EMF}{BW}$$

where

C = concentration of chemical in food (i.e., mg-chem/kg-food)

FI = food intake rate (kg-food/day)

EMF = exposure modifying factors such as area use (percent of home range that is contaminated) or exposure frequency (percent of time spent in contaminated area) that describe the magnitude and frequency of exposure (default value is 1.0) (unitless)

BW = body weight of receptor (kg)

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* (EPA 1993e) 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 (1994) *Toxicological Benchmarks for Wildlife.* Allometric equations for estimating wildlife feeding and drinking rates are provided in Exhibit 15. Some general points that should be considered when selecting exposure factors are identified in Exhibit 16. 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.

If C and FI vary over time, they may be averaged over the exposure duration (ED). 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 reference toxicity value that is used.

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. To calculate daily dose for diets with more than one component, the following generic equation may be used:

Daily intake (mg-chem/kg-bw/d) =

$$\frac{[(C_1 \times FI_1)\, f_1 + (C_2 \times FI_2)\, f_2 + \ldots (C_i \times FI_i)\, f_i] \times EMF}{BW}$$

where

C_i = concentration of chemical in food (i.e., mg-chem/kg-food or ppm)

FI_i = food intake rate (kg-food/day)

f_i = fraction of food item in diet

EMF = exposure modification factors (default value is 1.0) (unitless)

BW = body weight of receptor (kg)

The same generic equation can be used to estimate daily intake of the contaminant from food, water, and soil/sediment ingestion routes. For example, to calculate the daily dose for a receptor exposed to a contaminant in diet and water, the following equation may be used:

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)

EMF = exposure modifying factors (default value is 1.0) (unitless)

BW = body weight of receptor (kg)

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 single 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., "hot-spot" 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 "hot-spot" areas should be factored into the intake equation. Use of a "hot-spot" high end as well as use of the 95th UCL exposure scenario are also applicable to ecological risk. 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 Variable-s. To develop a "high end" assessment, EPA 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. EPA human health guidance ***(RAGS I)*** recommends applying 90th or 95th percentile values for the exposure point concentration term" and exposure frequency variables, and average values for other parameters such as body weight.

The average exposure (central tendency) 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 an arithmetic mean, is more meaningful since it represents a midpoint value (i.e., half the population above and half below). Specific ERA guidance is lacking regarding the use of average versus 95th UCL values for exposure frequency and intake variables, as quite often are the data to calculate such values for specific ecological receptors.

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 dative 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.

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 (EPA 1983, USDA 1983, DOE 1984).

A number of models are also available for determining plant uptake of contaminants from soil (Kabata-Pendias and Pendias 1984, Briggs, Bromilow, and Evans 1982, Topp et at. 1986). 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 EPA (1990d). 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 (EPA 1990d). Similar methods for wildlife tissue are generally not available and thus the livestock factors are sometimes used.

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

[11] According to EPA (1992h) guidance, the chemical concentration relating to the 95% UCL 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.

conducted at Superfund sites where tissue sampling was performed. 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.

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.

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 (see ORNL 1994). Defensible information should be available to make this modification.

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.

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 exposure characterization, 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 COEC toxicity values, discussed in the following section, to derive estimates and characterize potential ecological risk.

Uncertainties associated with the estimation of chemical intake should be summarized at the conclusion of the exposure characterization. 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 Section 4.5.2.

4.4 Analysis Phase-Ecological Effects Characterization

The ecological effects characterization (toxicity assessment) includes a preliminary evaluation of chemical-specific ARARs, 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 EPA-derived critical toxicity values, when available, in addition to selected literature pertaining to site- and receptor-specific parameters.

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 COEC. Data pertaining to site-specific species are emphasized, and information on domestic or laboratory animals is used when site-specific biota data are unavailable. Adequacy of the existing database is also to be evaluated as part of this task.

4.4.1 Objectives

The Tier I effects characterization fulfills two specific objectives in a risk assessment. First, available toxicological literature is reviewed to identify appropriate literature benchmark values to use. The toxicological literature forms the basis for developing summaries of the potential toxicity of the COECs for inclusion in the risk assessment. Second, appropriate reference toxicity values (RTVs) (EPA 1993e; also abbreviated TRVs by other authors) are developed using literature benchmark values and uncertainty factors to estimate potential ecological risks associated with key receptor chemical exposure. This is accomplished by reviewing the available information on COEC toxicity and summarizing the factors pertinent to the exposures being assessed. In the following sections, each of these components of the effects characterization is discussed.

The Tier I effects characterization is based on a desk-top hazard index (HI) or hazard quotient (HQ) approach. Numerous bioassessment tools,[12] however, are available to the risk assessor to employ for directly measuring or investigating toxicity, or even risk. While these bioassessment techniques are presented as a Tier II effort in this manual (see Chapter 5.0), it is advisable to consider these techniques early on in the planning process as a potentially expedient means to directly address the assessment endpoints, particularly in aquatic ecosystems. Bioassessment techniques offer several advantages over the HQ or model approaches to toxicity estimation: they

- Demonstrate whether the COECs are bioavailable.
- Evaluate cumulative impacts due to exposure to multiple COECs.
- Evaluate toxicity of COECs for which no RTVs can be found.
- Characterize the nature of the toxicity.
- Integrate media variations and spatially characterize toxicity.
- Monitor impacts before and after remediation.
- Develop remedial levels in terms of toxicity and then monitor effectiveness and success of remedial actions.

4.4.2 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 (i.e., tier). If the level of effort (time and money) is limited as is the case in Tier I and possibly Tier II, 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.

[12] 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.*

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 (1994) however, has recently 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, Adema, and Dirven-Van Breeman 1993, Kabata-Pendias and Pendias 1984, USFWS 1990, Overcash and Pal 1979, Gough, Schacklette, and Case 1979, Callahan, Shirazi, and Neuhauser 1994). PHYTOTOX, a database dealing with the effects of organic and inorganic chemicals on plants, is also available for government, academic, and industrial users (Royce, Fletcher, and Risser 1984). A new EPA database, ECOTOX, which integrates aquatic and terrestrial receptor databases is expected to become available in late-1995 (see Appendix B, Information Sources).

Published ERAs, such as those reviewed in EPA (1993f) *Case Studies from a Risk Assessment Perspective,* offer additional sources of terrestrial and aquatic toxicity data. Toxicity data and information for developing wildlife RTVs 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 EPA and DoD (U.S. Army, U.S. Navy) BTAG/ETAG persons can also be contacted for assistance. Other sources for aquatic and terrestrial laboratory data are presented in Appendix B and include the following:

- EPA Criteria Documents. Include ambient water criteria documents, proposed sediment quality criteria documents, drinking water criteria documents, air quality criteria documents, and health effects assessment documents.

- USFWS Contaminant Hazard Reviews. (Author: R. Eisler, dates 19851994). This is a series of reports reviewing the hazards of over 25 metals and organic compounds to fish, wildlife, and invertebrates.

- Oak Ridge National Laboratory (ORNL 1994), Toxicological screening benchmarks for ERAs (available in PC-database). 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.

- Toxicological Profiles developed by the Agency for Toxic Substances and Disease Registry (ATSDR 1989).

- Aquatic and terrestrial toxicological data (and in some cases, literature citations). Available in public or on-line databases such as Toxline, BIOSIS, AQUIRE, ASTER, QSAR, HSDB, Ecological Abstracts, Biological Abstracts, Current Contents, Duckdata (USFWS).

- National Academy of Sciences publications such as *Mineral Tolerance of Domestic Animals* (1980).

- Integrated Risk Information System (IRIS). This is EPA's primary database for the reporting of up-to-date human health toxicity values that have been verified by the EPA. IRIS may be accessed through TOXNET and other commercial services. IRIS contains numerous chemical profiles that present verified chronic reference doses for laboratory animals. The study(s) from which the toxicity value was derived is summarized, and the method of derivation is explained (e.g., applied uncertainty and modifying factors, level of confidence, extrapolation model).

- Health Effects Assessment Summary Tables (HEAST). HEAST is published annually by EPA, and is a collection of interim and provisional toxicity values developed by EPA. Verified toxicity values are not presented in the most current version of HEAST: rather, the user is directed to IRIS. HEAST can be obtained through the National Technical Information Service (NTIS).

4.4.3 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 (>365 days), intermediate or subchronic (15-364 days), and acute <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 EPA (1995b) arbitrarily consider chronic to be 10 percent of the organism's lifespan. According to EPA'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.

In selecting data to be used in the derivation of the RTV, 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 [ALAD] from exposure to lead) or increased tissue concentrations, while they may serve as good biomarkers indicative of an organisms's 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 RTV. 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 to determine the RTV.

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

- Literature benchmark values should be obtained from bioassays having test conditions as similar as possible to onsite 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.

- The literature benchmark values and RTV should correspond to 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).

- The RTV 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, RTVs. RTVs for different toxicity endpoints in different receptors or receptors groups may need to be developed.

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

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

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 Tier I HI or HQ approach, the RTV 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 RTV. Caution should be taken in the assessment and selection of the RTV. For example, if the RTV were based on "acute" lethality, it would not be protective of chronic exposure conditions.[13]

4.4.4 Development of Reference Toxicity Values

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

[13] As Tier I assessment endpoints are typically phrased in terms of protecting populations, the RTVs 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.

Federal AWQC are frequently used as the equivalent of an RTV for aquatic organisms. On some sites, AWQC may be judged to be overly cautious RTVs for the specific key receptors, if the organisms on which the AWQC are based are far more sensitive than any onsite 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 RTV.

In terrestrial ecosystems, two types of RTVs are needed: concentration-based RTVs for soil-dependent organisms and dose-based RTVs for wildlife. RTVs for soil-dependent organisms (e.g., plants, earthworms) are similar to AWQC in that they are concentration based. RTVs for wildlife are similar to the critical toxicity values (reference doses) used in human health risk assessments. Unlike human health toxicity values, however, RTVs for terrestrial wildlife are generally not available and thus need to be developed by the risk assessor. In order to appropriately select and use RTVs and to identify assumptions and uncertainties associated with RTVs, an understanding of the general practice currently followed in selecting RTVs is needed. Site-specific RTVs for aquatic and terrestrial ERAs should be developed in consultation with local wildlife and regulatory agencies.

4.4.4.1 Development of Aquatic RTVs

As stated above, aquatic RTVs 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 values include: ambient water chemistry, different patterns of toxicity for different metals, metals fate and transport, and 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" (EPA 1986b) and more recently in the EPA's *Water Quality Standards Handbook* (EPA 1993g) and *Interim Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria* (EPA 1992j, 1993c, 1995f). To determine the basis for a particular chemical, the AWQC document for that metal or compound should be consulted. As is the case with literature benchmark values, use of AWQC for RTVs may involve division of the criterion by uncertainty factors to account for greater sensitivity or uncertainty regarding the selected site receptor as compared to the AWQC species tested, life stage, test endpoint, and test duration. In the case of metals, the basis (total, total recoverable, or dissolved concentration) for the RTV or criterion and the chemical concentrations to which it is compared should be verified and consistent.

4.4.4.2 Development of Terrestrial RTVs for Soil-Dependent Organisms

EPA is currently evaluating the development of standardized protocol for deriving ecological effects-based soil criteria for contaminated sites. EPA plans to use an approach similar to that used for calculating sediment quality guidelines for the National Status and Trends Program (NSTP) (Long and Morgan 1990). This method uses a percentile of the effects data set or combined effects and no effects data set to estimate a concentration in the sediment expected to cause no adverse biological effects.

ORNL (1994) has published two documents containing benchmarks useful for screening potential COEC effects on terrestrial plants and litter invertebrates/heterotrophic processes (e.g., soil- and litter-dwelling invertebrates, including earthworms, other micro- and macroinvertebrates, or heterotrophic bacteria and fungi).

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).

4.4.4.3 Development of Terrestrial RTVs for Wildlife

Two general steps are performed in the derivation of RTVs for terrestrial wildlife: a hazard identification and **a** dose-response evaluation. A hazard identification is a qualitative assessment that determines whether exposure to a chemical can cause an increase in the occurrence of a particular adverse effect in the key receptors. A hazard identification includes a review of the physical and chemical properties of the chemical, examination of typical routes of exposure, and a review of the toxicologic effects of the chemical (acute, subchronic, and chronic).

When a chemical has been identified as potentially producing adverse health impacts on wildlife, a dose-response evaluation is performed that quantifies the relationship between the dose or exposure to a chemical and the

incidence of adverse effects. The available data are reviewed from a number of viewpoints, and the study or studies that best describe the potential toxicity of the chemical are selected as the basis for deriving a quantitative description of the chemical's toxicity. Uncertainty factors or extrapolation models are commonly applied to transform the dose-response relationship observed in an experimental study to one that can be used to describe potential wildlife exposures to environmental media.

Central to the determination of the RTV is the evaluation of the threshold or exposure level that must be exceeded for the adverse impact of the chemical to manifest itself. Below this threshold, factors such as the body's protective mechanisms (e.g., metabolism, elimination) can handle the chemical, preventing expression of adverse effects. The basis of the derivation of the RTV, then, is to identify this threshold level, and modify it to express potential toxicity to a wildlife population. In deriving the RTV, however, it is important to examine both LOAEL and NOAEL values in order to select the most reasonable endpoint and benchmark value that is protective of the more sensitive receptors without being overly conservative.[14]

Derivation of an RTV for ecological receptors is similar to derivation of a reference dose (RfD) for humans. An RTV may thus be similarly defined as "a provisional estimate of a daily exposure to the ecological receptor population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a portion of a lifetime, in the case of a subchronic RTV, or during a lifetime, in the case of a chronic RTV" (EPA 1992k).

To develop a chronic RTV, available toxicological studies are reviewed and a critical literature benchmark study (or studies) is selected as the basis for the RTV. Depending on the types of key receptors for the site, literature studies on a variety of organisms may need to be reviewed. The selection of a critical study or studies and their benchmark values is made by professional judgment, but includes consideration of study quality, relevance of the study to wildlife exposures, and other factors. Field studies, as well as laboratory studies are useful in the RTV determinations. Often field studies provide key ecological information showing that while the chemical elicits a toxic response in laboratory studies, it may not necessarily elicit similar results under field conditions. When laboratory studies are used, preference may be given to laboratory studies with wildlife species over traditional laboratory animals to reduce uncertainties in making interspecies extrapolations.

The highest level of exposure associated with the NOAEL or LOAEL is identified (i.e., the literature benchmark value).[15] A NOAEL or LOABL value is preferred over a lethal dose value for calculation of the RTV. In order to compare benchmark values, dietary concentrations (mg/kg) must be converted to dose values (mg/kg-bw), so that dose is not under- or overestimated when applied to organisms consuming different amounts of food per body weight. Average ingestion rate and body weight for a species (and life stage) are reported in relevant studies or may be obtained from various literature sources (EPA 1993e, Appendix B).

Where lacking, chronic NOAEL RTVs may be generated for a species of concern by applying "safety factors" (also called uncertainty or modifying factors) to available toxicity data on a specific COEC. Specific methodologies for deriving RTVs have been published by EPA (1995b), Newell, Johnson, and AlIen (1987). and USAERDEC (1994). Application of safety factors represents a specific area of uncertainty inherent in the extrapolation of experimental laboratory data to wildlife and should be evaluated for its eventual impact on risk estimation. To derive an oral RTV, the NOAEL or LOABL may be divided by various uncertainty factors as shown below:

$$RTV = \frac{\text{NOAEL or LOAEL}}{UFs_s \times UF_c \times UF_e \times UF_i}$$

[14] Selection of a conservative literature benchmark value when combined with conservative uncertainty factors can lead to the development of an RTV that is far below that of typical background concentrations (inorganics). Use of such RTVs, when combined with reasonable bioconcentration factors, to estimate intake for lower trophic level receptors sometimes indicates that the background concentrations pose extreme and unrealistic hazards. Caution, accompanied by an appropriate uncertainty discussion, should be used in developing RTVs.

[15] NOAELs and LOAELs ate artifacts of the specific dosing regime employed in the individual toxicity studies and can vary considerably from study to study. Despite the connotations associated with the acronyms, these values do not represent actual threshold levels for toxicity. Therefore, their use in selecting benchmark values or RTVs introduces an additional element of uncertainty.

The uncertainty and modifying factors used by EPA include the following:

- UF_s = an intertaxon uncertainty factor between 1.0 and 100 for extrapolating toxicity data across test species. Also called a species sensitivity factor (SSF), this adjustment may be necessary where toxicity information does not include representative wildlife species or the species identified as requiring greater protection. If data are from numerous species and represent the most sensitive mammalian and avian species, the SSF may be equal to 1.0. Caution should be taken in using uncertainty factors to extrapolate across widely disparate taxonomic groups; e.g., birds to mammals and vice versa.

- UF_c = an uncertainty factor between 1.0 and 10 for subchronic to chronic exposures. This factor may be used when assessing highly bioaccumulative chemicals, where toxicokinetic considerations suggest that a bioassay of limited length may underestimate hazard.

- UF_e = an uncertainty factor between 1.0 and 10 for LOAEL to NOAEL extrapolations.

- UF_i = an uncertainty factor of 10 for intraspecies toxicological differences to protect, in special cases, sensitive individuals rather than a population. Also called an intraspecies uncertainty factor (ISF).

Values other than 1.0 (or maximum values) would rarely if ever be used for all uncertainty factors simultaneously (EPA 1995b), as this tends to result in an unreasonably conservative benchmark value. Also, where an intermediate uncertainty factor is to be applied, a value of 3.0, based on a logarithmic scale, can be applied rather than a 5.0, based on a linear scale (EPA 1995b). An additional modifying factor between 0 and 10 may also be applied, if it is judged to be necessary, to account for miscellaneous factors not specifically addressed by the above four uncertainty factors. An example of the process for developing an RTV for a small mammalian receptor is shown in CS 12.

Guidance as to the determination of the magnitude of the numerical value to be assigned to each uncertainty factor is lacking for ERAs. For further guidance on selection of an appropriate uncertainty factor, the risk assessor should consult the regional EPA or DoD (U.S. Army, U.S. Navy) BTAG/ETAG experts. Typically, separate RTVs are developed for large mammals (herbivores/carnivores), small mammals (rodents), and birds.

4.4.4.4 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 RTV.

4.4.4.5 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 RTVs. 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 RTVs should be clearly stated in the assessment.

4.4.4.6 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.

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

CASE STUDY 12

DERIVATION OF A SMALL MAMMAL RTV FOR ACETONE

The following describes the process for deriving a site-specific reference toxicity value (RTV), in this case for small mammal receptors that ingest site soil.

Selection of Literature Values

The toxicological data for acetone are assembled from available literature sources and screened to select the lowest LOAEL and highest NOAEL literature values (mg/kg-bw/day) for chronic (long-term) effects, if available.

The literature values collected are shown below:

TOXICITY DATA FOR ACETONE

Test Species	Form	Duration	Effect level/Effect	Dietary (mg/kg-food)	Dose (mg/kg-bw/day)	Reference
MAMMALS						
Rat	–	13 weeks	NOAEL/ respiratory, cardiovascular, gastrointestinal, musculoskeletal, hepatic, dermal, body weight effects	–	3,400	NTP 1991, Dictz et al. 1991
Rat	–	14 days	LOAEL/bone marrow hypoplasia	–	6,942	NTP 1991, Dietz et al. 1991
Rat	–	14 days	NOAEL/hepatic, renal, body weight effects	–	8,560	NTP 1991, Dietz et al. 1991
Rat	–	13 weeks	LOAEL/reproductive effects	–	3,400	NTP 1991, Dietz et al. 1991
Mouse	–	14 days	NOAEL/renal, body weight effects	–	12,725	NTP 1991, Dietz et al. 1991
Mouse	–	14 days	LOAEL/hepatic effects	–	3,896	NTP 1991, Dietz et al. 1991

LOAEL - Lowest observable adverse effects level
NOAEL - No observable adverse effects level

Reference Toxicity Value

Each selected literature value is then divided by a conservative total uncertainty factor to calculate a long-term RTV that is used to screen measured surface soil and dietary concentrations in order to determine whether acetone may need to be evaluated further. The total uncertainty factor is the product of one or more separate uncertainty factors for each of two sources of uncertainty: (1) study duration and (2) study endpoint. Within the study endpoint category, two toxicity test endpoint categories are listed: nonlethal effects (e.g., a change in fecundity) and lethal effects (i.e., some level of reported mortality). A frank effect level is the concentration of a chemical that causes an obvious deleterious effect; the lethal frank effect level is the LD_{50} concentration (a concentration or dose that is lethal to 50% of animals in the study). The uncertainty values assigned to each category are described below:

UNCERTAINTY FACTOR PROTOCOL FOR LONG-TERM REFERENCE TOXICITY VALUES

Basis for Uncertainty		Uncertainty Value Assigned
Study Duration Category		
Chronic studies where contaminants attained equilibrium		1
Chronic studies where equilibrium not attained or possibly not attained, including subchronic studies		5
Acute studies (7 to 14 day, 2 to 7 day, 1-day single dose)		10, 15, 20
Study Endpoint Category**	**Nonlethal**	**Lethal**
No observed effects level	NOEL: 1	NOEL: 3
No observed adverse effects level	NOAEL: 1	NOAEL: 3
Lowest observed effects level	LOEL: 3	LOEL: 10
Lowest observed adverse effects level	LOAEL: 5	LOAEL: 10
Frank effects level	FEL: 10	FEL: 15

** To estimate an appropriate NOAEL

REFERENCE TOXICITY VALUES

A summary of the information used to derive the RTV for acetone is presented next. The two uncertainty factors most applicable to the toxicological study were selected, combined, and then divided into the selected literature value. The resulting RTV dose (mg/kg-bw/day) is used in the conservative risk screening for comparison to the site-specific surface soil dose (mg/kg-bw/day) to determine if acetone may need further evaluation.

LONG-TERM REFERENCE TOXICITY VALUES

Chemical (COC)	Species	Literature Value: Dose (mg/kg-bw/day)	Literature Value: Effect Level	Study Duration Uncertainty	Study Endpoint Uncertainty	Total Uncertainty Factor	Reference Toxicity Value (RTV) (mg/kg-bw/day)
Acetone	Rat	3400	NOAEL	5	1	5	680

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 RTV 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 (% solid/100).[16]

where % solids = 100 - % moisture

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, RTECS (NIOSH 1987 or 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 EPA (1988k, 1993e) can be used to calculate feeding and drinking rates (Exhibit 15). Reference food and water intake values for a variety of wildlife are also provided in ORNL (1994).

4.4.5 Additional Considerations in Developing RTVs

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

4.4.5.1 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 RTV 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.

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 RTV 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).

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 COEC 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).[17]

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

[17] 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 permit 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's adequate information to the contrary.

4.4.5.2 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." 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.

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 (EPA 1993e). 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 EPA (1993e). A procedure for calculating inhalation exposure is also published by USDOI (1991).

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 EPA's (1990e) *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.

4.4.5.3 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.

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 EPA's (19921) *Dermal Exposure Assessment: Principles and Applications* and may be followed to some extent where dermal exposure concentrations for wildlife need to be calculated.

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.

4.4.5.4 Body Scaling Factors

In the ORNL (1994) document, body scaling factors are applied to derive screening toxicity benchmark values for various sized organisms, based on a select reference

toxicity value. Application of a 2/3 or 3/4 exponential factor for wildlife is based on the human health practice of applying an exponential factor of 2/3 in adjusting animal data to an equivalent human dose. Wildlife toxicologists, however, commonly scale dose to body weight when deriving benchmark values without incorporating this exponential factor.

4.4.6 Special Chemicals

Some commonly detected chemicals require special consideration in the generation of an RTV (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:

- Metals.
- Polycyclic Aromatic Hydrocarbons (PAHs).
- Organochlorine Pesticides (OCPs) and Polychlorinated Biphenyls (PCBs).
- Chlorinated Dibenzo-p-dioxins and Dibenzofurans (CDDs/CDFs).
- Total Petroleum Hydrocarbons (TXH) and other petroleum groupings.
- Military chemicals.

4.4.6.1 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.

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 or indirectly (Gough, Shacklette, and Case 1979).

Aquatic Organisms and Metals

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 onsite metals to bioavailable forms with migration offsite.

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

- Relationships among the various physical forms reported in water quality results.
- 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.
- Observed ratios between dissolved metals and total recoverable metals in order to facilitate interpretation of AWQC and the more bioavailable dissolved metals.

Plants and Metals

Plants are intermediate reservoirs through which trace metals from primary sources move to other living things. 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).

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.

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, Haynes, and Martinez 1992).

Terrestrial Fauna and Metals

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 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 (EPA 1995b).[19] Bioaccumulation of inorganic metals may be inappropriately overestimated if concentrations are at or below normal background levels due to, for example, nutritional requirements of the test organisms (EPA 1995b).

4.4.6.2 Polycyclic Aromatic Hydrocarbons (PAHsl

PAHs, also known as polynuclear aromatic hydrocarbons, or 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 semivolatile 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.

In general, PAHs are rapidly metabolized and considered unlikely to biomagnify despite their high lipid solubility (Eisler 1987). Inter- and in&a-species responses to individual PAHs are quite variable, however, and are significantly modified by many inorganic and organic compounds (Eisler 1987). Until these interactive effects are clarified, extrapolation of laboratory test results to field situations where there is suspected PAH contamination should proceed cautiously. The intermediate metabolites, however, have been identified as mutagenic, carcinogenic, and teratogenic agents (Sims and Overcash 1983). In most cases, the process of carcinogenesis occurs over a period of many months in experimental animals, although for some PAHs, malignancies may be induced by acute exposures to microgram quantities.

[19] Cam 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.

Amphibians are reported as quite resistant to PAH carcinogenesis when compared to mammals due to the amphibian's inability to produce mutagenic metabolities of BaP and perylene (Anderson, Doos, and Rose 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.

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 1987). Eisler (1987) 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, Collins, and Gillet (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.

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 is dependent on numerous factors including concentration, solubility, molecular weight of the PAH, and on the plant species (Edwards 1983).

4.4.6.3 Organochlorine Pesticides (OCPs) and Polychlorinated Biphenyls (PCBsl

OCPs and PCBs are extremely stable compounds and slow to degrade under environmental conditions. The toxicoiogical 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, Chaney, and Ryan 1990, Sawhney 1988, Strek et al. 1981).

PCBs and pesticides are strongly sorbed in soils, sediments, and particulates in the environment, with levels usually highest in aquatic sediments containing microparticulates (Eisler 1986, EPA 1980, Duinker, Hillebrand, and Boon 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).

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 1986, 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.

4.4.6.4 Chlorinated Dibenzo-p-dioxins and Dibenzofurans (CDDs/CDFs)

CDDs/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.

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-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) is considered the most potent CDD, and is the reference against which all other CDDs and CDFs are compared.

Analysis of CDDs and CDFs is most commonly reported by congener group (i.e., as either tri-, tetra-, penta-, hexa-, hepta, or octachlorodibenzop-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.

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. A recent 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 EPA (1993h).

Two basic methods are recommended for evaluating the toxicity of mixtures of PCBs, PCDFs, and PCDDS in environmental samples to determine sample "toxic equivalents" relative to TCDD (EPA 1993h). In the first method (commonly used in screening ERAs), individual PCB (Section 4.4.6.3), 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 CDDs/CDFs, the toxicity of the TCDD compounds is 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 dioxins/furans may be calculated by applying congener-specific TEFs to the concentrations of the dioxins or furans 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 EPA (1995b) and Safe (1990) are frequently used in screening ERAs (see Exhibit 17). Recent publications (Newsted et al. 1995) presenting TEFs for fish should be considered for preferential use in aquatic risk assessments.

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 (EPA 1993h). 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 (EPA 1993h). Further discussion of TEFs for 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* (EPA 1993h). EPA's (1994g) dioxin wildlife workshop report, and in the GLWQI (EPA 1995b).

4.4.6.5 Total Petroleum Hydrocarbons (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.

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 COECs in ERAS. Aromatic constituents such as benzene and xylene and the carcinogenic PAH compounds are the primary COECs 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.

The impacts of TPH on terrestrial ecosystems are not as well documented as the impacts on aquatic ecosystems.*' 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 pro vi&s valuable descriptors of the potential toxicity of the components comprising the TPH detection. The BTEX and PAH compounds are currently used in characterizing potential risks and cleanup requirements for TPH because these chemical groups include the most toxic known TPH constituents and represent a broad range of physical and chemical properties influencing environmental mobility.

4.4.6.6 Military Chemicals

Many DoD sites contain potentially toxic chemicals not commonly found on nonmilitary 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, EPA is often unable to supply toxicity information. Profiles containing toxicological information relevant to an ERA can be obtained from USACHPPM and USAEC.[21] Technical reports that summarize environmental fate and behavior (plant uptake, mammalian and aquatic toxicology) of munitions material are also available in the open literature (Burrows et al. 1989, Cataldo, Harvey, and Fellows 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 EPA or U.S. Army BTAG/ETAG **persons.** Appendix F presents several ecotoxicological profiles on military chemicals.

[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.

[21] Contacts for toxicity information on military chemicals: USAEC (Mr. Robert Muhly @ 410-612-6839 and Ms. Mary Ellen Maly @ 410-671-1523); USACHPPM (Dr. Glen Leach @ 410-671-3980).

4.4.6.7 Toxicologic Uncertaintles

Use of EPA-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:

- What are the cumulative uncertainties and modifying factors applied to derive the RTV?
- 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?
- 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 RTVs are based.
- 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?
- Has any route-to-route extrapolation been performed? Was it reasonable to do so, and were assumptions used in the extrapolation appropriate?
- 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 reasonnable?
- Were BCFs or BAFs applied in the development of the RTV? BAFs and BCFs developed for one study may be quite different than bioaccumulation factors at other areas.

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 NOEL 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.

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 Tier II or higher effort), a parallel series of toxicity tests are run using site water and laboratory test water as dilution water and then calculating a WER (site water LC_{50}/lab water LC_{50}).

4.5 Risk Characterization

Risk characterization includes two major steps: risk estimation and risk description (EPA 1992a). The risk estimation consists of comparing the exposure and toxicity profiles, as well as estimating and summarizing the associated uncertainties and assumptions to characterize current and potential adverse biological effects posed by the COECs. The potential impacts from all exposure routes (direct contact, ingestion, and inhalation) and all media (water, sediment, soil, and air) are included in this evaluation as appropriate according to EPA guidance (EPA 1989c). The risk description consists of a summary of the results of the risk estimation and uncertainty analysis and an assessment of confidence in the risk estimates through a discussion of the weight of evidence. 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 would be conducted in subsequent tiers.

4.51 Risk Estimation

In Tier I, risk estimation can be either qualitative or quantitative, depending on the data available, DQOs, and the stated level of effort. Typically, the Tier I risk estimation is performed through a series of quantitative quotient calculations that compare exposure values with RTVs. The RTVs, as derived from literature benchmark values, serve in this case as surrogate measurement endpoints. Simple ratios of exposure values to RTVs are known as HQs which are summed (where appropriate) for all chemicals and exposure pathways for a given receptor to pro vide the HI. The HI method is described below. 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 are used in the higher tiers include comparing probabilistic distributions of effects, and exposure and simulation modeling.

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 am not well documented for most species. RTVs that are usable and applicable for the evaluation of ecological effects in ecosystems are generally limited. 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 according to EPA guidance (1989c, 1989a), except in the case of threatened and endangered species, where individuals require protection in order to preserve the population. 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.

4.51.1 Objectives

Most ERAs and nearly all Tier I ERAs provide a comparison of single effect values (RTVs) with predicted or measured exposure concentrations for one or more key receptors. In risk estimation, the chemical intakes

calculated in the exposure characterization are combined with the appropriate critical toxicity values identified in the effects characterization. The results are the estimated ecological hazards posed by the exposures. This ratio or quotient of the exposure value to the effects value (i.e., RTV) provides the risk calculation. Along with the numerical calculations (quotients) of potential ecological risks (hazards), a narrative describing the primary contributors to ecological risks and factors qualifying the results is presented.

4.5.1.2 Ecological Evaluation Techniques

A variety of ecological evaluation tools, techniques, or approaches may be used to evaluate and estimate the magnitude and importance of the 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. Many of these evaluation techniques are more appropriately conducted as part of a Tier II, III, or IV effort (see Sections 5.0 through 7.0). 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 and follow HTRW *Technical Project Planning Guidance* (USACE 1995b).

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 (HEP) (USFWS 1987) and Index of Biological Integrity (IBI) (Karr et al. 1986) can be used to quantify injury 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 OUs 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.

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. Also, some of these tools are restricted as far as their applicability (e.g., Wetland Evaluation Technique [WET] and the sediment-water equilibrium partitioning approach 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.

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

- HQs and HIs.
- Sediment-Water Equilibrium Partitioning (EP) or Water Quality Approach (Long and Morgan 1990).
- Evaluation of Dredged Material Proposed for Ocean Dumping (EPA 1991g).
- Screening Level Concentration Approach (Long and Morgan 1990).
- Apparent Effects Threshold (AET) or Species Approach (Long and Morgan 1990).
- Bioeffect/Contaminant Co-Occurrence Analyses (COA) Approach (Long and Morgan 1990).
- Sediment Quality Triad Approach (Chapman 1989).
- Rapid Bioassessment Protocols for Use in Streams and Rivers (EPA 1989j).
- Sediment Quality Criteria Approach (Chapman 1989).
- Bioassay Approach (Toxicity Tests) (EPA 1989c).
- Diversity Indices (Pielou 1975).

- Species Richness/Relative Abundance Indices.
- WET (USACE 1987).
- IBI (Karr et al. 1986).
- HEP (USFWS 1987).
- Exposure Pathway Analysis (Fordham and Reagan 1991).
- Probabilistic/Sensitivity/Uncertainty Analysis (Macintosh. Suter, and Hoffman 1994).
- Linear Structural Modeling (Johnson, Huggins, and DeNoyelles 1991).
- Linked Deterministic and Simulation Models.

4.5.1.3 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.

4.5.13.1 Hazard Quotient (HQ) Method. The HQ method as applied to ecological risk 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 reference toxicity value, RTV). The comparison (quotient) of estimated intake and acceptable exposure level is called an HQ and is derived in the following manner:

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

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

The HQ is used as a basis for deciding whether or not there is a negligible potential for ecological impacts. An HQ of 1 indicates that the estimated intake is the same as the RTV; an HQ of greater than 1 indicates the estimated intake is greater (i.e., the threshold has been exceeded): less than 1, it is less (i.e., the threshold has not been exceeded). The interpretation of the results of an HQ is outlined by Barnthouse et al. (1986) and others. In general, an HQ greater than 1 is interpreted as a level at which adverse ecological effects may occur. An HQ less than 1 does not indicate a lack of risk, but should be interpreted based on the severity of the reported effect and the magnitude of the HQ.

The HQ should not be viewed as a statistical value or risk: for example, an HQ of 0.01 does not indicate a l-in-100 probability of the adverse effect occurring. Rather, it indicates that the intake is 100 times less than the RTV for the chemical. In addition, the Intake/RTV ratio does not infer a linear relationship, i.e., the hazards posed by exposure to the chemical do not increase linearly as the HQ increases linearly. This is so for several reasons, including the fact that RTVs are not precise descriptors of hazard (developed by using multiple uncertainty factors), and the severity of potential ecological effects varies with different chemicals (dose-response relationships differ).

To examine the potential for the occurrence of adverse ecological effects as a result of exposure to multiple chemicals through multiple exposure pathways, it is assumed that an adverse effect could occur if the sum of the HQs exceeds 1. In other words, even if exposure to each individual chemical is below its RTV (HQ ratio less than 1). if the sum of the ratios for multiple chemicals exceed unity, 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:

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

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

Deriving an overall I-II using an additive approach assumes the following:

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

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

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 may be segregated according to toxicological endpoint. These segregated HIs may then be examined independently.

Segregation of HIs according to toxicological endpoints 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 RTV 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) (EPA 1989f).

4.5.1.3.2 Probabilistic Methodologies. Probabilistic methodologies, which use distributions of effects levels and exposure estimates (as opposed to single exposure point estimates), may be used in the development of risk estimates. Risk is quantified by the degree of overlap between the two distributions -- the more the overlap, the greater the risk. To apply probabilistic methods such as these and to construct valid distributions, it is important that sufficient data amenable to statistical treatment are available[22] Collection of **such data, if not** available, may be more appropriately performed as a Tier II or higher effort. where actual field data are available.

Probabilistic methods can also be used for developing more appropriate exposure concentrations, where factors such as area use need to be considered. 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).

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 exposures associated with the 90th or 99.9th percentile may be viewed as "high end" exposure.

[22] Although relatively simple to execute, probabilistic methodologies should be applied judiciously in ERAs (Burmaster and Anderson 1994). Using a probabilistic distribution for intake values and RTVs is only as appropriate as the quality of the input data. For example, using probabilistic distributions to account for a wide range of literature benchmark values that have not been reviewed for quality or applicability to site-specific conditions and receptors would not be appropriate.

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. An example of a Monte Carlo simulation is presented in Appendix E.

4.5.1.4 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.

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

$$HQ = \frac{\text{measured concentration(mg/l)}}{\text{aquaticRTV(mg/l)}}$$

where the measured concentration may be the overall RME concentration, maximum concentration, or other appropriate measurement of exposure concentration and the aquatic RTV is the AWQC, sediment criteria (units would be mg/kg), or a species-specific RTV. As in the description of HQs for terrestrial receptors, an HQ greater than 1 is generally interpreted as a level at which adverse ecological effects may occur. An HQ less than 1 does not indicate lack of risk, but should be interpreted based on the severity of the potential reported effect and the magnitude of the calculated quotient.

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).

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 RTVs.

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.

4.5.2 Characterization of Uncertainty

In a Tier I ERA, 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 values) 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.

452.1 Objectives

EPA has identified two requirements for full characterization of risk. First, the characterization must address qualitative and quantitative features of the assessment through a weight-of-evidence discussion. This was discussed in the preceding section. Second, it must identify any important uncertainties in the assessment. This section discusses methods of identifying and describing uncertainties in a risk assessment.

Full disclosure and clear articulation of risk uncertainties are guiding principles for this portion of the risk assessment (EPA 1992g, 1995a,d).

> "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 1992g).

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

- Information from different sources carries different kinds of uncertainty, and knowledge of these differences is important when uncertainties are combined for characterizing risk.
- Decisions must be made on expending resources to acquire additional information to reduce uncertainties.
- A clear and explicit statement of the implications and limitations of a risk assessment requires a clear and explicit statement of related uncertainties.
- Uncertainty analysis gives the decision-maker a better understanding of the implications and limitations of the assessments.

The output from the uncertainty analysis is an evaluation of the impact of the uncertainties on the overall assessment and, when feasible, a description of the ways in which uncertainty could be reduced (EPA 1992a).

4.5.2.2 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 in the screening or Tier I ERA, 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.

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.

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

- 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.
- Locations Sam&d. 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 toward greater assumed exposures.
- 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 "II" 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.
- 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 cornpositing); 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 by an adequate SAP; however, planning does not prevent the occurrence of sampling errors.

- 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).

- 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).

Evaluation of the data to select COECs for the ERA may result in uncertainties. Application of selection criteria may inadvertently result in the inappropriate exclusion or inclusion of chemicals as COECs. 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:

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

- 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 included as COECs.

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

- Toxicity/Concentration Screening. Removal of chemicals as COECs 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

It is possible that the wildlife selected as key receptors in an ERA am 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 data 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 judgment used in the selection of key receptors.

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.

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:

- 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 COECs. 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 offsite, and exposure pathways will add uncertainty to the assessment.

- 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.

- 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.

- 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).

RTVs 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 RTVs will usually result in overestimates of potential risk. Factors that contribute to uncertainty include:

- Use of UFs in the RTV. RTVs are primarily derived from laboratory animal toxicity studies performed at high doses to which UFs of 10 or more are applied.

- **Choice of Literature Benchmark Study to Derive an RTV. The inclusion or exclusion of studies in the derivation of an RTV is usually made by professional judgment; this affects the numerical RTV value.**

- The Assumption of the Most Sensitive Species. When deriving RTVs, the animal study showing an adverse effect at the lowest exposure or intake level is often the basis for deriving the RTV. 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 RTV and the key receptor(s) under consideration.

- 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 RTV 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.

Standardized algorithms to calculate chemical intakes and associated risks ate 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.

4.5.2.3 Evaluation of Uncertainty

Various approaches can be applied to describe the uncertainties of the assessment, tanging 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 indepth 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.

4.5.2.3.1 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.

4.5.2.3.2 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, which were described previously, are more complex forms of uncertainty analyses that simultaneously examine the combined uncertainty contributed by a number of parameters. An example of this approach, *Analysis of Extrapolation Error,* is presented in Barnthouse et al. (1986).

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

- Define the numerical range over which each parameter varies.

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

- 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.

4.5.3 Risk Description

Risk description has two primary elements. The first is the ecological risk summary, which summarizes the results of the risk estimation and uncertainty analysis and assesses confidence in the risk estimate through a discussion of the weight of evidence (EPA 1992a). The second element is interpretation of ecological significance, which describes the magnitude of the identified risks to the assessment endpoint and the accompanying uncertainty (EPA 1992a). A third element, discussion of the effect of additional data or analyses on uncertainty, should also be included.

4.5.3.1 Ecological Risk Summary

The ecological risk summary presents the results and uncertainties of the quantitative risk analysis. Weight-of-evidence discussions should be provided in the risk summary. The identification of data gaps and the need to conduct or not conduct additional analyses through another iteration (tier level) of the risk assessment process should be identified at this step.

4.5.3.1.1 Summary of Risk Estimation and Uncertainty. Every ERA should present the actual intake and risk calculations performed for the site in an appendix to the report. These calculations should show the chemical concentrations, the intake/exposure values, and the RTVs (including derivation) for each chemical assessed. A summary table should also be presented in the body of the risk assessment that provides a synopsis of the results of the quantitative assessment. This summary table should include the following factors:

- Receptor name
- All exposure pathways assessed for the receptor
- Risk and/or HI for each pathway
  - Expressed to one significant figure only
  - Short-term, subchronic, and chronic, as appropriate
  - Average and high end exposure
- Predominant chemical, i.e., the chemical contributing the greatest amount to the risk or hazard estimate
- Overall HI

A discussion should accompany the presentation of the quantitative risk estimates that interprets and qualifies the results, and highlights the important factors inherent in the values. Conclusions of the risk estimation should be described as some type of quantitative statement (e.g., there is a 20 percent chance of 50 percent mortality) (EPA 1992a). The uncertainties identified during the risk assessment are summarized either quantitatively or qualitatively, and the relative contribution of the various uncertainties to the risk estimates should be discussed wherever possible.

The summary of ecological risk should relate back to the originally selected assessment endpoints. The scale of the assessment endpoint is an important consideration in the overall interpretation of risk. Some degree of mortality, for example, can occur in a population without resultant significant adverse effects on the population.[23]

45.3.1.2 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. After identifying sensitive receptors and habitats, complete exposure pathways, exposure points, and COEC 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 HIs, may be used in the weight-of-evidence characterization of potential and actual ecological risk.

If actual or potential adverse impacts are found, those impacts am 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.

4.5.3.2 Interpretation of Ecological Significance

The interpretation of risk provides a critical link between the estimation of risks and the communication of assessment results. Ranges or levels that are considered acceptable by EPA are presented and discussed in the following sections.

4.5.3.2.1 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

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[23] Although highly controversial, a 20% population reduction level is proposed by some as an acceptable threshold (Hull and Suter 1993). Selection of an appropriate and acceptable population reduction level ultimately depends on the site-specific population parameters and assessment endpoint for the receptor(s) of concern.

predicted (EPA 1992a). 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.

The spatial and temporal distributions of the effect provide another perspective important to interpreting ecological significance (EPA 1992a). 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 (EPA 1992a).

4.5.3.2.2 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.

One means to organize and systematically consider the ecological significance of multiple receptors and multiple exposure pathways at large, complex sites is through the use of simplified ranking matrices (Figures 4-1 and 4-2) for important ecological receptors, based on the likelihood that they may be impacted by a specified pathway or numerous exposure pathways and COECs or COEC groups. For example, in the matrix shown in Figure 4-1, individual species (e.g., eagle or hawk) or groups of organisms with similar feeding strategies and habitat preferences (e.g., seed-eating birds, fish) arc listed in the left column. Across the top of the matrix are the chemical groups (e.g., heavy metals, pesticides and PCBs, munitions), exposure media (surface soils and surface water), and ingestion routes (primary or secondary). Differences in exposure between primary and secondary ingestion are principally due to differences in relative tendencies of the listed chemical groups to bioaccumulate and biomagnify through the food web. Each potentially completed exposure pathway is indicated by either an open (possible exposure) or a filled-in circle (potentially significant exposures).

This initial qualitative screening is done on a site-wide basis in order to refine the list of receptors that would be evaluated at smaller, separate locations (e.g., SWMUs or OUs). Completion of the matrix presented in Figure 4-2 provides identification of those key receptors likely to be at greatest risk, as well as those pathways which likely pose the greatest risk to various receptors at the facility. By identifying receptor(s) potentially at greatest risk and exposure pathways which potentially pose the greatest risk, the risk assessment process becomes more focused and manageable for interpretation. This same matrix (Figure 4-2) can also be used to rank COECs for each identified key receptor/exposure pathway combination.

Matrix ranking processes may be subjective, as in this example, or quantitative (depending on data availability) based on site characterization, ecotoxicological information, and EPA guidance. The ranking process may incorporate weighting 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. Matrices can be updated or revised during the risk assessment process should additional data regarding the COECs, 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.

4.5.3.2.3 Discussion of Additional Data or Analyses. The third element, the risk description, serves as a conclusion and is an evaluation of the level of uncertainty and the potential for reducing the uncertainty by conducting additional analyses of the existing data, or collecting additional data and analyzing these data. The types of data needed to reduce the uncertainty (i.e., the data gaps) are examined, and an assessment of which tier to enter is made. Detailed descriptions of Tiers II, III, and IV are provided in Sections 5.0 through 7.0.

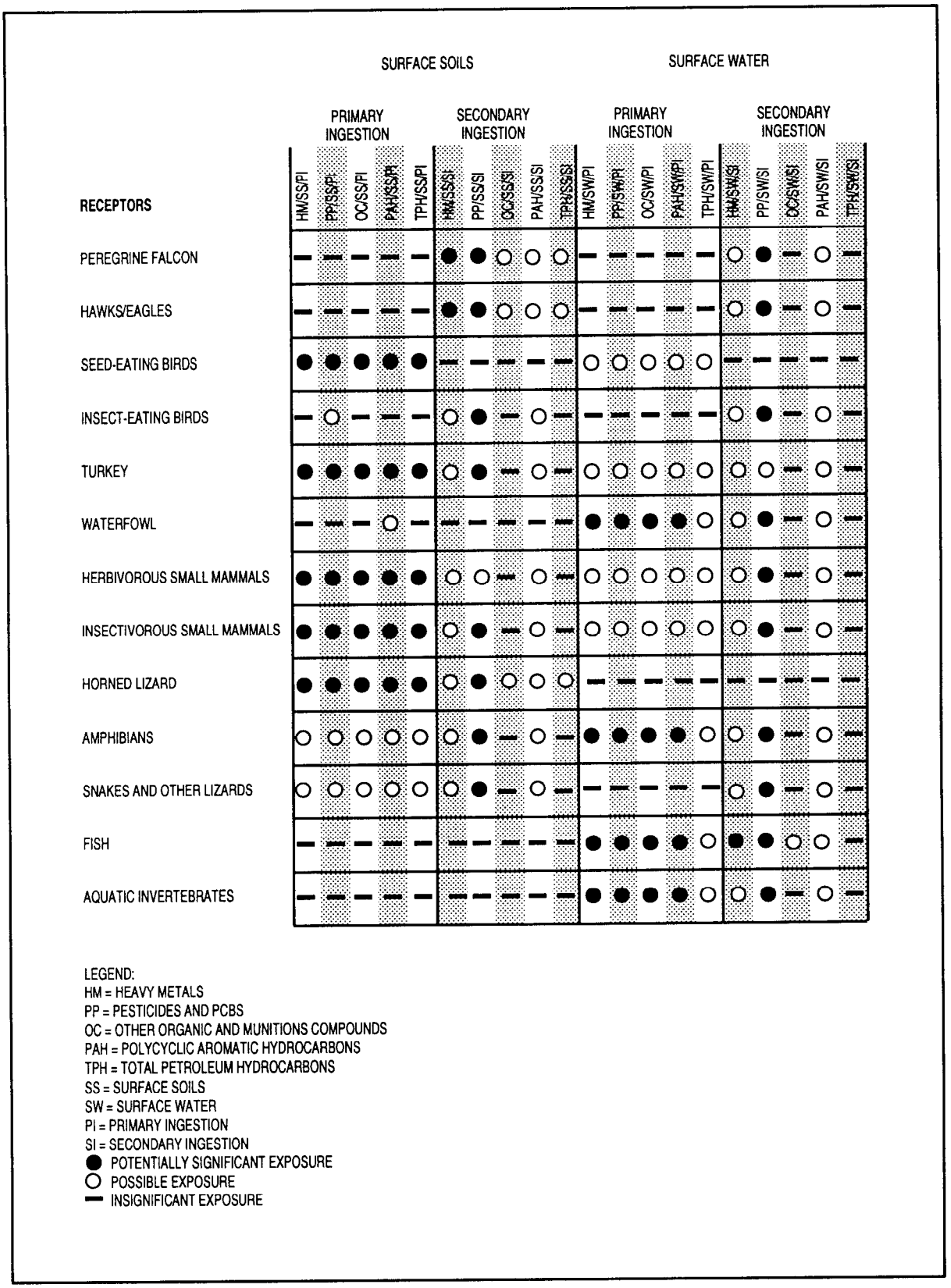


Figure 4-1. Site-wide exposure matrix

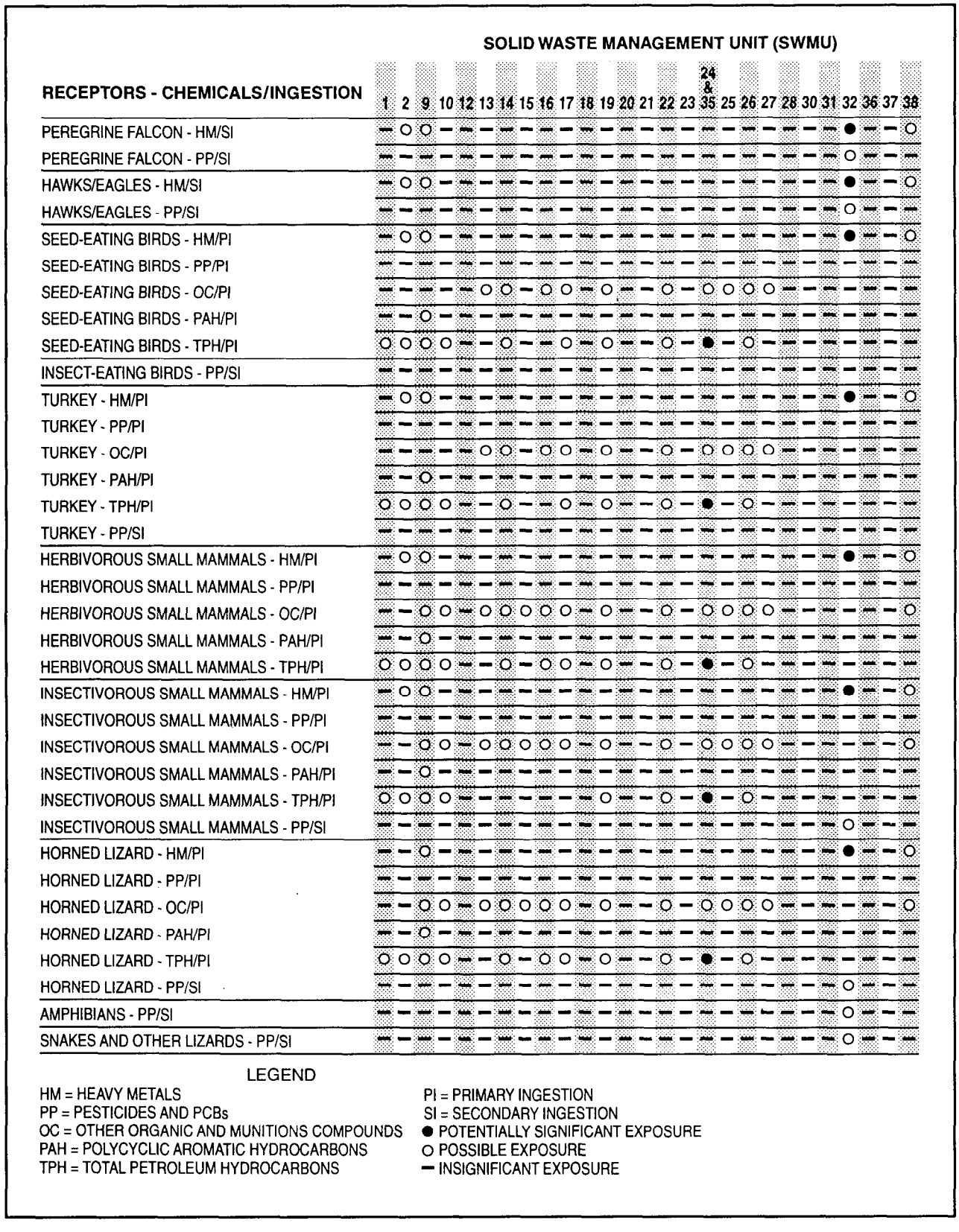


Figure 4-2. SWMU specific exposure matrix

Chapter 5
Evaluating the Tier II Baseline Ecological Risk Assesment

5.1 Introduction

Proceeding to Tier II is recommended where there is a need to reduce uncertainty from previous investigative phases and to verify the Tier I findings. Proceeding to a Tier II, Tier III, or Tier IV ERA may also be necessary when field studies or bioassays are desired, when Tier I risk is not well-characterized, or when significant questions remain and remediation decisions cannot be adequately addressed (as part of the FS or RD). In Tier II, a shift is made to evaluating population and community level effects. as well as mixtures of chemicals and chronic effects using a biological effects-based approach. The overall objective in Tier II is to produce more accurate, quantitative predictions regarding current and future risks to ecological populations, communities, and ecosystems due to migration of chemicals from the contaminated site.

Tier II 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. Tier II may include inexpensive, 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, semiquantitative sampling of the contaminated and reference sites 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.

The biological sampling methods employed in Tier II are simple, short-term, and inexpensive relative to Tiers III and IV. Tier II data, when integrated with data (primarily chemical) collected from the previous phases, should generally be adequate to provide information on the significance of potential or observed ecological effects, the need for remediation/removal actions, and the develop ment of preliminary cleanup goals based on ecological concerns and remedial action objectives.

For specific models and methods that may be employed in a Tier II or higher effort, recent publications from USAERDEC (1994), WERF (1994), and NOAA (1992) can be consulted. Additional resources for ERA sampling and modeling methodologies are provided in Appendix B, Information Sources.

The decision as to which tier to enter depends upon the nature of the site (large versus small site: simple versus complex ecosystems), type(s) of data required (single versus multiple measurement endpoints): and the methods to be employed (desk-top, field, or laboratory). Tie and cost limitations also determine level of effort and tier. Problem reformulation and the identification of data needs should follow guidance provided in the USACE (1995b) *Technical Project Planning* document. If the identified data needs are for short-term, focused, biological sampling and analysis methods, then Tier II activities are appro priate. It is possible, however, that a Tier III or, under unusual circumstances, a Tier IV program may be the more appropriate level of additional activities following Tier I.

In some situations, Tier II procedures such as bioassays may be initiated prior to completion of the Tier I ERA. For example, 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;* EPA 1991g) to determine whether a particular abiotic medium (sediment, soil, surface water) is toxic to biota or contains chemicals at concentrations of ecological concern. Exhibit 18 and Figure 5-1 describe such a case and present an example of how the tiered ERA approach may be followed in the assessment of sediment quality and characterization of risk in an aquatic ecosystem. 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. A comparison of various methods for assessing sediment quality is shown in Table 5-1.

In addition to methods described in Risk Characterization (Section 4.5). the following tier 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 in each tier should be carefully evaluated. When selecting ecotoxicological methodologies, the biological response under consideration and the proposed methodology should satisfy USACE (1995b) Technical Project Planning guidance, as well as consider the following more specific criteria:

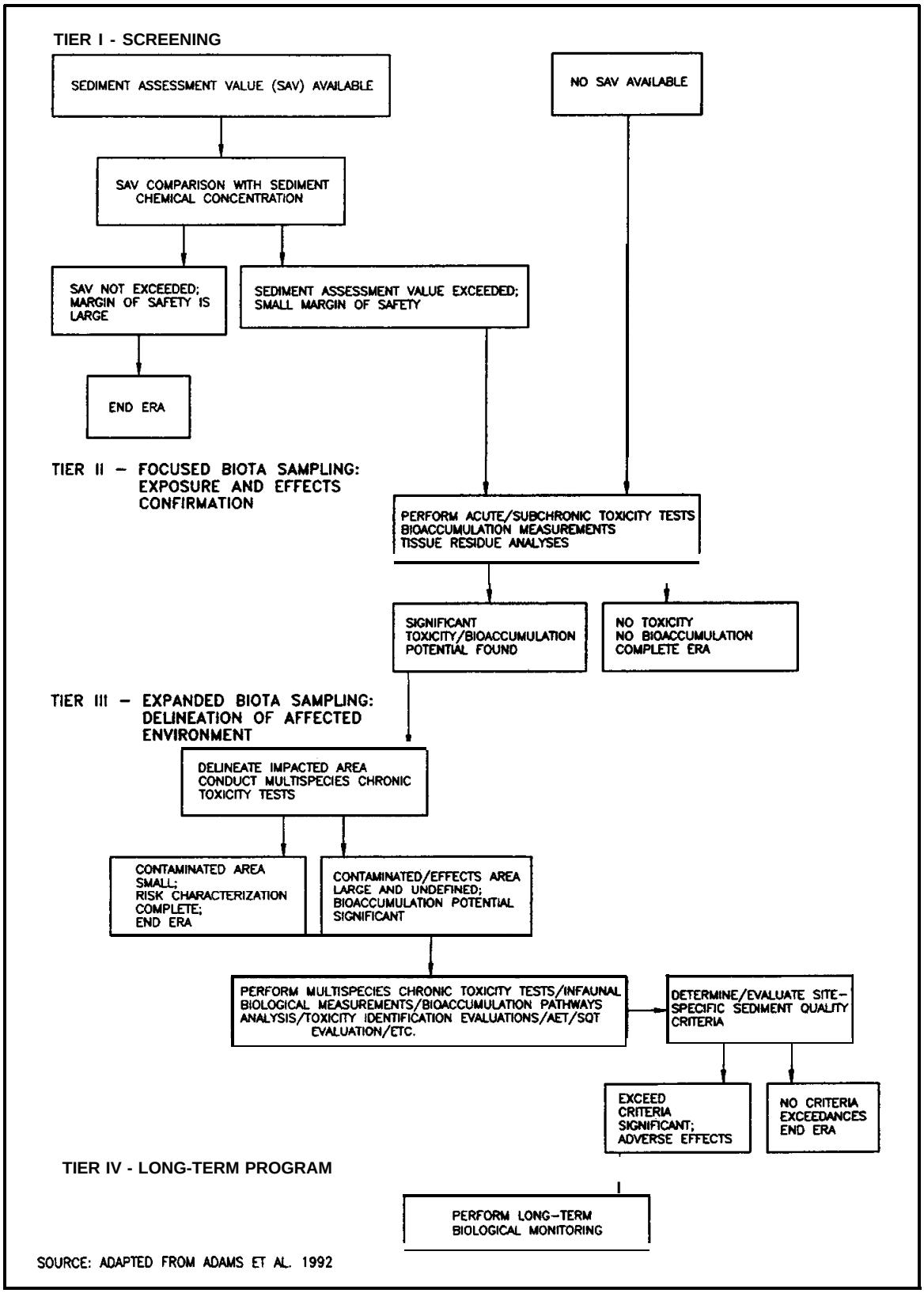


Figure 5-1. Interrelationship of tiers: Sediment quality assessment

Table 5-1
Comparison of Methods for Assessing Sediment Quality (See Exhibit 18)

Sediment Method	Chemical Specific	Site Specific	Integrates Multiple Chemicals	Field Validated	Relative Cost	Method Uncertainty[1]
Equilibrium Partitioning	Yes	No	No	Partially	Low	Moderate
Apparent Effect Threshold	Yes	Yes	Yes	Yes	High	Low/Moderate
Sediment Quality Triad	Yes	Yes	Yes	Yes	High	Low/Moderate
Bulk Sediment Toxicity	No	Yes	Yes	Yes	Low	Low
lnterstitial Water Approach	Yes	Yes	Yes	Partially	Moderate	Moderate
Spiked Sediment Approach	Yes	Yes	No	Partially	Moderate	Moderate
Tissue Residue Approach	Yes	Yes	No	No	High[2]	Unknown
Freshwater Benthic Approach	No	Yes	Yes	Yes	High	Low
Marine Benthic Approach	No	Yes	Yes	Yes	High	Low
Ionic Chemicals	Yes	No	No	No	Low	Unknown
Metals	Yes	No	No	Partially	Low	Moderate/High

[1] The degree of uncertainty for each method is subjective and reflects the authors' opinion and experience. as well as previously reported evaluations
[2] The cost of this approach would be high if both sediments and tissue were analyzed.

Some: Adams, Kimberle. and Barnett 1992.

- The biological response is a well defined, easily identifiable, and documented response to the designated COECs (i.e., methodology and measurement endpoint are appropriate to the exposure pathway).
- Exposure to the COEC is known to cause the biological response in laboratory experiments or experiments with free-ranging organisms.
- Methodology is capable of demonstrating a measurable biological response distinguishable from other environmental factors such as weather or physical site disturbance.
- The biological response can be measured using a published standardized laboratory or field testing methodology.
- 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).

The process for deciding which methods to use in each tier should follow Phase II project planning on DQOs, as well as general guidance provided in the following tier planning descriptions. Standardized protocol and detailed descriptions of some of the numerous ecotoxicological investigative methods available are provided in various agency (EPA, ASTM, FDA, USAERDEC, NOAA, WERF) publications (see Appendix B, Information Sources). Tables 5-2 and 5-3 provide an overview of the types of methods that are available and the types of information provided by such methods.

5.2 Problem Formulation

A listing and assessment of the ecological issues and data needs that remain following the Tier I ERA should be conducted The assessment and measurement endpoints used in the Tier I BRA should be reviewed to see if they

Table 5-2
Ecological Risk Assessment Approaches, Techniques, and Endpoints Used to Characterize Potential Risk

Characterization of Potential Risk

Approaches	Techniques	Endpoints*	Information Provided	Information Not Provided
Comparison of Measured and/or Projected Contaminant Concentrations to Ecological Benchmark Levels	Measured Concentrations Projected Concentrations (Quotient Method)	Mortality Reproduction Growth Community Structure AWQC NOELs/LOELs	Yes/No information as to whether impacts are likely: Impacts resulting from direct exposures as well as indirect exposure via food chains Ecologically based cleanup criteria for single contaminants	Quantitative measures of severity of impacts if benchmarks are exceeded Impacts to communities or ecosystems (unless benchmarks specifically account for these)
Estimate of Exposure Potential (No Benchmark)	Measured Concentrations Projected Concentrations Qualitative Evaluation	Mortality Reproduction Growth Community Structure	Types of ecosystems and receptors potentially exposed to contaminants Identification of potential exposure pathways	Likelihood or severity of impacts Areal extent and reversibility of impacts Uncertainty of the characterization.
Estimate of Hazard Potential (Media Toxicity Tests)	Laboratory Toxicity Tests In-Situ Toxicity Tests	Mortality Reproduction Growth Tissue Residue Level	Quantification of likelihood and severity of impacts to populations of test organisms Identification of hazards to site-specific populations Areal extent of impacts (if media tested at sufficient number of locations) Ecologically based cleanup criteria for mixtures of contaminants	Impacts to communities or the ecosystem: Interpretation of test results can be difficult (e.g., basis for the toxic response)
Quantitative Risk Modeling	Fault-Tree Analysis Probabilistic Pathway Analysis Multiple Attribute Ranking (Linear Models)	Reproduction Failure	Specific probabilistic prediction of the likelihood of specific impacts to individual organisms, populations, communities, or the ecosystem Severity and areal extent of impacts Quantification of ecological risks for risk management decisions	Major disadvantage can be cost to implement

Source: EPA 1989k. Ecological Risk Assessment Methods: A Review and Evaluation of Past Practices in the Superfund and RCRA Programs. EPA/600/8-89/043.

* Definition of endpoint in this table is different from the *Framework* (EPA 1992a) definition of endpoint currently in use.

are appropriate and applicable to anticipated remediation decisions. The additional biological/toxicological data requirements should be identified to help identify the appropriate tier and scope of additional investigations. Existing applicable data regarding potentially affected biological communities, environmental fate of COECs, bioconcentration and bioavailability of the COECs, toxicity data, and COEC concentrations in abiotic exposure media should be reviewed and data needs identified. Conclusions of the Tier I ERA that require a reduction in the associated uncertainty levels should be identified.

Once the additional data types that are needed are identified and the appropriate tier confirmed, problem formulation should commence. An initial step in problem formulation may be the development of working hypotheses. Hypothesis development is essential when statistical

Table 5-3
Ecological Risk Assessment Approaches, Techniques, and Endpoints Used to Characterize Actual Risk

Characterization of Actual Risk

Approaches	Techniques	Endpoints*	Information Provided	Information Not Provided
Evaluation of Biotic Community Structure	Quantitative Sampling	Diversity Indices	Identify large, major, and readily apparent impacts	Subtle impacts Impacts to populations Severity of impacts
	Qualitative Surveys Aerial Photography	Description of Community	Areal extent of impacts Identify small subtle impacts Potential exposure pathways and contaminant effects	Minor impacts Likelihood, severity or ecological significance of minor impacts
Evaluation of Individual Morphology or Physiology	Field Sampling Histopathology Necropsy Records of Mortality	Tissue Residue Levels Disease/ Abnormalities Reproduction	Direct evidence of injury to individuals Areal extent of major impacts to individuals	Impacts to populations, communities, or the ecosystem
	Detailed Field Studies	Tissue Residue Levels Disease/ Abnormalities Reproduction	Quantification of small, subtle impacts to individuals or populations	Impacts to communities or the ecosystem
Qualitative Surveys Aerial Photography				

Source: EPA 1989k. Ecological Risk Assessment Methods: A Review and Evaluation of Past Practices in the Superfund and RCRA Programs. EPA/600/8-89/043.

*Definition of endpoint in this table is different from the *Framework* (EPA 1992a) definition of endpoint currently in use.

comparisons are anticipated (e.g., comparisons of onsite with offsite biotic populations).

Next, appropriate sampling and analysis methods should be identified and detailed Tier II work plans developed. The biological sampling methods employed should be simple, short-term, and inexpensive relative to Tiers III and IV. Because most of the sampling conducted within Tier II 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 bids, more appropriate seasons for surveys are spring and fall. Also, locations of biological sampling should be chosen in view of the previous sampling of exposure point media and any anticipated Tier II abiotic sampling and chemical analysis.

Tier II may include descriptive sampling and measurement of ecological attributes such as tissue residue levels or biological diversity in the contaminated area compared with a nearby reference area. Ecological attributes that can be adversely affected by contaminants are numerous (see Table 54). Selection of which attributes to measure should be well documented and based on USACE (1995b) Technical Project Planning guidance. 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 contaminated and reference communities does not necessarily indicate that contaminants are exerting biological effects.

Table 5-4
Ecological Atributes

Distribution
Sex-specific
Breeding-related
Age-specific
Food-supply related
Migration-staging related
Molting-related
Seasonal migration
Vertical migration

Population Characteristics
Population size
Uniqueness of population
Proportion of population likely to be affected
Location of recolonization populations
Population dispersion efficiency and mechanisms

Life History Characteristics
Fecundity
Number of offspring
Number of reproductions
Generation time
Mortality rate and pattern
Biochemistry and enzyme systems
Behavioral characteristics
  Dormancy
    Hibernation
    Estivation
  Physical movement
    Dispersal
    Migration
    Refuging
    Dispersion
  Selective behavior (e.g., feeding, habitat selection)

Habitat-Related Characteristics
Habitat specificity
Habitat availability
Extent of habitat
Potential for habitat destruction
  Direct vegetation destruction
  Factors affecting soil nutrients
  Factors affecting nutrient quality of vegetation
  Factors that interrupt energy flow or otherwise alter resource relationships

Community and Ecosystem Characteristics
Intra-specific competition stress
Inter-specific competition stress
Trophic relations
Species diversity and numbers/evenness
Food web diversity
Community structure
Primary/secondary production rates
Guild structure biomass
Nutrient transfer/cycling

Adaptation and Resistance
Induced detoxication mechanisms
Altered rates of uptake and/or excretion
Sequestering
Behavioral adaptation

Sensitivity Characteristics
Temperature tolerance
Depth tolerance
Salinity tolerance

Source: Conover et al. 1985, Stakhiv 1988.

When quantitative risk estimates are available and HI results indicate a significant potential for risk, conclusions from biological field studies and bioassays can be used as confirmatory weight-ofevidence to support risk conclusions and interpretation. Some additional abiotic sampling and analysis may also be needed so that the biotic data collected can he related to the chemical and physical habitat currently affecting the biota. The fate and transport of chemicals may be modeled in Tier II if needed to supplement the chemical analysis of physical media.

If there are indications that a NBDA action is being contemplated by the resource trustees for the site, it may be expedient to employ field collection efforts that satisfy both EEA Tier II data requirements and NRDA data collection requirements. For example, if baseline biotic data are to be collected from reference areas, they can be collected using methods that follow NRDA requirements for baseline determinations (43 CFR, Subtitle A, Part 11).

Following are brief descriptions of the focused field and laboratory studies appropriate within Tier II:

5.2.1 Field Studies

. Quantitative (semiquantitative) 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 1992) (Table 54). For example, data on vegetation community composition, structure, and diversity can be collected using semiquantitative methods such as

releve analysis and Braun-Blanquet rating methods (Mueller-Dombois and Ellenberg 1974).

- 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).

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

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

- One-time confutation 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 COECs. This is in keeping with the NCP directive to "assess threats to sensitive habitats and critical habitats of species protected under the ESA" [NCP 300.43(e0(2)(i)(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.

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

5.2.2 Laboratory Studies

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

- Chemical analysis of collected tissue samples for COECs that are known or suspected of bioaccumulating or biomagnifying.

- Acute bioassays using onsite exposure media to determine LC_{50}s or LD_{50}s.

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

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

5.3 Data Collection and Analysis

Data collection from both field and laboratory studies and data analysis should be conducted in accordance with the Tier II work plan and USACE (1995b) Technical Project Planning guidance. The work plan should provide guidance from the USACE (1995b) Technical Project Planning document. At a minimum, the work plan should provide data collection objectives appropriate for Tier II, details of the proposed field studies methods, laboratory analytical methods with quantitation limits described, data quality review methodology, and plans for data presentation and integration with existing data, including data collected in Tier I.

5.4 Revision of the Tier I Era

Following the collection and compilation of biological/toxicological data from field samples and laboratory analyses, the Tier I ERA should be revised to incorporate the information and results provided by the Tier II effort. This additional information can be used to provide further quantification of ecological risk assessment and to improve risk interpretation through additional weight-of-evidence. Overall, the additional information provided through Tier II investigations should reduce the level of uncertainty associated with the baseline ERA.

Chapter 6
Evaluating the Tier III Baseline Ecological Risk Assessment

6.1 Introduction

The Tier III ERA includes longer term field or laboratory studies (1 year or more), and employs 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, elements of a Tier III ERA may be the most appropriate type of additional investigation following Tier I. The biological sampling conducted in Tier III 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 in this tier.[1] Additional chemical analyses of abiotic exposure media also may be appropriate in order to ensure areal and temporal correlation with biological data, Additional 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 at this tier. Biological modeling may include single species modeling to evaluate exposure-response for a species co-located with multiple contaminants, to multiple-species pathway analysis to simulate bioconcentration/bioaccumulation within the community food web.

Results of the additional field and laboratory investigations fill the data gaps identified following completion of the previous tier (Tier II or I) and supplement the results from all studies conducted previously. The combined results are used to present revised risk estimates with less uncertainty than the preceding tiers, and provide a rationale for long-term monitoring (Tier IV) if needed,

[1] 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.

Tier III population studies may be required in the event that there is an apparent decline in a key receptor's population sire that is deemed important in the presence of a low HI, or no apparent effect on population sire in the presence of a high HI. Population studies are typically more long-term and complex, although simple, short-term population studies may be performed in Tier II. 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 (USAF 1990). 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.

Tier III 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 (Appendix E) 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 in Tier III. Tier III investigations, if needed, are most likely conducted following a Tier II determination of the need for additional biotic data to support modeling efforts. It is possible, however, depending on site conditions, that a Tier III sampling and analysis effort may be the appropriate level of additional investigation following Tier I.

6.2 Problem Formulation

Following completion of the Tier I or Tier II ERA, adequacy of the results to support the FS/RD-RA should be examined again. If it is determined that expanded biological or toxicological investigations are needed to support remediation decisions, then guidance from the USACE (1995b) *Technical Project Planning* document should be followed. Similar to the problem definition stage of Tier II, previously collected Tier I and Tier II data should be reviewed and any data gaps identified.

Once data needs are identified, Tier III problem formulation should commence. The biological sampling methods employed are likely to be more extensive than those used in Tier II, but they should be complementary to those used in Tier II in order to have analogous data. Biological sampling locations should be the same as those in

Tier II unless they did not yield defensible biological data. If additional toxicological testing or tissue sampling is planned, organisms and methods used should complement those used in Tier II. Because of the elapsed time between tiers in the ERA, additional chemical samples may be needed to correlate with the additional biological and toxicological studies conducted in Tier III.

Following are brief descriptions of the field, modeling, and laboratory studies appropriate within Tier III:

6.2.1 Field Studies

- Quantitative biota (population/community) sampling extending over multiple seasons within one year to document seasonal variability of potentially exposed biota.
- Quantitative biota sampling in reference areas employing the same methodology used at the exposure points to provide sufficient data for statistical comparisons with the data collected at exposure points.
- Additional tissue sampling of the key receptor species or their diets or prey.
- Collection of exposure point media (e.g., surface water, sediment) for use in additional acute or chronic (long-term) laboratory bioassays.
- In situ acute or chronic bioassays to determine LC_{50}, LOAEL, or NOAEL contaminant concentrations.
- Additional surveys of Federal- or state-protected species suspected of being exposed to COECs.
- Additional sampling of abiotic exposure point media (e.g., soils, sediment, surface water) to supplement existing chemical data and correlate with the Tier III biological samples.
- Additional collection of abiotic media from reference areas for chemical analyses.

6.2.2 Modeling Studies

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

6.2.3 Laboratory Studies

- Laboratory analysis of biological community samples (e.g., periphyton, benthic invertebrates, plants), as needed for taxonomy.
- Chemical analysis of collected tissue samples for COECs that are known or suspected of bioaccumulating or biomagnifying.
- Acute or chronic bioassays using onsite exposure media in order to determine LC_{50}s LOAELS, or NOAELs.
- Acute or chronic bioassays using doses of COECs suspected of presenting a risk in order to determine LD_{50}s, LQAEL, or NOAEL doses.
- Chemical analysis of exposure point abiotic media for the COECs, specific species of COECs, or selected COECs at detection levels lower than RTVs for the selected ecological receptors.
- Chemical analysis of physical media collected from reference areas.

6.3 Data Collection and Analysis

Data collection from both field and laboratory studios and data analysis should be conducted in accordance with the Tier III work plan and the USACE (1995b) *Technical Project Planning* document. As discussed for Tier II, the work plan should provide, at a minimum, data collection objectives appropriate for Tier III, details of the field studies methods, laboratory analytical methods with quantitation limits described, data quality review methodology, and plans for data presentation and integration with existing data, including data collected in Tiers I and II.

6.4 Revision of the Tier II Era

Following the collection and compilation of biological/ toxicological data from the Tier III field samples and laboratory analyses, the Tier II ERA should be revised to

incorporate the information collected. In contrast to data from Tier II, this additional information is most appropriately used to better quantify the risk assessment. Overall, the additional information provided through Tier III investigations should further reduce the level of uncertainty associated with the ERA.

Chapter 7
Evaluating the Tier IV Baseline Ecological Risk Assessment

7.1 Introduction

Tier IV is reserved for the largest and most complex sites requiring multiple-year sampling or modeling programs and is only appropriate where data and an ERA with the highest degree of certainty are required for the FS/RD-RA. Complex sites are those with complex chemical interactions among numerous COECs and exposure matrices, widespread contamination or numerous contamination sources, and sites requiring the examination of potential risk reduction over time (e.g., Rocky Mountain Arsenal [EPA 1993f]). This tier includes biological studies of longer duration and greater expense (e.g., multiyear population and community level studies) or complex exposure modeling.

Tier IV investigations are expected to be warranted at very few sites. The Tier IV effort may require additional abiotic sampling and/or tissue residue sampling to establish correlation of cause-effect and or verification of a model.[1] 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 in this tier. Methods for linking laboratoryderived toxicity data to fish population models may be applied (Barnthouse, Suter, and Rosen 1990). Other models which address ecosystem functions (energy and nutrient cycling) may be developed.

7.2 Problem Formulation

Following completion of the Tier III ERA, adequacy of the results to support the FS/RD-RA should be examined again. Although unlikely, if it is determined that expanded biological investigations or complex modeling are needed to support multiple remedition decisions, then problem formulation for Tier IV should proceed. Similar to the problem formulation stages of Tiers II and III, previously collected data should be reviewed for adequacy and any data gaps identified.

Once the data needs are identified, Tier IV problem formulation should proceed. Biological community sampling methods employed in Tier IV may be more extensive than those used in Tier II and Tier III, but they are more apt to be the same as those used in Tier III. The sampling methods chosen for use in Tier IV would be used over a period of several years: however, timing of the sampling (e.g., monthly, seasonally) should be the same as in Tier III. Locations of biological sampling should be the same as those in Tier III. Because of the elapsed time between Tiers III and IV, additional chemical samples may be needed to support any biological studies and modeling conducted in Tier IV.

Following arc brief descriptions of the biological studies and modeling appropriate within Tier IV:

7.2.1 Field Studies

- Quantitative biota (population/community) sampling extending over multiple seasons and years to document long-term variability or trends of potentially exposed biota.
- Quantitative biota sampling in reference areas during selected seasons to provide sufficient data for statistical comparisons to the data collected at exposure points.
- Additional surveys of Federal- or state-protected species suspected of being exposed to COECs.
- If needed, collection of exposure point media for additional chemical analysis to support the biological sampling and modeling results.
- If needed, collection of abiotic media samples from reference areas.

7.2.2 Ecosystem Modeling Studies

- Complex, mathematical ecosystem models addressing such attributes as energy flow, material cycling, and food web assembly (Hull and Suter 1993).

[1] All these models are likely to require high costs and biological monitoring/field validation efforts involving multiyear and multiseasonal studies. These population and community models are often data intensive.

7.2.3 Laboratory Analysis

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

- If needed chemical analysis of exposure point media for the COECs or specific species of COECs.

- If needed, chemical analysis of reference area physical media for the COECs.

7.3 Data Collection and Analysis

Data from field and laboratory studies and modeling should be generated in accordance with the Tier IV work plan and USACE (1995b) Technical Project Planning document. As discussed above, the work plan should provide, at a minimum, a description of objectives appropriate for Tier IV details of the field and laboratory methods, including analytical quantitation Emits; full descriptions of the models to be used, including applicability of the model, assumptions, input data requirements, database compatibility, input/output formats, and output description; data quality review methodology; and field and modeling data presentation and integration with previously collected data.

7.4 Revision of the Tier III ERA

Following the collection and compilation of biological and modeling data from the Tier IV analyses, the Tier III ERA should be revised to incorporate the additional information collected. Overall, the additional information provided through Tier IV investigations should further reduce the level of uncertainty associated with the ERA. It is recommended that if multiyear biological sampling is included in Tier IV, the resulting data should be compiled, reviewed, and the ERA revised on an annual basis. By conducting annual data reviews and ERA updates, it may be determined that the Tier IV data collected to date are sufficient to provide risk-based answers to the remediation alternative questions, and further sampling is not necessary.

Chapter 8
Evaluating the Ecological Risk Assessment of Remedial Alternatives

8.1 Introduction

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 Tier I baseline ERA 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. Scoping of a higher tiered ERA 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 or trophic levels. Again, early project planning with involvement of expert ecological risk assessors, BTAG/ETAG persons, regulatory agencies, and stakeholders will be the key to avoid overscoping and to identifying the type of ERA most appropriate for specific site conditions.

The baseline ERA methodology presented in Chapters 4 through 7 has focused thus far upon the assessment methodology as appropriate for CERCLA RIs and RCRA RFIs. This methodology serves as the framework for all ERAs. As mentioned earlier, an ERA may also be performed for other aspects of site activities. One aspect discussed in this chapter is the performance of risk assessments to support activities undertaken during the FS or CMS. 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 chapter 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. Each type of BRA is discussed individually in the following sections.

8.2 Development of Remediation Levels

Remediation (remedial) levels, which are not synonymous with preliminary remediation goals or 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 levels.

Remedial levels differ from PRGs in that site-specific factors am considered. PRGs are developed as a screening level tool prior to the performance of an RI or RFI. Conversely, remedial levels are developed from the site-specific baseline risk assessment that was developed during the RI or RFI. 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 baseline risk assessment in order to assist the risk manager in the remediation decision-making process.

Remedial levels 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, TELs, and AETs (see Exhibits 7 and 18). Remedial levels may also be derived by performing the baseline risk assessment in reverse by rearranging the terms in the terrestrial or aquatic HQ equations:

HQ = dose (terrestrial) / RTV

where

$$\text{DOSE} = \frac{\text{chemical concentration (C) x ingestion rate (IR)}}{\text{body weight (BW)}}$$

for aquatic receptors

HQ = concentration in water or sediment (aquatic)/RTV.

The HQ (or HI) is set equal to an acceptable level (e.g., HQ = 1), the exposure route-specific intake factors developed during the baseline risk assessment are applied, and the chemical concentrations associated with the ingestion factors and HQs (or HI) am calculated. In the baseline risk assessment, hazards for terrestrial receptors are calculated by the following expression (equations are similar for aquatic receptors):

$$\text{Hazard quotient} = C \times (IF_1 + IF_2 + \ldots IF_n) \times 1/RTV$$

where

Hazard quotient = the hazard quotient associated with exposure of key receptors to the individual chemical

IF = the pathway-specific ingestion factors, each of which incorporates the intake rate, exposure frequency, exposure duration, body weight, and averaging time for the applicable exposure pathway (i.e., all of the risk equation except chemical concentration and reference toxicity value).

For example

$$IF_1 = \frac{\text{ingestion rate for water}}{\text{key receptor body weight}}$$

$$IF_2 = \frac{\text{ingestion rate for food (fish)} \times \text{BCF}}{\text{key receptor body weight}}$$

RTV = the reference toxicity value

C = the chemical concentration or remedial level associated with the HQ

To develop remedial levels, this equation is rearranged

$$C = \frac{\text{hazard quotient}}{[\ IF_1 + IF_2 + \ldots IF_n) \times 1/RTV]}$$

As this equation illustrates, remedial levels are chemical-specific. If more than one chemical is to be remediated at the site, the application of remedial levels developed by this approach can possibly result in residual risks exceeding the target hazard level.

Remedial levels should be based upon all key receptors and all significant exposure pathways assessed in the baseline risk assessment for that medium. However, since the pathways resulting in the highest degree of risk will most greatly influence the remedial level, exposure pathways that have minimal contribution to overall risks can be excluded from the remedial level development with little or no impact.

Exhibits 19 and 20 illustrate the development of remedial levels for a terrestrial receptor and for aquatic-based wildlife receptors, respectively.

8.3 Comparative Risk Assessment of Remedial Alternatives

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. RCRA has similar criteria.

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). In these instances, an assessment of the long-term residual risks associated with both alternatives can be developed as a tool to assist in selecting an alternative. By comparing the degree to which an alternative reduces potential risks with respect to other factors such as cost, acceptability, and effectiveness, one alternative may be identified preferable. For example, Alternative A may reduce risks to an HI of well below 1, but cost $5 million to implement; Alternative B may reduce risks to an HI 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.

In addition to cost, the reduction of risk offered by the alternative should be examined with respect to the risks estimated in the baseline assessment. If the risk reduction offered is not significant, or does not address the primary risks identified in the baseline assessment, these factors should be considered in the remedy evaluation.

The reduction of risk offered by the alternative should also be examined with respect to the nature of the assessment endpoint or the size of the population affected by the baseline risks or remedial alternative's reduction of risk. 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.

The potential risks to be addressed in a comparative risk assessment are those remaining after the implementation and completion-of the remedial alternatives (those potentially incurred during the implementation are discussed in Chapter 9). The calculational methodology for performing the comparative risk assessment is the same as for a baseline risk assessment. The potential exposure pathways and receptors should also be the same as the baseline risk assessment unless exposure pathways have been 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.

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 (for some other valid reason) 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.

8.4 Other Applications of Ecological Risk Assessments

The same approach for development of remedial levels and comparative risk assessments can be applied to the support of RD/RA and the assessment of residual risk. Further discussion of the risks generated during remediation and the screening evaluation process for RD/RA alternatives is presented in Sections 9.2.3.4 through 9.2.3.6.

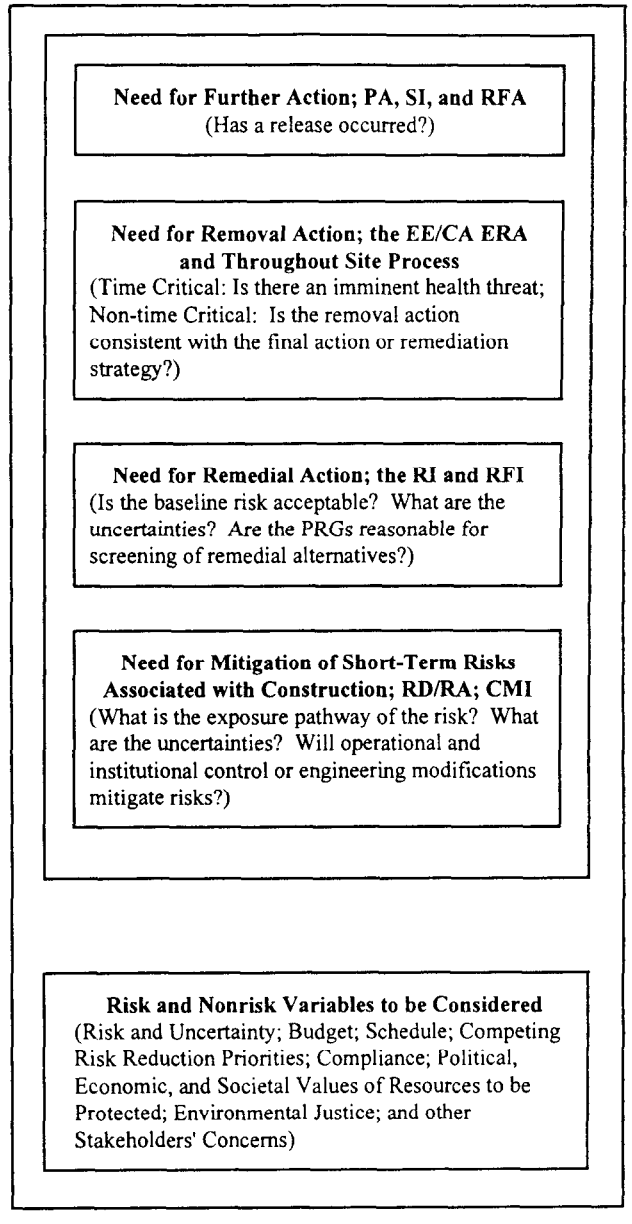
Chapter 9
Risk Management -- Information Needed for Decision-Making

9.1 Introduction

The National Academy of Sciences (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" (NRC 1983). NAS has identified four key components for managing risk and resources: public participation, risk assessment, risk management, and public policy decision-makers (NRC 1994). Risk characterization is considered the "bridge" or "interface" between risk assessment and risk management. EPA recommends that risk characterization should be clearly presented and separated from any risk management considerations. EPA (1995d) 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 nonscientific.

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 (Figures 9-1, 9-2). 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 nonrisk factors. DoD has developed a similar concept to help prioritize installations according to environmental risks (see Section 1.3.1.1).

Risk and uncertainty are important factors to be considered in RMDM (EPA 1991d, 1995d). 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



Fibure 9-1. Inputs for risk management decision-making HTRW project decision diagram

Figures 9-2. HTRW risk management decision-making process flow diagram

driven by statutes and regulations which explicitly require the "protection of human health and the environment"[1]

Therefore, selecting the proper risk tool and collecting data to assess environmental risk are primary responsibilities of the PM and the risk assessor.

The HTRW risk management decision-making process can be represented by the following equation, with many variables contributing to the final decision:

$$RM = f(X_1, X_2, X_3, X_4 \ldots X_N)$$

where

RM = risk management decision

f = function of

X_i = input variables (e.g., risk and uncertainty)

In addition to risk and uncertainty, there are many nonrisk variables influencing the risk management decision. The major ones are cost, schedule, value of resources to be protected, competing risk reduction priorities among sites managed by the customer, compliance/regulatory, political, economic. 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 clean up sites located in "poor and disadvantaged" areas.

The risk assessment, in conjunction with other important "nonrisk" 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 EPA officials: Habicht (EPA 1992g). Denit (EPA 1993i). Browner (EPA 1995a). DoD (1994a) and various proposed legislations by the 104th Congress (e.g., Dole-Johnston Bill (S-343) and HR 1022) suggest that the need for risk reduction be based on "real world" or realistic risk assessment, cost benefit analysis, and prioritization of environmental issues. The HTRW RMDM paradigm (Figure 9-3) presents an overview of this process.

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:

- PA/SI or RFA: A screening risk assessment, an environmental mapping, and an exposure pathways analysis may be performed to determine the need for further investigations.
- RI or RFI (prior to FS and CMS): The. baseline ERA determines the need for the remedial action.
- FS or CMS: Results of the ERA are used to develop preliminary remedial goals (i.e., chemical concentrations which pose acceptable hazard or ecological effects).
- FS or CMS: 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.
- RD (prior to conducting RA and CMI): 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

[1] 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; RCRA Sections 3004(u), 3004(v), 3008(h), 7003 and/or 3013 for requiring corrective actions at hazardous waste treatment, storage, and disposal facilities to protect human health/environment; and the risk-based determination for no-further action (40 CFR 264.514) and selection of remedy (40 CFR 264.525) under the proposed Subpart S RCRA corrective action rules.

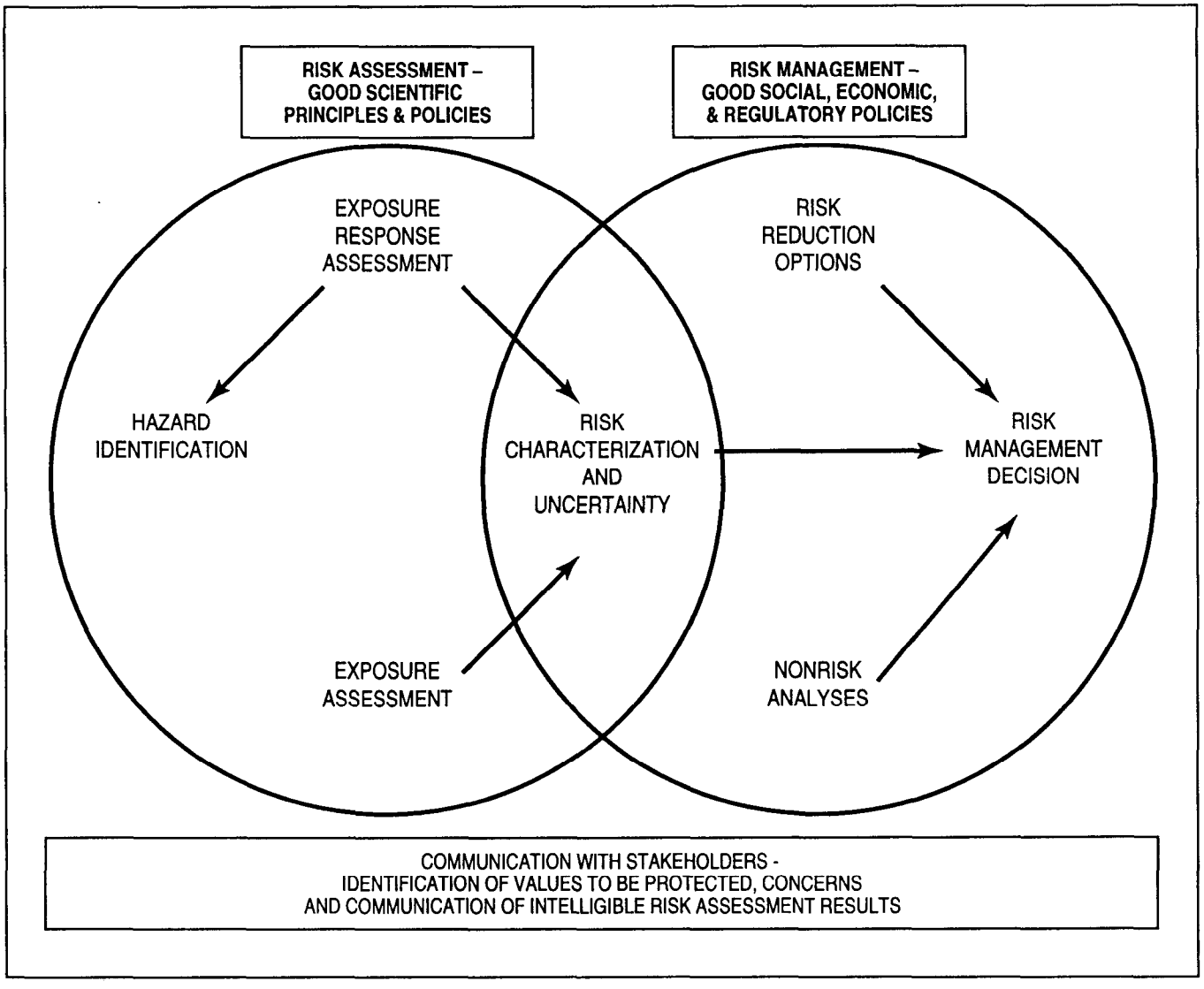


Figure 9-3. HTRW paradigm for risk management decision-making

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 nonchemical stressors, e.g., habitat alteration and destruction, siltation, or other physical or chemical changes in the environment caused by construction of the remediation.

This chapter 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 9-1). 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.[2]

It is important to recognize that risk managers often make difficult decisions with considerable uncertainties in both risk and nonrisk 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 nonrisk 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:

Section 9-2 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 nonrisk considerations and emphasizes the importance of integrating the ERA results and uncertainties into an overall risk management decision.

Section 9-3 discusses the design considerations for implementing an overall site remediation strategy. Such a strategy considers issues such as offsite source areas, current and future land uses, compliance with chemical and site-specific ARARs (EPA 19891). and verification of cleanup.

9.2 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 (55 FR 8660, March 8, 1990) and the proposed RCRA Corrective Action Rule (55 FR 30798, July 27, 1990) 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 9-1). Risk information required to support a decision is presented below:

9.2.1 PA/SI and RFA

The purpose of PA/SI under CERCLA and the RFA under RCRA is to identify if chemical releases have occurred, or if the site can be eliminated from further action. The PAs and RFAs are typically performed by the state, EPA, 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 or the TM to methodically review each identified site. area of contamination, SWMU, 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 requite. an early response action (e.g., non-time critical removal actions, interim measures, or interim remedial action).

9.2.1.1 Actual or Potential Release/Exposure

Under the PA/SI or RFA 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.

9.2.1.2 Potential Natural Resource Damage Assessment (NRDA) Action

Under CERCLA Sections 104(b)(2) and 107(f)(2)(C), the lead agency for cleanup (e.g., DoD, EPA) must notify appropriate Federal and state trustees of natural resources of any discharges or releases that may have injured natural resources under their jurisdiction. The PM is responsible for coordinating all response activities with the natural resource trustees. The PM should also consult with the USDOI (i.e., USFWS), DOE, or Department of

[2] This chapter does not address comparative analyses of other environmental risks, i.e., risks from radon gas, cigarette smoking, exposure to ultraviolet 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 PM should be familiar with the statutory language/limitations regarding the application of funds under DERA, BRAC, and other HTRW response actions.

Table 9-1
The Potential Use of Risk Assessment Concepts/Procedures as a Risk Management Tool

Project Phase	Objectives	Risk Management Options [1]	Product/Deliverable
PA/SI, RFA	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 or RFI	NO FURTHER ACTION (NFA); LIMITED SAMPLING/VER.; STAB, REMOVAL, RESP; LIMIT SCOPE OF RI/RFI; PHASED RI/RFI SAMPLING	Chemical fate and transport properties. Toxicity assessment (chemicals not expected to pose an ecological concern). Environmental mapping (sensitive receptors and food source identification). Exposure pathway analysis/food web and use of ECSM. Land use assessment.
RI, RFI	Does the site pose an ecological risk? Need for FS or CMS	NFA; MONITORING; INTERIM MEASURES/ INTERIM REMEDIAL ACTIONS; CONDUCT FS OR CMS	Baseline risk assessment. - Comparison with published criteria or benchmark toxicity values. - Toxicity-based ERA to assess stress-response relationship
FS, CMS	Preliminary Remediation Goals Select remedial alternatives	REMEDIAL ACTION OBJECTIVES; ONSITE/OFFSITE MANAGEMENT; NFA; MONITORING	Development of site-specific PRGs or benchmark toxtcity values. Assessment of short-term risks from remedial alternatives.
RD/RA, CMI	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 doseout	Residual risks & year review. permit review	NFA: MONITORING; RA OR CORRECTIVE MEASURES; 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)

NFA = no further action
PRO = preliminary remediation goals
RAO = remedial action objective
RI/RFI = remedial investigation/RCRA facility investigation
SWMU = solid waste management unit
VER = verification

Commerce (DOC) 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 or RFA is an early project phase and the potential for an NRDA action may not be known, the PM 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 close-out 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.

9.2.1.3 Risk Screening and Prioritization of Units of Concern

Initial risk screening (Chapter 3) is an important tool for ranking or prioritizing units (OUs/SWMUs). 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.[3]

[3] EPA's Deputy Administrator (1994) 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. EPA 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. EPA 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. EPA 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.

It is not uncommon to have tens or hundreds of "sites" or SWMUs 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 or SWMUs should be pared down if possible. The risk manager may negotiate with the agencies and enter in the IAG or FFA to permit the use of an approach that "addresses the worst sites first," and at the same time, group SWMUs within the same ecological receptor exposure units or geographical locations, as appropriate. This prioritization should result in the greatest environmental benefit with limited available resources. Site prioritization should include the following:

- Eliminate sites or SWMUs administratively by record review (including ascertaining if endangered or sensitive species/environment or valued resources are present on site), by interviews with current and former workers, and by ascertaining whether the unit of concern meets the definition of an "SWMU."

- Conduct a site reconnaissance and group sites or SWMUs with common exposure pathways or EUs, if appropriate.

- Rank the remaining sites or groups of sites qualitatively or quantitatively based on the ECSM or a screening risk analysis.

Generally, the above-listed tools will serve well if they are objectively and uniformly applied. The use of site prioritization:

- Provides justification for no further action (NFA) for low-priority sites.

- Allows better resource allocation for investigation of the remaining sites.

- Provides the opportunity to develop ECSMs to guide data collection (see Chapter 4).

- Helps identify potential boundaries where the ecological receptors of concern are to be protected.

- Identifies high-priority sites or SWMUs for non-time critical response actions.

DoD's (1994b) *Relative Risk Site Evaluation Primer* recommends evaluation based on three criteria: (1) contaminant hazard factor; (2) migration pathway factor; and (3) receptor factor (Figure 9-4). Information generated from the initial ecological risk screening (Chapter 3) can be used as a decision-malting basis using a similar site ranking process. Sites may be ranked high, medium, or low based on nonquantitative 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 released or transported) and limited potential for receptors to exist.

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.

3. Medium Relative Risk; Sites with characteristics not indicated in (B)(l) and (B)(2) 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.

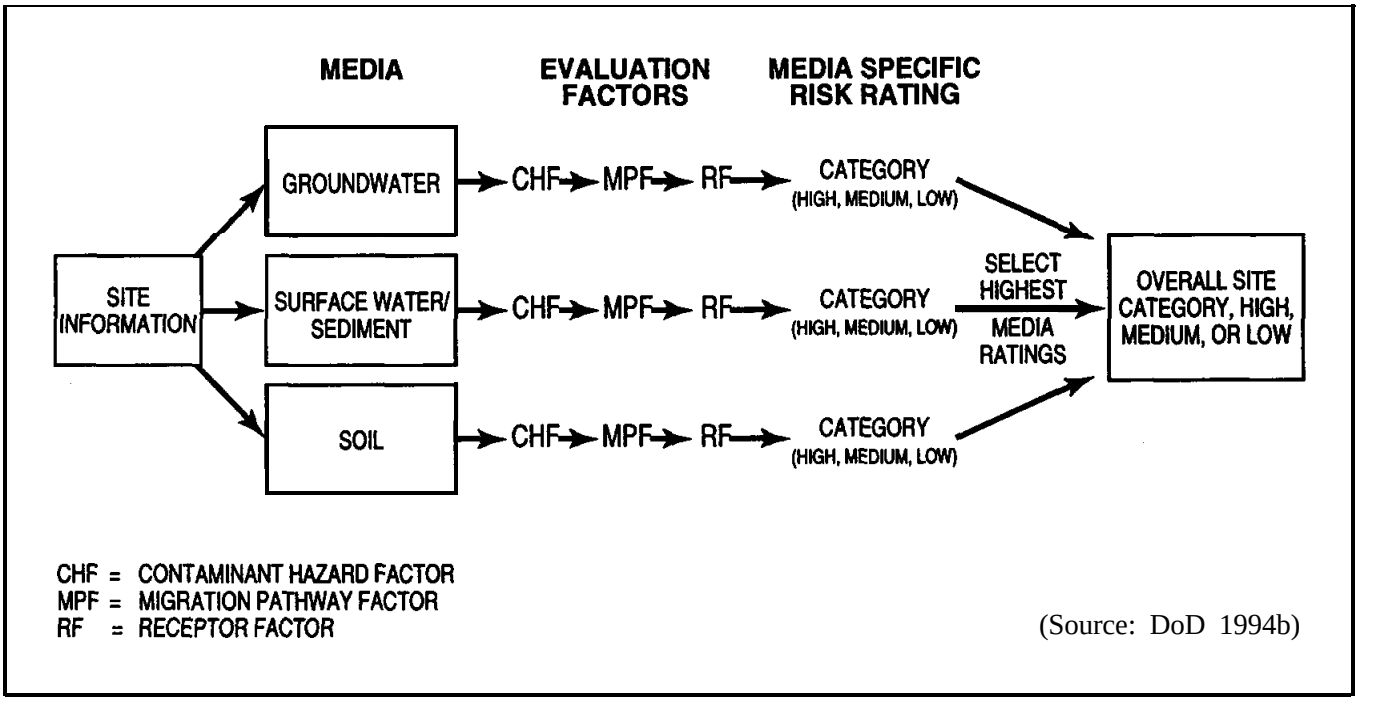


Figure 9-4. Flow diagram of relative risk site evaluation framework

3. Low Relative Risk: Sites with characteristics not indicated in (C)(2) above.

9.2.1.4 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 Section 9.2.4.

Risk Management Decision

- Should a site be eliminated from further investigation in the RI or RFI 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 or RFI) will be needed.

- No Further Action (NFA)

Rationale:

- Environmental mapping, functional group characterization, database searches, or 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.

  . No knowledge of documented releases or major spills/low likelihood of spills/procedures existed to promptly clean up all spills.

  . Transport mechanisms do not exist, e.g., presence of secondary containment.

  . The substances released are not expected to be present due to degradation and attenuation under the forces of nature.

- Spills or releases have been addressed by other regulatory programs (e.g., the Underground Storage Tank (UST) program or RCRA closure under Subpart G of 40 CFR 264 or 265).

  . The unit does not meet the definition of an "SWMU."

- The unit is part of another identified unit or site which will be addressed separately.

Although risk assessment is traditionally performed in the RI or RFI project phases 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: I) 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.[4] 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?

[4] 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: (9 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, EPA 1990f). Items (3) through (5) could be used to reduce exposure to ecological receptors of concern.

Risk Management Options/Rationale

- No Early Response Action

  Rationale:

  - 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.)

  - Transport mechanisms probably do not exist, e.g., presence of secondary containment.

  - 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.

  - There is no anticipated risk of stress or physical hazards.

  - Site contaminants are not likely to be persistent or the contaminants are relatively immobile.

- Early Response Action

  Rationale:

  - There is no current impact, but if uncontrolled, the site could pose a substantial threat or endangerment to humans or the environment. (Examples ate: physical hazard, acute risk from direct contact of the unit or site, or effluents or contaminated media are continuously being discharged to the a sensitive environment, e.g., a spill that could impact salmon spawning, egg hatching, or survival of fry.)

  - The principal threat has reasonably been identified because of the evidence of adverse impacts. In this context, the 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.

  - 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.

  - The boundary of contamination is reasonably well defined. so that removal action(s) can be readily implemented.

  - 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.

  - The early actions are consistent with the preferred final remedy anticipated by the customer, reducing risks to both human and ecological receptors.

  - 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 closeout or further investigation.

  - If removal actions ate 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.

  - 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.

  - High concentration (acute hazard level) of site contaminant is found in the exposure medium.

  - Highly toxic chemicals or highly persistent and bioaccumulative chemicals found onsite which may be transported offsite.

- Documented unacceptable sediment, soils, surface water, or groundwater seep contamination in media that could be contacted by endangered species.

- Ecological impacts have been observed due to volume of the release and the habitat destruction of valued resources.

- A high risk of physical hazards or stress to the environment.

- The exposure pathway(s) for ecological species was the reason or one of the reasons for the basis for NPL listing or ongoing enforcement actions on spills or releases.

- Noncomplex site (no cost recovery issue, limited exposure pathways, small area sites, etc.)

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, EPA 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. EPA's *RCRA Stabilization Strategy* (EPA 1992m) and *Superfund Accelerated Cleanup Model* (SACM) (EPA 1992n) emphasize 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:

- Environmental mapping/functional assessment.

- Exposure pathway analysis: development of ECSM.

- Identifying short-term (acute) benchmark toxicity values for screening site data.

- Qualitative evaluation of removal actions for their effectiveness to reduce exposure to ecological receptors.

- 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.

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.

Early actions or accelerated cleanup can often be justified as long as the actions are consistent with the preferred site remedy. Since remedies am generally not selected until late in the FS or CMS, 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, EPA has identified certain site types where final remedies are anticipated to be the same (presumptive remedies). The current list of presumptive remedies includes:

- Municipal Landfill -- capping and groundwater monitoring.

- Wood Treatment Facility - soil and groundwater remediation.

- Groundwater contamination with VOCs - air stripping/capture wells.

- Soil contamination with VOCs - soil vapor extraction.

Additional presumptive remedies are being developed by EPA Region VII for PCB sites, manufactured gas plants, and grain fumigation silos. EPA 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 onsite or nearby the site for the ecological receptors of concern; there is low or generally low-level, widespread 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).

9.2.1.5 Qualitative Evaluation of Response Actions for Their Effectiveness to Reduce Risks

Removal of hot spots can 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 concentration. 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 bow the removal option can eliminate risk or reduce the level of exposure both onsite and offsite, if contaminant migration has occurred at offsite 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.

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 onsite or offsite ecological receptors, the removal action should either be discarded or monitoring/control measures be instituted. (As discussed later, the risk assesor 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.

9.2.2 RI/RFI

The primary objective, of RFI, 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 RCRA corrective action process is similar to Superfund for determining the need for remediation, albeit initially, the TSDF owner/operator may simply compare a specific set of SWMU data with established AWOC or literature effect range levels. The proposed corrective action rule does not provide additional guidance on how action levels are to be developed for other media based on ecological concern. ERA generally considers performance of a Health and Environmental Assessment (HEA) to be functionally equivalent to the Superfund baseline risk assessment (human health and ERA) in the RI/FS while a few ERA regions have developed ERA guidelines for RCRA. The RCRA HEA should be conducted prior to or early in the CMS to determine the need for corrective measure implementation.

The ERA or HEA associated with the RI/RFI project phase can assist the risk management decision-making process in the following ways:

- 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 in the Tier IV assessment. Risks can be estimated for the entire site. OUs, AOCs, SWMUs, or CAMUS.

- 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.

- 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.

- If removal actions ate still appropriate and are to be implemented, the short-term impact of such actions should be evaluated.

Risk Management Decision

- Should remedial action or corrective measure 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 PM. The review may lead to the need for additional data to more fully characterize potential risk. Alternatively, the manager 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 or corrective measure..

. No Further Action (NFA)

The rationale for no action based on the ERA could be any (or a combination) of the following:

Rationale:

- 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.

- Lack of habitat or food sources to support the ecological receptors of concern and potential offsite 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.

- 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).

- 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 am acceptable.

- The potential environmental risk or injuries associated with any and all remediation is grater than the baseline risk (i.e., further efforts should be expended to find a suitable remedial action or viable alternatives, such as offsite mitigation, restoration, or compensation).

- 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.

- There could be marginal risks: however, considering uncertainties, the potential incremental gain does not justify the action.

- 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.

- Potential remedy will cause substantial economic or scenic damage and is not consistent with the public and stakeholders' goals and objectives.

- Interim remedial action or interim measures have removed the migration/transport mechanisms to impact ecological receptors.

- Site contaminants are not likely to ever pose unacceptable risk as they am not persistent or the contaminants are relatively immobile and not bioavailable.

. Remediation/Removal Action Required.

The requirement for removal action taken at the RI/FS or RFI/CMS project phase is the same as that described under Section 9.2.1.4 above. Upon

completion of RI/FS (and before signing of the Superfund Records of Decision or the completion of RCRA Part B permit modification), a decision will be made whether remedial action or RCRA corrective measure implementation 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:

- 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.

- Viable habitat and sufficient food sources are available to sustain the ecological receptors of concern.

- The COECs are persistent or bioaccumulative and will potentially impact ecological receptors of concern.

- The site poses an unacceptable risk.

- The environmental risk associated with the remedial action or the corrective measure implementation is acceptable.

- Short-term impacts from remediation, although potentially severe, are not permanent and outweigh the alternative of long-term, chronic exposure.

- COECs are persistent and expected to pose a long-term threat to the ecological receptors of concern.

- The remedial action objective (RAO) or target cleanup level (TCL) is based on a reliable or adequately characterized exposureresponse relationship and is practical for use to verify cleanup and the environmental gain is measurable.

- There is a low potential for recovery without removal or remedial actions.

- Remediation is consistent with the stakeholders' goals and objectives.

9.2.2.1 Risk Characterization/Uncertainty Information for RMDM

The sources of uncertainties in a Tier I baseline ERA were presented in Chapter 4. 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.

From the risk manager's perspective, the baseline ERA should adequately present risk estimates in an objective and unbiased manner. The risk manager or 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.

When making site decisions, the risk manager or PM can substantially benefit from 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 risk manager or PM 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.

In order to make informed risk management decisions, the risk manager should have a clear understanding of the following:

- What are the receptors or resources to be protected?

- Does the ecological risk involve individual organisms, communities, populations, or different trophic levels?

- What is the aggregate hazard index (HI)?

- How do effects or ecosystem characteristics between the site and the reference locations compare.?

- 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?

- How do hazards under RME and average (typical) exposure compare? What are the "or&r of magnitude" differences?

- 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?

- 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?

- What are the COBC(s) and exposure pathways that constitute the principal threat?

- How are the exposure units defined in the baseline ERA?

- Are there any "hot spots" which would require further characterization. or removal action?

- 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?

- If removal or early response actions are desirable, how effective are the proposed removal actions to reduce site risk?

- Which are the anticipated or preferred options for actions?

9.2.3 FS/CMS and RD/RA

The FS or CMS 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 or CMS could be driven by a legal requirement to meet ARARs, although ARARs are not necessarily risk-based The FS or CMS evaluates potential remedial alternatives according to established criteria in order to identify the appropriate remedial alternative(s). The FS or CMS can be performed for the entire site or any portion of the site that poses unacceptable risks. The results of the FS/CMS include recommendations for the risk managers or site decision-makers, including an array of remedies for selection, RAOs, or TCLs for verification of cleanup.' The selected remedies/TCLs or revisions thereof will be entered into the ROD or the Part B permit.

Risk Management Decision

- What are the Remedial Action Objectives (ROAs)?

Risk Management Options/Rationale

The risk management decision for selection of final remedies depends substantially on the RAOs. Uses of RAOs are summarized below:

- Developed or agreed upon by the agencies prior to the FS or signing of the ROD (or modification of the RCRA permit), RAOs are used to evaluate the feasibility of candidate remediation technology in the FS;

- Initial estimation and costing of remediation (e.g., excavation and stabilization);

- Delineation of cutlines for remediation:

[5] 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 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.

- For use in negotiation or final determination of specific areas, SWMUs, 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 cons&red when RAOs are used as the basis for designing and implementing remediation are presented below:

9.2.3.1 Remedial Action Objectives Must be Based on ECSM

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 or RFI/CMS.

9.2.3.2 Remediation Goals Must be Protective and Practical

Remediation goals are performance and numerical objectives developed in the FS/CMS 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 8). 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.[6]

[6] Certain sites may be. contaminated with natural or anthropogenic substances which pose matrix interferences and cause high sample detection limits, i.e., the practical quantitation limits (PQLS) may be higher than the environmental-based preliminary remediation levels. For these sites, it may be advantageous to design a representative sampling program of the background medium to establish PQLs for use as alternative remediation goals.

9.2.3.3 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 or CMS and remedy selection. Therefore, data used in the FS or CMS must interface with the RI/RFI and other previously collected site data. Inadequate data or data of poor quality m&present 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 or RFA data.

RAOs may be selected based on one of the following:

- 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.

- 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.

- Risk-based Remediation Go& (Cleanup GO&).

  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.

Minimal information or guidance has been developed by EPA regarding the development of RAOs for RCRA and Superfund sites. RCRA has issued the Alternative Concentration Limit (ACL) Guidance based on 40 CFR 264.94(b) criteria and case studies (EPA 1988j) 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. Under the. proposed subpart S rule for RCRA corrective action, the state water quality criteria can be used to screen if a CMS should be conducted. 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 ate 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.

Environmental and human health-based RAOs should be developed together and proposed to the risk manager and agencies for use in the CMS 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, and cost of cleanup verification analyses).

Risk Management Decision

- **What are the Remedial Alternatives or Corrective Measures?**

- **What are the Preferred or Optimal Remedial Alternatives?**

Risk Management Options/Rationale

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 (fun&-mental) criteria which must be met by any selected remedy. More recently, EPA 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.

Screening and detailed analyses of remedial alternatives will be conducted in the FS and CMS 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.

In the FS, potential risk reductions associated with remedial alternatives am 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.

9.2.3.4 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 are 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.

Risk screening of alternatives should generally be qualitative or semiquantitative. 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 or RFI 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.'

[7] The bench sale 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.

Key information needed prior to conducting the screening evaluation of remedial alternatives include:

- Identity and quantity of emissions, effluent, byproducts, treatment residues, which may be released to the environment (during normal, start-up, and shut-down operations).
- Toxicity of chemical substances or COECs in the above discharges.
- Potential for dilution and attenuation.
- Existence of exposure pathways and likelihood of the pathways to be significant and complete.
- Potential for spill or releases during remediation, material handling, storage, and transportation of remediation wastes.
- Potential for the causation of nonchemical 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.
- Temporal attributes associated with a remedial action which could be altered to reduce the action's impact.
- 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 bioavailabitity).

The following are lists of qualitative evaluation criteria:

- Risk Reduction Attributes (environmental protection, permanence, and toxicity reduction).
  - Able to remove, contain, or effectively treat site COECs.
  - Able to address the exposure pathways and media of concern.
  - Able to meet the remedial action and overall project strategy goals.
- Assessment of Residual Risk Potential.
  - 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).
  - Quantity of residues or discharges to remain on site.
  - Toxicological properties of the residues.
  - Release potential of residues based on their fate/transport properties (e.g., log octanol/water partition coefficient, water solubilities. vapor pressure, density, etc.).
  - Properties or characteristics of the environmental medium which facilitate transport (e.g., hydraulic conductivity, organic carbon contents, wind speed and direction, etc.).
  - Potential for dilution and attenuation for residues released into the environment.
  - 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.

9.2.3.5 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) assessment of the potential for the risks to be magnified due to simultaneous implementation of this and other preferred alternatives; and (c) identification of 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 or RCRA Part B permit modification. All preferred remedies or options should satisfy remedial action goals and should pose minimum health and environmental impact.

Key information needed prior to conducting the screening evaluation of remedial alternatives include:

- Identity and quantity of emissions, effluent, byproducts, treatment residues, which may be released to the environment (during normal, start-up, and shutdown operations).
- Toxicity of chemical substances or COECs in the above discharges.
- Potential for dilution and attenuation.
- Existence of exposure pathways and likelihood of the pathways to be significant and complete.
- Potential for spill or releases during remediation, material handling, storage, and transportation of remediation wastes.
- Potential for the causation of nonchemical 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.
- Temporal attributes associated with a remedial action which could be altered to reduce the action's impact.
- 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).

The following are lists of qualitative evaluation criteria:

- Risk Reduction Attributes (environmental protection, permanence, and toxicity reduction).
  - Able to remove, contain, or effectively treat site COECs.
  - Able to address the exposure pathways and media of concern.
  - Able to meet the remedial action and overall project strategy goals.
- Assessment of Residual Risk Potential.
  - 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).
  - Quantity of residues or discharges to remain on site.
  - Toxicological properties of the residues.
  - Release potential of residues based on their fate/transport properties (e.g., log octanol/water partition coefficient, water solubilities, vapor pressure, density, etc.).
  - Properties or characteristics of the environmental medium which facilitate transport (e.g., hydraulic conductivity, organic carbon contents, wind speed and direction, etc.).
  - Potential for dilution and attenuation for residues released into the environment.

9.2.3.5 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) assessment of the potential for the risks to be magnified due to simultaneous implementation of this and other preferred alternatives: and (c) identification of 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 or RCRA Part B permit modification. All preferred remedies or options should satisfy remedial action goals and should pose minimum health and environmental impact.

This evaluation may be qualitative. semiquantitative, or quantitative. If the analysis is quantitative, procedures and approaches similar to the baseline risk assessment may be followed. EPA's (1995g) *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* (EPA 19920). 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

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:

- 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.

- Time required and extent of recovery from exposure to the above COECs and nonchemical stressors.

- The potential for fire, explosion, spill, and release of COECs from management practice of excavated or dredged materials should remain qualitative or semiquantitative. 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).

9.2.3.6 Risks from Simultaneous lmplementation of Preferred Remedies

- Common exposure pathways for effluent or discharges from remedies.

- Period of exposure to the ecological receptors of concern via the common locations, time, and pathways.

- Sensitive environments and other threatened or sensitive wildlife or aquatic populations.

- Risk estimates or characterization results.

- 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.

- Qualitative or quantitative assessment of potential short-term or residual risks.

Short-Term Risks Associated with Construction; the Design Risk Analysis. All removal or remedial alternatives have a potential to pose short-term risks to onsite mitigation workers, ecological receptors, and offsite humans. Risks may be associated with vapors, airborne particles, treatment effluent, resuspension of sediment resulting in an increase in the total suspended solids (TSS) or siltation of substrate for macroinvertebrates, 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 implementation 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).

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 onsite after the remedial action should be assessed for their potential risks.

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.

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.[8]

9.2.4 Nonrisk 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 nonzero risk and return the site to its beat current use (not to conditions of a pre-industrialization era). Under RCRA, the preamble to the proposed Subpart S recognizes that cleanup beyond the current industrial land use should be justified. This section presents and discusses the nonrisk 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 nonscientific factors, as explained below.

[8] One exception (i.e., remedial action risk which is long-term) is a pump-and-treat remedy of groundwater to meet MCLs 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.

9.2.4.1 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

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 problema must be overcome before actual selection or implementation of the action. The following are a few examples:

- Scale up.
- Downtime and maintenance (including supplies).
- Ownership/control.
- Throughput to meet the required completion schedule.
- Skills required or training requirements.
- Quantitation and detection limits.
- Space requirements for the remediation process and management of remediation wastes.

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 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 if contamination from offsite sources is not controlled.

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:

- Adequacy of bench-scale or pilot-scale treatability data.

- Data uncertainties (volume, matrices, site geology/hydrogeology).
- Field data and modeling data.
- Overall uncertainty of the source of site contamination.

9.2.4.2 Nonscientific Factors

Nonscientific 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.

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.[9] Nonetheless, the requirements specified in the enforcement documents or administrative order of consent, IAG, or FFA should be followed by the risk manager or PM with few exceptions. When risk-related factors or other nonrisk 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.

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.

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.

Community Input. Opportunity for the stakeholders or community to provide input into the permit modification is provided when primary documents are prepared, i.e.. RFI Work Plan, RFI/CMS reports, the proposed remedies, and the CMI 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:

- Ineffective communication of risks and uncertainties.
- Lack of action (some action is preferred to no action).
- Not in my backyard (offsite transportation of contaminated soil, debris, or sediment should avoid residential neighborhoods).
- Any treatment effluent or discharge is unacceptable (onsite incineration is seldom a preferred option except for mobile incinerators, in certain instances).
- The remedy should not impede economic growth or diminish current economic and recreational value of resources to be protected.
- Cleanup will improve the quality of life and increase property values or restoration of recreational/ economic resources.

Societal/Economic Value of the Resources to be Protected. This nonrisk factor concerns the community sentiment on how fast or in what manner the resources

[9] USACE has published the *Technical Project Planning -- Guidance for HTRW Data Quality Design* (USACE 1995b) which purpose is to build flexibility for site decision-making based on data need, use, and project objective and strategy. This new way of project planning and execution will be likely to result in a more effective risk management decision-making for the new HTRW sites.

impacted by site contaminants should be restored. These resourcea 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.

9.2.4.3 A Balanced Approach

In conclusion, the risk manager should consider all risk and nonrisk 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 nonrisk 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 Chapter 2). and which may evolve throughout the project.

9.3 Design Considerations

Risk assessment methodology can be an important tool in the design phase of CERCLA remedial actions or RCRA corrective measure implementation. During the early phase of RD/RA or CMI, 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-considers TBCs) in determining design changes of control measures.

This section addresses the above issues. i.e., risk management considerations in remedial design, compliance with ARARs, including the CAA, CWA, ESA, and other major environmental statutes, and control measures required to mitigate risks.

9.3.1 Potential Risk Mitigation Measures

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:

- VOC and SVOC emissions - activated carbon canisters, afterburners, or flaring, prior to venting.
- Metals and SVOC airborne particles - wetting of work areas; particulate filter/bag house, wet scrubber, or electrostatic precipitator (for thermal treatment devices or incinerators).
- 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).
- Neutralization or chemical deactivation of effluent (continuous process or batch).
- Use of remote-control vehicle for handling, opening, or cutting of drums containing explosive or highly reactive or toxic substances.

9.3.1.1 Operational Control

Where appropriate, administrative control measures (procedural and operational) safeguards should be recommended by the PM, design engineer, and field supervisor during RA, with inputs from the risk assessor and other relevant technical and compliance specialists. Examples of these control measures include:

- 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 bigger levels. These levels should be developed in the RD/RA or CMI project phase by the risk assessor and other technical specialists, including the modeler.

- Consistent with the above trigger or acute concern levels. evaluate onsite performance with field equipment to ensure adequate remediation.

- 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.

- Establish a zone of decontamination and proper management of effluent or waste generated from this zone.

- Secure and control access to areas where remedial actions are being implemented at all times.

9.3.1.2 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, onsite 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:

- Recording land use restrictions in the deeds (deed restrictions) for future use of certain parcels or areas where hazardous substances or wastes are contained.

- Erection of placards, labels, and markers which communicate areas where human exposure may pose short-term or residual risks.

- Security fences and barriers.

9.3.2 Risk Management; Degree of Protectiveness

Not only should a selected remedial action (corrective measure) 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:

- **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.

- **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.

- **Effectiveness of the remediation.** Remediation should effectively address onsite contamination if there is a continuing offsite (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 offsite influences or contribution to the contaminants requiring remediation. Offsite source control and containment. waste minimization, and closure issues should be raised by the risk manager to the agencies, USACE customers, and higher echelon.

- **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 redevelopment commissions, state, and other stakeholders.

- **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.

Risk management decisions during the design phase of a CERCLA or RCRA 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 versus 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.

Glossary

This glossary includes definitions from several sources. A superscript number next to a word identifies the reference from which the definition was adapted (listed at the end of the Glossary).

Abiotic [1,2] Devoid of life; nonliving. In reference to environmental factors includes temperahue, pH, humidity, and other physical and chemical influences.

Absorption.[3] The net movement (transport) of water and solutes from outside a cell or organism to the interior.

Absorption Efficiency. A measure of the rate at which an organism absorbs a substance across exchange boundaries (e.g., gastrointestinal tract).

Accuracy [20] measure of the closeness of a statistic obtained using a certain sampling procedure to the true value of a population parameter.

Acute.[4] Having a sudden onset, tasting a short time. Of a stimulus, severe enough to induce a response rapidly. Can be used to define either the exposure or the response to an exposure (effect).

Acute Teats. The duration of an acute aquatic toxicity test is generally 4 days or less and mortality is the response usually measured. A toxicity test of short duration, typically 4 days or less. and usually of short duration relative to the lifespan of the test organism.

Administered Dose? The mass of a substance given to an organism and in contact with an exchange boundary (i.e.. gastrointestinal tract) per unit body weight per unit time (e.g., mg/kg-day)

Adsorption.[3] The surface retention of solid, liquid, or gas molecules, atoms, or ions by a solid. or liquid, as opposed to absorption, the penetration of substances into the bulk of the solid or liquid.

Algorithm.[3] A set of well-defined rules for the solution of a problem in a finite number of steps.

Allometry.[3] The quantitative relation between a part and the whole or another part as the organism increases in size.

Analyte.[5] The chemicals for which a sample is analyzed.

Antagonism.[6] In toxicology a situation in which two chemicals, administered together, interfere with each other's actions or one interferes with the action of the other chemical. The result is that the combined effect of the two chemicals is much less than the sum of the effect of each agent given atone.

Anthropogenic.[3] Referring to environmental alterations resulting from the presence or activities of humans.

Areal.[2] Any particular extent of space or surface. as a geographical region.

Area Use Factor. The ratio of an organism's home range, breeding range. or feeding/foraging range to the area of contamination or the site area under investigation.

Assessment Endpoint.[7] An explicit expression of the environmentat value that is to be protected.

Avian.[8] Of, relating to, or derived from birds (Aves).

Benthic.[3] Of, pertaining to, or living on the bottom or at the greatest depths of a large body of water.

Bias.[3,20] In estimating the value of a parameter of a probability distribution, it refers to the difference between the expected value of the estimator and the true value of the parameter. In biostatistics, bias is a consistent under- or overestimate of the true population parameter by a statistic. Statisticat bias is usually a result of a consistent inaccuracy in a sampling procedure or, in some cases, a formula.

Bioaccumulation.[4] General term describing a process by which chemicals are taken up by an organism either directly from exposure to a contaminated medium or by consumption of food containing the chemical. Test used to evaluate the relative potency of a chemical.

Bioassay.[4] Test used to evaluate the relative potency of a chemical by comparing its effect on living organisms with the effect of a standard preparation on the same type of organism. Bioassay and toxicity teats arc not the same - see toxicity test.

Bioavailability.[9] The degree to which a material in environmental media is assimilable by an organism.

Bioconcentration[4] A process by which there is a net accumulation of a chemical directly from an exposure medium into an organism.

Bioconcentration Factor (BCF).[10] Provides a measure of the extent of chemical partitioning at equilibrium between a biological medium such as fish tissue or plant tissue and an external medium such as water, soil, or sediment. The higher the BCF, the greater the accumulation in living tissue is likely to be.

Biomagnification.[4] Result of the process of bio-accumulation by which tissue concentrations of chemicals increase as the chemical passes up through two or more trophic levels. The term implies an efficient transfer of the chemical from food to consumer.

Biomarker.[11] General molecular change that is taken as an indicator of pollution/stress. May be general or specific.

Biotic.[2] Pertaining to life or living organisms, caused or produced by or comprising living organisms.

Body Burden. The concentration of a material which accumulates in the biological tissues of an exposed organism.

Breedinn Range. The area utilized by an organism during the reproductive phase of its life cycle and during the time that young are teared.

Characterization of Ecological Effects.[7] A portion of the analysis phase of ecological risk assessment that evaluates the ability of a stressor to cause adverse effects under a particular set of circumstances.

Characterization of Exposure.[7] A portion of the analysis phase of ecological risk assessment that evaluates the interaction of the stressor with one or more ecological components. Exposure can be expressed as co-occurrence, or contact depending on the stressor and ecological component involved.

Chemicals of Potential Ecological Concern. Chemicals that are potentially site-related and have the potential to adversely affect ecological receptors due to concentration, distribution, and/or mode of toxicity.

Chronic. Involving a stimulus that is lingering or con-tinues for a long time; often signifies periods from several weeks to years, depending on the reproductive life cycle of the species. Can be used to define either the exposure or the response to an exposure (effect). Chronic exposures typically induce a biological response of relatively slow progress and long duration.

Chronic Response. The response (effect) of an organism to a chemical which is not immediately or directly lethal to the organism.

Chronic Tests.[12] A toxicity test used to study the effects of continuous, long-term exposure of a chemical or other potentially toxic material on an organism.

Community.[7] An assemblage of populations of different species within a specified location and time.

Concentration[4] Quantifiable amount of a chemical in environmental media.

Concentration Response Curve.[4] The quantitative relationship between exposure concentration and percent of the test population responding.

Correlation.[13] An estimate of the degree to which two sets of variables vary simultaneously, with no distinction between dependent and independent variables.

Degradation.[3] Conversion of an organic compound to one containing a smaller number of carbon atoms.

Depuration.[4] A process that results in elimination of toxic material from an organism.

Direct Effect (toxin).[7] An effect where the stressor itself acts directly on the ecological component of interest, not through other components of the ecosystem.

Dose.[14] A measure of integral exposure. Examples include (1) the amount of a chemical ingested, (2) the amount of a chemical taken up, (3) the product of ambient exposure concentration and the duration of exposure.

Dose-Response (Curve).[4] Similar to concentration-response curve except that the dose (i.e., the quantity) of the chemical administered to the organism is known. The curve is plotted as Dose versus Response.

Dose-Response Evaluation.[5] The process of quantitatively evaluating toxicity information and characterizing the relationship between the dose of a contaminant administered or received and the incidence of adverse health effects in the exposed population. From the quantitative dose-response relationship, toxicity values are derived that are used in the risk characterization step to estimate the likelihood of adverse effects occurring in or to receptors at different exposure levels.

Duplicate.[15] A sample taken from and representative of the same population as another sample. Both samples arc carried through steps of sampling, storage, and analysis in an identical manner.

Ecological Risk Assessment.[7] The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.

Ecosystem.[7] The biotic community and abiotic environment within a specified location and time.

Endpoints. See assessment and exposure endpoints.

Error. The difference between a statistic and the true value of a population parameter. It is important to realize that bias and error may arise both in the original collection of data and in the subsequent manipulation of the data.

Excretion.[3] The removal of unusable or excess material from a cell or a living organism.

Exposure.[7] Co-occurrence of or contact between a stressor and an ecological component. The contact reaction between a chemical and a biological system, or organism.

Exposure Assessment' The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure.

Exposure Pathway.[5] The course a chemical or physical agent takes from a source to an exposed organism. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, transport/exposure media (i.e., air, water) are also included.

Exposure Point.[5]A location of potential contact between an organism and a chemical or physical agent.

Exposure Route.[5] The way a chemical or physical agent comes in contact with an organism (i.e., by ingestion, inhalation, or dermal contact).

Exposure Scenario.[7] A set of assumptions concerning how an exposure may take place, including assumptions about the exposure setting, stressor characteristics, and activities that may lead to exposure.

Fate.[4] Disposition of a material in various environmental compartments (e.g. soil or sediment, water, air. biota) as a result of transport, transformation. and degradation.

Food Chain.[10] Hierarchical arrangement by trophic level of which species eat other species.

Food Guild. Organisms that feed in a similar manner (i.e., woodpeckers, birds that probe bark for insects).

Food Web." Interconnecting food chains. Such pathways do not always follow a strict progression from a lower trophic level to a higher trophic level. In addition, many species have mixed diets of plant and animal material or change their feeding habits seasonally or at different life stages.

Forage (feeding) Area. The area utilized by an organism for hunting food or gathering food.

Gestation (Period).[3] The period in mammals from fertilization to birth.

Guild.[2] A group of species having similar ecological resource requirements and foraging strategies and, therefore, having similar roles in the community.

Habitat.[1] Place where a plant or animal lives, often characterized by a dominant plant form or physical characteristic.

Hazard. Likelihood that a chemical will cause an injury or adverse effect under specified conditions.

Hazard Identification.[5] The process of determining whether exposure to an agent can cause an increase in the incidence of a particular adverse effect, and whether an adverse effect is likely to occur.

Hazard Index (HI).[5] The sum of more than one hazard quotient for multiple substance and/or multiple exposure pathways.

Hazard Quotient (HQ).[5] The ratio of a single substance exposure level over a specified time (e.g., chronic) to a toxicity value selected for the risk assessment (i.e., LOAEL or NOAEL).

Herbivores? An animal that eats only vegetation.

Home Range.[16] The area to which an animal confines its activities.

Indirect Effect.[7] An effect where the stressor acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest

Ingestion Rate. The rate at which an organism consumes food, water, or other materials (i.e., soil, sediment). Ingestion rate is usually expressed in terms of unit of mass or volume per unit of time (i.e., kg/day, L/day).

Invertebrate.[3] An animal lacking a backbone and internal skeleton.

Lethal.[4] Causing death by direct action.

Life Stage. A given phase in the growth and development of an organism (e.g., embryo, larva, fetus, juvenile, adult).

Lipid.[17] One of a variety of organic substances that are insoluble in polar solvents, such as water, but that dissolve readily in nonpolar organic solvents. Includes fats, oils, waxes, steroids, phospholipids, and carotenes.

Liponhilic.[3] Having a strong affinity for fats (lipids).

Log P. See octanol-water partition coefficient.

Lowest-Observed-Effect Concentration (LORC). Same as lowest-observed-effect level except using concentration-response data.

Lowest-Observed-Effect Level (LOEL).[5] In dose-response experiments, the lowest exposure level at which there are statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control group. Same as LOAEL (lowest-observable-adverse-effect level).

Matrix.[3] The analyte as considered in terms of its being an assemblage of constituents, each with its own property.

Measurement Endpoint.[7] A measurable ecological characteristic that is' related to the valued characteristic chosen as the assessment endpoint, Measurement endpoints are often expressed as the statistical or arithmetic summaries of the observations that make up the measurement.

Media.[18] Specific environments - air, water, soil, sediment - which are the subject of regulatory concern and activities.

Median Effective Concentration (EC_{50}).[4] The concentration of a material to which teat organisms are exposed that is estimated to be effective in producing some sub lethal response in 50 percent of the teat population. The EC_{50} is usually expressed as a time-dependent value (e.g., 24-hour EC_{50}). The sublethal response elicited from the test organisms as a result of exposure must be clearly defined.

Median Effective Dose (ED_{50}). Same as median effective concentration except refers to administered dose instead of concentration.

Median Lethal Concentration (LC_{50}).[4] A statistically or graphically estimated concentration that is expected to be lethal to 50 percent of a group of organisms under specified conditions.

Median Lethal Dose (LD_{50}). Same as median lethal concentration except refers to administered dose instead of concentration.

Mesophyte.[3] A plant requiring moderate amounts of moisture for optimum growth.

Metabolism? The physical and chemical processes by which foodstuffs are synthesized into complex elements (assimilation, anabolism), complex substances are transformed into simple ones (disassimilation, catabolism), and energy is made available for use by organisms.

Metabolize.[3] To transform by metabolism.

Mortality. Death

No-Observed-Effect-Concentration (N0EC). Same as no-observed-effect-level except dealing with exposure concentration.

No-Observed-Effect-Level (NOEL).[4] The highest level of a stressor evaluated in a test that causes no statistically significant difference in effect as compared with the controls. Same as NOAEL (no-observable-adverserse-effect-level).

Octanol-Water Partition Coefficient (K_{ow}).[10] Provides a measure of the extent of chemical partitioning between water and octanol at equilibrium. Octanol is used as a surrogate for lipids (fats) and can be used to predict bioconcentration in aquatic organisms. The logarithm of K, is referred to as the log P. The greater the K_{ow} (or

log P) the more likely a chemical is to partition in lipid than to remain in water.

Parameter. A known characteristic of a population (e.g., density).

pH.[2] A numerical measure of acidity or hydrogen ion activity. Neutral is pH 7. All pH values below 7 are acid, and all above 7 arc alkaline.

Phreatophyte.[3] A plant with a deep root system which obtains water from the groundwater or the capillary fringe above the water table.

Piscivorous.[3] Feeding on fish.

Population.[20] An aggregate of individuals of a species within a specified location in space and time. In biostatistics, population is the entire collection of individual Sample Units that are potentially observable in an ecological community. It is from this population that a sample will be drawn and statistical inferences made.[20]

Population Dynamics.[3] The aggregate of processes that determine the size and composition of any population.

Precipitation.[3] The process of producing a separable solid phase within a liquid medium.

Precision.[20] A measure of the degree of repeatability of a statistic in replicated samples using a certain sampling procedure. The standard error is considered the basic expression of sampling precision, Note that it is possible to have a precise estimate without accuracy, since a particular sampling procedure may be precise but biased.

Predator.[3] An animal that preys on other animals as a source of food.

Primary Producers.[10] Green plants (including algae and microscopic aquatic plants called phytoplankton) which capture solar energy through photosynthesis which converts carbon dioxide and water into carbohydrates, a form of energy storage suitable for use by other organisms.

Receptor. A biotic component of the ecosystem that is or may be adversely affected by a chemical or other stressor.

Reference.[14] A relatively unpolluted site used for comparison to polluted sites in environmental monitoring studies, often incorrectly referred to as a control.

Reference Dose (RfD).[5] The US EPA's preferred toxicity value for evaluating noncarcinogenic effects resulting from exposures at Superfund sites. Can refer to a variety of exposure durations or effects (e.g., acute, chronic, subchronic, developmental). The acronym RfD, when used without modifiers, either refers generically to all types of RfDs, or specifically to chronic RfDs.

Residue. See body burden.

Risk.[4] A statistical concept defined as the expected frequency or probability of undesirable effects resulting from a specific exposure to known or expected environmental concentrations.

Risk Assessment. The technical evaluation of the degree of hazard or risk associated with exposure of a receptor or receptor populations to contamination of an environmental medium or media.

Risk Characterization.[7] A phase of ecological risk assessment that integrates the results of the exposure and ecological effects analyses to evaluate. the likelihood of adverse ecological effects associated with exposure to the stressor. The ecological significance of the adverse effects is discussed, including consideration of the types and magnitudes of the effects, their spatial and temporal **patterns,** and the likelihood of recovery.

Risk Management[5] The process of weighting 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.

Sample.[3] Representative fraction of a material tested or analyzed; a selection or collection from a larger collection.

Sediment.[19] Particulate material lying below water.

Species.[17] A group of organisms that actually or potentially interbreed and are reproductively isolated from all other such groups; a taxonomic grouping of morphologically similar individuals; the category below genus.

Stakeholder. Broadly defined as regulators, concerned citizens, environmental groups, and other appropriate public and private interested parties.

Statistic.[13] **A computed or estimated statistical quantity** such as the mean, the standard deviation, or the. correlation coefficient.

Stressor. Any physical, chemical, or biological entity that can induce an adverse response.

Sublethal.[4] Below the concentration that directly causes death. Exposure to sublethal concentrations of material may produce less obvious effects on behavior, biochemical and/or physiological functions, and histology of organisms.

Synergistic.[2] Situation in which the combined effect of two chemicals is much greater than the sum of the effect of each agent given alone.

Taxon.[3] A taxonomic group or entity which are hierarchial levels in the biological classification of organisms (e.g., family, genus, species).

Threshold Concentration (or Level).[4] A concentration (or exposure level) above which some effect (or response) will be produced and below which it will not.

Toxicity Assessment. Review of literature regarding the **toxicity of any given material to an appropriate receptor.**

Toxicity Test.[4] The means by which the toxicity of a chemical or other test material is determined. A toxicity test is used to measure the degree of response produced by exposure to a specific level of stimulus (or concentration of chemical).

Toxicity Value.[5] A numerical expression of a substance's dose-response relationship that is used in risk assessments.

Toxin. A poisonous substance.

Trophic Level.[7] A functional classification of taxa within a community that is based on feeding relationships (e.g., aquatic and terrestrial plants make up the first trophic level, and herbivores make up the second).

Update.[4] A process by which materials are transferred into an organism.

Uncertainty.[14] Imperfect knowledge concerning the present or future state of the system under consideration; a component of risk resulting from imperfect knowledge of the degree of hazard or of its spatial and temporal distribution.

Volatilization.[3] The conversion of a chemical substance from a liquid state to a gaseous vapor state.

Xerophyte.[3] **A plant adapted to life in areas where the water supply is limited.**

Endnotes

[1] Krebs 1978, [2] Cooperrider et al. 1986, [3] Parker 1994, [4] Rand and Petrocelli 1985, [5] U.S. EPA 1989a, [6] Amdur et al. 1991, [7] U.S. EPA 1992a, [8] Merriam-Webster 1975, [9] Freedman 1989, [10] U.S. EPA 1989b, [11] Calow 1993, [12] ASTM 1993a, [13] Sokal and Rohlf 1981, [14] Suter 1993, [15] U.S. EPA 1992b, [16] Wallace et al. 1981, [17] Curtis 1983, [18] Sullivan 1993, [19] ASTM 1993b, [20] Ludwig and Reynolds 1988.

References

Amdur, Doull, and Klassen 1991
Amdur, M. o., Doull, J., and Klassen. C. D., (eds.). 1991. *Casarett and Doull's Toxicology: The Basic Science of Poisons*. Fourth edition. New York, NY: McGraw-Hill.

American Society for Testing and Materials (ASTM) 1993a
American Society for Testing and Materials (ASTM). 1993a ASTM Standard E 943. Standard terminology relating to biological effects and environmental fate.

American Society for Testing and Materials (ASTM) 1993b
American Society for Testing and Materials (ASTM). 1993b. ASTM Standard E 1525. Standard guide for designing biological tests with sediments.

Calow 1993
Calow, P., (cd.). 1993. *Handbook of Ecotoxicology. Volume 1.* Boston, MA: Blackwell Publishing.

Cooperrider, Boyd, and Stuart 1986
Cooperrider. A. Y., Boyd, R. J., and Stuart, H. R., (eds.). 1986. Inventory and monitoring of wildlife habitat. U.S. Dept. Inter., Bur. Land Manage. Service Center. Denver, Co. xviii, 858 pp.

Curtis 1983
Curtis, H. 1983. *Biology,* Fourth Edition. New York, NY: Worth.

Freedman 1989
Freedman, B. 1989. *Environmental Ecology. The Impacts of Pollution and Other Stresses on Ecosystem Structure and Function.* New York, NY: Academic Press.

Krebs 1978
Krebs, C. J. 1978. *Ecology: The experimental analysis of distribution and abundance.* Second edition. New **York, NY: Harper &** Row.

Ludwig and Reynolds 1988
Ludwig, J. A., and Reynolds, J. F. 1988. Statistical Ecology. John Wiley & Sons, New York, NY.

The Merriam-Webster Dictionary (Merriam-Webster) 1975
The Merriam-Webster Dictionary (Merriam-Webster). 1975. 7th Printing, Simon and Schuster, Inc., New York, NY.

Parker 1994
Parker, *S.* P., (ed.). 1994. *Dictionary of Scientific and Technical Terms.* Fifth Edition. New York, NY: McGraw-Hill.

Rand and Petrocelli 1985
Rand, G. M., and Petrocelli, S. R. 1985. *Fundamentals of Aquatic Toxicology. Methods and Applications.* New York, NY: McGraw Hill.

Sokal and Rohlf 1981
Sokal, R. R., and Rohlf, F. J. 1981. *Biometry.* Second Edition. New York, NY: W.H. Freeman and Company.

Sullivan 1993
Sullivan. T. F. P. 1993. *Environmental Regulatory Glossary.* Government Institutes, Inc.

Suter 1993
Suter,, G. W., II. 1993. *Ecological Risk Assessment.* Ann Arbor, MI: Lewis Publishers, Inc.

U.S. Environmental Protection Agency (EPA) 1989a
U.S. Environmental Protection Agency (EPA). 1989a. Risk Assessment Guidance for Superfund: Volume I - Human Health. Washington, DC Office of Emergency and Remedial Response; EPA/540/1-89/002.

U.S. Environmental Protection Agency (EPA) 1989b
U.S. Environmental Protection Agency (EPA). 1989b. Risk Assessment Guidance for Superfund: Volume II - Environmental Evaluation Manual. Washington, DC: Office of Emergency and Remedial Response; EPA/540/1-89/001.

U.S. Environmental Protection Agency (EPA) 1992a
U.S. Environmental Protection Agency (EPA). 1992a. framework, for Ecological Risk Assessment. Washington, DC: Risk Assessment Forum; EPA/630/R-02/011.

U.S. Environmental Protection Agency (EPA) 1992b
U.S. Environmental Protection Agency (EPA). 1992b. Sediment Classification Methods Compendium. Washington, DC Office of Water, EPA/823/R-092/006.

Wallace, King, and Sanders 1981
Wallace, R. A., Ring, J. L., and Sanders, G. P. 1981. *Biology. The Science of Life.* Second Edition. Scott, Foresman & Co., Ill.

Exhibits

EXHIBIT 1

EXAMPLES OF MINIMUM REQUIREMENTS FOR ECOLOGICAL RISK ASSESSMENTS

PROBLEM FORMULATION

Ecological Site Characterization

- Adequate ecological description of site.
- Identification of sensitive, critical, or protected ecological receptors and their habitat.

Data Collection and Evaluation

- Chemical-specific analysis of appropriate media (abiotic and biotic) (for direct assessment or modeling).
- Quantitation/detection limits lower than concentrations of concern.
- Appropriate analytical methods and sample handling (DQO process).
- Sample numbers adequate to attain desired degree of confidence and power (DQO process).
- Sample collection/handling method.
- Sample locations adequate to describe area of interest.
- Adequate background samples (in terms of location, number, media, detection limit, analytical methodology).
- Chemicals of ecological concern selected using acceptable criteria.

ANALYSIS - EXPOSURE CHARACTERIZATION

- Intake and exposure modifying factors reflect site-specific conditions.
- "Exposure area" concept for mobile receptors used.
- All potentially complete exposure pathways are evaluated (quantitatively, if possible, otherwise qualitatively).
- Basis for uncertainty factors used in the development of reference toxicity values are provided.

ANALYSIS - ECOLOGICAL EFFECTS CHARACTERIZATION

- Toxicity benchmark values are appropriate for the chemical form, exposure duration, intake route, and ecological receptor.
- If surrogate toxicity values are applied, basis for their use is provided.

EXHIBIT 1

(Concluded)

RISK CHARACTERIZATION

Risk Quantitation

- Potential additive effects of co-occurring exposure pathways are evaluated.
- Numerical hazard estimates are accompanied by a narrative discussion.

Uncertainty Analysis

- Major sources of uncertainty identified; impact on risk assessment results evaluated.
- A qualitative uncertainty analysis is included.
- A sensitivity analysis of key factors should be performed if unacceptable health risk or hazard estimates are derived.

EXHIBIT 2

FACTORS TO CONSIDER WHEN REVIEWING DATA

FOR THE ERA

- Was the scope of analysis appropriate for the site? If good quality information is already available on the extent of chemical types present on the site, a focused chemical analysis may be appropriate. If the site has no previous chemical data available, a broad spectrum analysis (such as TCL/TAL) should be performed on at least one sample per medium from an area of suspected contamination (more if the site has multiple areas of suspected contamination). Further sampling can then be focused upon chemicals known to be present at the site and to be site-related. In planned ERA data collection, the DQO process should evaluate the need to perform a focused or broad spectrum analysis.
- Were potential chemical degradation products or parent chemical compounds analyzed for? If degradation to more toxic substances is known to occur, the resultant degradation products should be analyzed.
- Does the sampling adequately describe site conditions? The sampling design will influence data useability. For instance, was sampling random or purposive, spatially representative of the site or focused on a localized area? The DQO process should specify an appropriate sampling design for planned ERA data collection to support the type of data analysis desired (for example, statistical treatment of the data).
- Are the quality assurance/quality control (QA/QC) protocols and results available? Determine whether appropriate sample collection, handling, and analytical procedures were performed. The scope and level of QA/QC required for the collection of planned ERA data should be specified as part of the DQO process. For historical data, the availability and compliance with appropriate QA/QC procedures should be determined.
- Are needed supplemental chemical/physical data available? Information such as organic carbon content, pH, water content, grain size, or porosity may be necessary to interpret the results of the data or to perform fate and transport modeling. Measures of bioavailability such as cation exchange capacity (CEC) or sulfide concentrations may also be useful. The need to collect these types of supplemental data should be specified as part of the DQO process for planned ERA data collection. Historical data may or may not include these parameters, which may limit the utility or interpretation of the data.
- Are the necessary sampling-specific factors available? These types of factors include depth of soil sample and any pertinent sample-handling factors (was the water sample filtered or unfiltered?). Again, the need for these factors should be specified as part of the DQO process for planned ERA data collection, and should be available for historical data.
- Are quantitation limits available for the nondetected chemicals? Information on the sensitivity of the analytical method is needed to interpret nondetected results and to estimate exposure point concentrations. When minimum requirements for laboratory analysis are identified in the ERA data planning stage, delivery of quantitation limits should be specified. If no information is available on quantitation limits for historical data, an assumption with regard to the degree of sensitivity of the analytical method may be made by a qualified chemist.

EXHIBIT 3

METHODS FOR IDENTIFYING

APPROPRIATE QUANTITATION LIMITS

Unlike human health risk assessments, EPA has not developed standard reference doses (RfDs) that can be used to define media concentrations that are protective of specific aquatic and terrestrial wildlife. Some criteria are available for the protection of aquatic organisms that can be used to define the level of detection needed in chemical analyses of water and sediment.

EPA's ambient water quality criteria (AWQC) for the protection of aquatic organisms and proposed sediment quality criteria (59 FR 2652) for the protection of benthic organisms can be used to initially identify quantitation limits. Individual states may also have promulgated water and sediment quality standards that may be used (60 FR 22228, May 4, 1995). The State of Washington Departments of Ecology and Natural Resources, EPA, and USACE, for example, jointly supported the development of quantitative sediment quality criteria using a "sediment quality triad" approach for Puget Sound as part of the Puget Sound Estuary Program and the Puget Sound Dredges Disposal Analysis. EPA's Final Rule: *Final Water Quality Guidance for the Great Lakes System* (60 FR 15366, March, EPA 1995b) also provides new aquatic criteria in addition to four newly proposed wildlife criteria to protect populations of fish-eating mammalian and avian wildlife. While the Great Lakes Water Quality Initiative (GLWQI) is intended to apply to the watershed of the Great Lakes area, it includes policy initiatives that could soon be applied throughout the U.S. Each of these screening criteria is discussed more thoroughly in Chapters 2 and 3, and while they are generally useful for screening purposes, they are not necessarily suitable as reference concentrations for site-specific ERAs. An additional consideration in using these criteria is that some criteria, particularly those that bioaccumulate, may be below available method detection limits.

Few means are available for defining the level of detection needed in soil analyses with regards to acceptable risks to wildlife. In the absence of such, quantitation limits developed for the human health risk assessment (HHRA) may be initially applied in the ERA.

Quantitation limits developed for the HHRA using RfDs may be used in ERAs where the human RfD is based on a laboratory rat or mouse toxicity benchmark value. A toxicity benchmark value is a daily intake level, expressed in mg/kg-day, used to evaluate the noncarcinogenic toxicity of a chemical. Intake at this level (or lower) is anticipated to be without adverse health effects over a lifetime exposure. Toxicity benchmark values can be expressed as water or soil concentrations when combined with conservative default exposure assumptions for the medium.

For a number of chemicals, the human RfD is developed by using a rat or mouse toxicity benchmark value and an appropriate safety or uncertainty factor (UF) of typically 1000. The human Rfd can thus be retained as a conservative reference toxicity value (RTV) for the ERA in order to account for the protection of small mammalian wildlife as well as sensitive top predator species. Lessor uncertainty factors of 10 or 100 may also be applied to the rat NOEL if appropriate to develop a wildlife RTV. To determine the concentration of Chemical A in soil that needs to be detected in order to assess potential ecological risks to small mammals as represented by the rat, default and assumed intakes associated with the experimental rat are applied. Default assumptions for the rat (adult, sex unspecified) include a 0.2-kg body weight (BW) and a 0.015-kg/day food ingestion rate (FIR). A soil ingestion rate (SIR) of 2% of the FIR is assumed. Using these values, the following calculation can be performed:

$$C_{soil}\ (mg/kg) = [RTV_{rat} \times BW] / [FIR \times SIR(\%)]$$

$$C_{soil}\ (mg/kg) = [(0.001\ mg/kg\text{-}day)(0.2\ kg)]/[(0.015\ kg/day)(0.02)]$$

$$C_{soil}\ (mg/kg) = 0.7\ mg/kg$$

EXHIBIT 3

(Concluded)

In other words, the highest acceptable detection limit for this fairly toxic, hypothetical chemical is 0.7 mg/kg.

For water, default assumptions of rat ingestion of 0.025 liters per day and a 0.2-kg body weight are usually appropriate:

$$C_{water}\ (mg/L) = [RTV \times BW] / IR$$

$$C_{water}\ (mg/L) = [(0.001\ mg/kg\text{-}day)(0.2\ kg)]/[(0.025\ L/day)]$$

$$C_{water}\ (mg/L) = 0.008\ mg/L \text{ or } 8\ \mu g/L.$$

The highest acceptable detection limit in water is 8 µg/L.

It is important to note that the above methods only apply to direct ingestion of soil and water by the small mammal and do not account for direct ingestion of chemicals in food or indirect ingestion of chemicals by higher trophic level organisms from prey items. While additional equations may be used to account for food intake, modeling of the food chemical concentrations may become an extensive exercise not appropriate to a screening-level investigation.

EXHIBIT 4

DATA QUALITY INDICATORS

Completeness. This is a measure of the amount of useable data resulting from a data collection activity, defined as the number of samples with accepted results out of the total number of samples collected (in percentage form). Although a few missing or rejected data points usually won't compromise useability of a data set, too many missing or rejected data points may prevent an adequate description of site contamination, and may suggest poor data quality overall. A small number of data points can also reduce confidence levels and power and may result in an inflated upper confidence limit. Occurrences of incompleteness should be examined by the risk assessor to evaluate whether data useability has been compromised. If so, re-sampling or re-analyses of the sample (if holding times have not been exceeded) can be performed.

Comparability. When multiple data sets are applied to the ERA, the degree of comparability (degree to which the different data sets are considered equivalent) should be considered. Similarity in collection techniques, analytical protocols, and time period, for example, are some indicators of comparability. If data were collected by different sampling protocols (for example, one was based on an unbiased or random sampling design, and the other was a purposively sampled "hot spot"), it may not be appropriate to combine the results. Similarly, if two data sets were analyzed by different methodologies (resulting in different detection limits or using different sample preparation techniques), the data again may not be comparable.

Representativeness. The data applied to a quantitative ERA should be representative of the exposure scenarios being assessed. Representativeness is best attained by the risk assessor providing input at the sample planning stage. However, data are collected for different objectives (e.g., treatment parameters, regulatory reporting), and otherwise high quality data may still not be useable in a ERA. The risk assessor should examine the data carefully to evaluate whether it is representative of the exposure point or scenario (e.g., surface soil rather than soil borings for soil contact scenarios) and whether the sample was collected and analyzed in a manner relevant to the exposure (e.g., filtered versus unfiltered surface water for water ingestion by wildlife).

The data should also be examined with regard to the degree in which the data meet the performance standards of the method. Factors such as holding time, sample handling and preservation, and analysis of blanks (are chemicals in samples really related to contamination) affect representativeness. Deviations from the performance standards may result in analytical results that do not represent site conditions (for example, holding times were exceeded and the chemical in the sample has degraded somewhat prior to analysis).

Precision. This is a quantitative measure of the variability of the data set, usually identified by the coefficient of variation or standard deviation of the mean. Variability may come from field or analytical variability and may indicate weaknesses in the sample collection or analysis. Precision in analysis is measured by duplicate analysis and split samples. Low precision in analysis can result in false negatives or false positives for measurements near the detection limit and increases the variability of the results.

If the risk assessor can provide input to the sampling design, minimal performance parameters (such as confidence level, power, and minimum relative percent differences) can be specified, and the sample protocol can be designed to meet these parameters. If, when results are obtained, these parameters have not been met, additional samples can be collected.

Accuracy. This is a measure of the closeness of a reported value to its true value, expressed as bias (high or low). Accuracy is determined by calculating the percent recovery from spiked samples. If spike recovery is low, the reported sample concentrations may be underestimated (potential for false negatives). If spike recovery is high, the reported sample concentrations may be overestimated (potential for false positives).

EXHIBIT 5

IMPORTANCE OF DATA QUALITY REVIEW IN AN ERA

Data Qualifiers. In response to variations or failures in certain data quality measures, individual data results may be qualified and assigned a data qualifier. A data qualifier is a letter or other character that symbolizes some meaning to the data result in addition to the numerical value presented. In general, chemicals with data qualifiers that indicate an estimated concentration on a positively detected chemical (e.g., "J" values) can be included in the ERA. Rejected data ("R") or chemicals in samples as a result of sample contamination ("B" for organic chemicals, see discussion below) should not be included in the ERA.

Presence of Chemicals in Blanks. Certain chemicals may be introduced into samples inadvertently during sampling or laboratory analysis. Examination of sampling (field and trip) blanks and laboratory (method, instrument) blanks for chemicals helps to identify any contamination that may have occurred.

The following have been identified as common laboratory contaminants by EPA:

Methylene chloride	Acetone
Toluene	2-Butanone (methylethylketone)
Carbon dioxide	Diethylether
Hexanes	Freons
Phthalates	Solvent preservatives (e.g., cyclohexanone)

Aldol reaction products of acetone (e.g., 4-hydroxy-4-methyl-2-pentanone)

During data validation, the amount of these common laboratory contaminants detected in site samples is compared with the amount detected in associated blank samples. According to EPA's CLP protocol, if the amount in the sample is less than or equal to ten times the amount in any blank sample associated with the sample (referred to as the "ten times" rule), the chemical is generally reported as undetected in the site sample, with the detection limit raised to the amount in the sample (or CRQL, if detected amount was below CRQL). If multiple blank samples are associated with a given sample, the blank containing the high concentrations of the chemical is used in the comparison. For chemicals other than those identified as common laboratory contaminants (i.e., all other chemicals not presented above), if the amount in the sample is less than or equal to five times the amount in any blank associated with the sample ("five times" rule), the chemical is reported as undetected in the site sample. (It is still useful, however, to also retain the blank designation, so that the risk assessor may better interpret the sample result.)

When modifications to the detection limit are made by the data validator, chemicals that are associated with blank contamination are appropriately qualified and require no modification by the risk assessor. In some instances, however, the amount of chemical detected in the sample is reported and denoted with a "B" (indicating blank contamination for organic analysis), rather than changed to "not detected." In these instances, the risk assessor must acquire information on the amount of chemical in the associated blanks, and apply the "five times" or "ten times" rule. If the chemical concentration in all site samples can be attributed to sampling or laboratory contamination, it should not be included in the ERA. This rule is intended as a guide, as professional judgement can play an important role in the application of this rule. For example, there are times when some detected compounds do not meet the criteria, yet the contamination could only be attributed to laboratory or sampling artifacts.

EXHIBIT 5

(Concluded)

Tentatively Identified Compounds (TICs) A data set may contain compounds reported as TICs. Compounds so reported are considered tentative because the analytical method did not specifically analyze for the analyte. The concentration of a TIC can only be estimated, because corresponding standards have not been analyzed to calibrate the instrument. TICs may be reported as specific compounds; however, often, TICs are reported in a generic manner, such as "petroleum hydrocarbons," "methylated benzene," or even "unknown compound." A site or medium containing a large number of TICs may pose a greater risk than that reflected by assessment of positively identified compounds alone. However, in many cases, the exact nature of the tentatively identified chemical is not known, making assessment of its potential ecological impacts difficult. Often, chemicals reported on a TIC list do not have toxicity values with which to assess their health risks. A large number of TICs in a sample of a medium suggests that additional chemicals not specifically analyzed for are present, and may suggest that the scope of chemical analysis was not broad enough.

EXHIBIT 6

CHEMICALS TO EXAMINE FOR BACKGROUND PRESENCE

Metals. Certain metals are naturally occurring in most environmental media (e.g., soil, groundwater, surface water, and sediments) and should be examined for presence in background locations (e.g., arsenic and zinc). If present in site media at concentrations comparable to background concentrations, they generally can be removed from consideration as a COEC.

Polycyclic Aromatic Hydrocarbons. The class of compounds polycyclic aromatic hydrocarbons (PAHs, sometimes abbreviated as PNAs) are often found in the environment from a number of ubiquitous sources, including burning of wood, combustion of gasoline, natural fires, and volcanoes. It may, in some instances, be appropriate to remove PAHs from the COEC list, provided that it can be demonstrated that PAHs are present in types and concentrations comparable to background and that PAHs were not disposed of, used, or generated at the site.

Pesticides. In areas where agricultural activities are commonplace, use of pesticides (insecticides, herbicides, fungicides, etc.) and other agricultural chemicals may result in commonplace presence in environmental media. If it can be demonstrated that pesticide concentrations are comparable to background concentrations (i.e., were applied according to their intended use) and that pesticides were not disposed of at the site, they can generally be removed from consideration as a COEC.

Phthalate Esters. When not site-related, phthalate esters are most often found in samples as a result of sampling or laboratory contamination. Phthalate esters are also ubiquitous in the environment as a result of their widespread use as plasticizers.

Other Organic Chemicals. Most organic chemicals have no natural or ubiquitous presence in the environment. However, some organic chemicals may have natural sources, such as carbon disulfide which is formed by microbial activity. Other organic chemicals may be present as a result of upgradient/offsite sources that are not being assessed. If background locations contain organic chemicals that are known not to have been used at the site and information is available to attribute the chemical to a specific offsite source, it may be appropriate to remove the chemical as a COEC.

EXHIBIT 7

REFERENCE TOXICITY VALUES FOR AQUATIC ECOSYSTEMS

Reference toxicity values (RTVs) for use in selecting COECs for the ERA are basically the water quality criteria for aquatic and marine life developed by EPA along with drinking water standards and water and organism ingestion. Basically there are four types of water quality criteria: acute and chronic criteria for freshwater and marine life. The acute criterion is a one-hour concentration average not to be exceeded more than once every three years. The chronic criterion is a four-day concentration not to be exceeded more than once in three years on the average.

There are currently five sediment criteria proposed by EPA (59 FR 2652). The proposed criteria are applicable only to those sediments which are "permanently inundated with water, intertidal sediments and to sediments inundated periodically for durations sufficient to permit development of benthic assemblages." The proposed criteria are not applicable to "sediments occasionally inundated so that they support terrestrial species." The proposed sediment criteria for the protection of benthic organisms are for acenaphthene, dieldrin, endrin, fluoranthene, and phenanthrene. Documents on the technical basis for deriving these criteria (EPA 1993j) and guidelines for deriving site-specific sediment quality criteria (EPA 1993b) are also available.

Literature-based guidance on chemical concentrations in sediments that were reported to produce effects can also be used for estimating ecological risk. Published values (Long and Morgan 1990, Long et al. 1995) can be used to establish screening level criteria based on ER-L and ER-M values for marine sediments and LEL and SEL values for freshwater sediments. Environment Canada has also published *Protocol for the Derivation of Canadian Sediment Quality Guidelines for the Protection of Aquatic Life* (CCME 1995).

The ER-L is a statistically calculated effects range-low which is a concentration at the low end of the range where effects were observed and the ER-M is the effects range-median, a concentration approximately midway in the range of values associated with biological effects.

The ER-L was established objectively by determining the lower 10th percentile in the literature database. The ER-L can be considered a concentration above which adverse effects may be predicted in some sensitive species or early life-stages, the ER-M is a value or concentration, when exceeded, almost always produces effects in most species. The ER-L and ER-M values (Long and Morgan 1990) are to be considered general values used for screening.

Ontario's freshwater sediment quality guidelines and criteria (Persaud, Jaugumagi, and Hayton 1992) can also be used for screening. Three sets of guidelines for freshwater sediments are provided: no-effect level (NEL), lowest-effect level (LEL), and severe-effect level (SEL). These guidelines can be used to address several sediment-related issues, including: evaluation of sediment quality, determination of the appropriate level of sediment cleanup, determination of the suitability of open-water disposal of dredge material. NELs, which are principally designed to protect against biomagnification through the food chain, were determined for nonpolar organics only using the Province Water Quality Objectives/Guidance values and an equilibrium partitioning approach. The LEL and SEL concentrations are both based on the screening level concentration (SLC) approach which uses field data to estimate the highest concentration of a contaminant that can be tolerated by a specified proportion of benthic infaunal species. The LEL numbers, which are meant to represent contaminant concentrations that can be tolerated by most benthic organisms, represent the 5th percentile of species SLCs. At sites where the LEL of a metal exceeds its naturally occurring concentration, the local background concentration forms the basis for risk management decisions. The SEL numbers, which indicate the level at which the sediment community would experience a pronounced disturbance, are based on the 95th percentile of species SLCs (Persaud, Jaugumagi, and Hayton 1992).

EXHIBIT 7

(Concluded)

Florida's Dept. of Environmental Protection has also published screening values (probable effects levels [PELs] and threshold effects levels [TELs]) for marine sediments in Florida coastal waters (MacDonald 1994). The numerical sediment quality assessment guidelines were developed for Florida Coastal waters using the weight of evidence approach.

Only a few of the many thousands of chemicals have specific criteria, standards, guidance or benchmark values that are protective of preventing toxicity to aquatic life or the related food-chain for bioaccumulative compounds. However, the USEPA ERL-D has available an information system that integrates AQUIRE and the QSAR system. AQUIRE is a database of aquatic toxicity test results. QSAR is a database which includes physicochemical properties and various quantitative structure-activity models. The integrated system is called ASTER. "ASTER uses mechanistically based predictive models to estimate ecotoxicity endpoints, chemical properties, bioconcentration, biodegradation, and environmental partitioning." "ASTER is designed to provide high quality data for discrete chemicals, when available in the associated databases, and QSAR-based estimates when data is lacking," for use by the ecological risk assessor. ERL-D is in the process of combining its terrestrial and aquatic databases into one database, ECOTOX. ECOTOX will include ASTER, AQUIRE, PHYTOTOX, and TERRETOX.

Even if the values calculated by QSAR or ASTER for toxicity and BCF and are no more then 2 to 10 times different from measured values in environmental media they can be used for screening level evaluations since they alert the assessor to potential toxicity problems. Information from the ASTER database may be applied in the screening of COECs or used in the development of toxicity profiles in the toxicity assessment phase of the ERA.

EXHIBIT 8

LEGAL PERSPECTIVE

PROTECTION OF THE INDIVIDUAL VERSUS THE POPULATION IN THE ENDANGERED SPECIES ACT AND MIGRATORY BIRD TREATY ACT

Neither CERCLA nor EPA ERA guidance dictates focusing on individual animals for risk assessment or remedial purposes. More significantly, the Endangered Species Act and the Migratory Bird Treaty Act both support focusing on protection at the species or population level rather than pursuing an approach predicted on protection of the individual *per se*.

The Endangered Species Act (ESA), 16 USC § 1531 *et seq.*, and the Migratory Bird Treaty Act (MBTA), 16 USC § 703 *et seq.* both prohibit the unpermitted taking of listed species. Neither, however, support or require the premise that either environmental remediation or wildlife conservation efforts should be focused on protection of the individual. Instead, examination of the statutes, both separately and together, demonstrates that as a matter of law and policy wildlife protection programs focus appropriately on impacts at the species or population level.

The ESA has frequently been characterized as the most stringent wildlife protection law in either the United States or the world. Its purpose is to:

> "provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, to provide a program for the conservation of such . . . species, and to take such steps as may be appropriate to achieve the purpose of the treaties and conventions set forth in subsection (a) [including migratory bird treaties with Canada, Mexico and Japan) . . ."

Id. § 1531(b). Under the ESA, "conservation" is the process whereby listed species are recovered and delisted.

Section 9 of the ESA prohibits the unauthorized or unpermitted "taking" of listed species. *Id.* § 1538(a). Section 9 notwithstanding, it is Section 7(a)(2) which provides the standard by which federal agency action is reviewed for acceptability under the ESA. Section 7(a)(2) prohibits Federal action that would "jeopardize the continued existence of any endangered ... or threatened species," absent an exemption from the requirements of the Act. *Id.* § 1536(a)(2). If a prospective agency action "may affect" a species listed as threatened or endangered, the action agency is required to consult with the U.S. Fish & Wildlife Service (or the National Marine Fisheries Service) prior to performing the action in question. The consultation process culminates in the issuance by the Service of a "biological opinion" which will authorize the action to proceed unless the Service finds that the action would "jeopardize the continued existence of"[1] the species and that there are no reasonable and prudent alternatives to the action which would avoid the jeopardy result. *See id.*, § 1536(b)(3).

As the phrase "jeopardize the continued existence of" the species indicates, the ESA's bottom line for authorized agency action is based on the impact of the action on the species as a whole, not on the impact on individual specimens *per se*. Furthermore, Section 7 specifically authorizes the issuance by the Service of an "incidental take" statement which allows the action in question to result in the take of one or more individuals of the listed species, provided that the species as a whole is not jeopardized by that result. It is therefore uncontrovertible that even under the ESA itself, the appropriate focus for determining the propriety of an agency action (such as approval of contaminant cleanup levels) which might affect individual members of a listed species is the impact that level of affect would have upon the viability of the species.[2]

EXHIBIT 8

(Concluded)

The MBTA contains a take prohibition similar to (but more limited than) that set forth in the ESA. As with the ESA, permits or authorization can be granted under the MBTA allowing the take of covered migratory birds. As a practical matter, this is a necessity. For example, migratory birds for which sports hunting is authorized in the United States (such as ducks and geese) are covered by the MBTA. The Service issues regulations allowing hunting activities and resulting take based on its evaluation of the impact such activities would have on the species concerned.

Clearly, neither the ESA nor the MBTA require that ERAs focus on protection of individual members of a covered species. Although the concept is most clearly expressed in the ESA,[3] both demonstrate that wildlife protection efforts should be focussed on impacts at the species level. Indeed, this is the thrust of Federal wildlife conservation programs generally, consistent with the principles of conservation biology and ecology which inform modern wildlife management. As a practical matter, a species-level focus is likewise more compatible with the degree of precision and resolution afforded by ERAs.[4]

Summary

From scientific, regulatory, and legal perspectives, the appropriate assessment endpoint for migratory birds in an ERA is at the population level of ecological organization. It is the effects on populations of animals in general, and migratory birds in particular, that are the values to be protected and considerations which will drive decision-making at a site. Data from all levels of ecological organization, including individuals, may be used as appropriate measurement endpoints; however, the information will be evaluated in the context of population-level effects.

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1 Service regulations define "jeopardize the continued existence of" to mean "to engage in an action that reasonably would be expected...to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, number, or distribution of that species." 50 CFR § 402.02 (1992) (emphasis added).

2 Similarly, in the case of purely private activities which have no Federal involvement and would affect individual members of a listed species, an incidental take statement can be obtained under Section 10 of the ESA which authorizes the taking, Section 9 notwithstanding. 16 USC §1539 (a)(1). In determining whether to issue the permit, the Service will consider whether the level of take for which permission is sought would jeopardize the continued existence of the species, utilizing the Section 7 consultation process discussed above.

3 Given the ESA's focus on those species most in need of protection, it would be anomalous to infer a more protective approach is required by the MBTA for common species such as the mallard duck and robin, whose populations are not likely to ever be at risk.

4 From a similarly pragmatic perspective, it is worth noting that both EPA and the U.S. Fish & Wildlife Service routinely authorize or perform activities resulting in the take of large numbers of migratory birds or other wildlife. In addition to the activities referenced in text, EPA, for example, routinely authorizes the sale and use of pesticide products which are responsible for the inadvertent deaths of large numbers of nontarget species including migratory birds.

EXHIBIT 9

COMPONENTS OF THE ECOLOGICAL CONCEPTUAL SITE MODEL

An ecological conceptual site model (ECSM) summarizes the exposure scenarios applicable to the site, often in pictorial form. An ECSM identifies original sources of chemicals at a site, the potential release mechanisms from those sources, media that may become secondary and tertiary sources through chemical transport, ultimate exposure media or areas, exposed receptors, and exposure routes. When initially conceived early in the ERA planning stage, the ECSM was based upon readily available and preliminary information and was used to direct sampling and other investigative activities. For the exposure assessment, the ECSM must be refined and supported by more specific information. Since the components of the ECSM are those being re-evaluated in the exposure assessment, and represent the "big picture," revision of the ECSM should be performed concurrently with the exposure assessment, and reviewed for reasonableness at the conclusion of the exposure assessment. The types of information needed to refine the ECSM are presented below.

- Primary and Subsequent Sources of Chemicals

  Information on the original source (or sources) of chemicals at a site should be confirmed, if possible, with information obtained from the site investigation. Facility operation records, interviews with personnel, identification of sources from field activities (such as electromagnetic surveys, trenching, etc.) can provide this information. In some cases, identification of the primary source or sources is not possible (such as at older or abandoned sites), or is largely irrelevant (if significant migration has already occurred).

  Secondary and tertiary sources (media that have become contaminated as a result of chemical release and transport) identified in the preliminary ECSM should be re-examined in light of data collected in the site investigations. If sampling of anticipated impacted secondary and tertiary media indicated that contamination was not present, this information should be used to modify assumptions regarding potential exposures.

- Primary and Subsequent Release Mechanisms

  The mechanisms by which chemicals were released from the original source(s) provide information on the media likely to be impacted and the potential fate and transport of the chemicals after release. At this point in the assessment, hypothesized release mechanisms need to be re-examined for correctness.

  The primary release mechanism is a function of the site history (i.e., spills or burial of chemicals, leaking of tanks) that can be determined through a review of the site activities and history. Secondary and tertiary release mechanisms, as well as the potential migration of a chemical after release, are a function of the release mechanism (how, when, and where it occurred) as well as the chemical and physical properties of the chemical. In the exposure assessment, these chemical and physical properties of the COECs should be compiled to identify the fate and transport characteristics of the COECs. This information should be examined to ascertain whether the appropriate fate of the chemical was considered when the sampling was designed and whether appropriate media have been sampled.

EXHIBIT 9

(Concluded)

- Potential Receptors

  Ecological receptors that have the potential to be exposed to chemicals in site media, or migrating from the site, are identified by examining the current and future use of the site and surrounding areas. Information such as biological assessments, natural history surveys, land use maps, and onsite reconnaissance can be used to assist in identifying potential receptors. In the exposure assessment, more specific information is evaluated on the potentially exposed receptors, such as habitat types and usage, feeding habits and activity patterns, or other factors which influence the receptors' magnitude and frequency of exposure. The assumptions regarding potentially exposed ecological receptors made in the preliminary ECSM should be re-examined for correctness and needed modifications.

- Food Webs

  Ecological exposure scenarios must also consider feeding (trophic) relationships and how they could result in potential exposure for the onsite receptors. Trophic relationships represented by general receptor categories or groups (small mammals, small birds) are developed early in the ERA process in the form of a diagrammatic food web. Because actual food webs are complex, the initial food webs are greatly simplified to clarify the movement of food from the primary producers (i.e., plants) to the primary consumers and further up through the higher trophic levels. The ECSM evaluates the flow of chemicals through the system (biotic and abiotic media) to the ecological components (assessment endpoints) to be protected. The model focuses on potential receptors of concern (usually the higher trophic level organisms) and evaluates whether these receptors have a potential for exposure. While the assessment may examine a number of trophic levels, receptors in these intermediate trophic levels are usually considered only in terms of how they may transmit site chemicals to the higher level receptors of concern and not in terms of whether they themselves are at risk.

- Potential Exposure Routes

  The exposure routes by which biological receptors may be exposed to chemicals were identified as part of the development of the preliminary ECSM. These assumptions should be re-examined to evaluate whether the appropriate exposure pathways have been identified and whether any modifications of the assumptions are in order. In addition to the impacts made by previously assumed sources, release mechanisms, fate and transport characteristics and receptors, the identified potential exposure-routes should be examined in light of the data collection from the site investigation. For example, did all the abiotic media actually contain COECs, or will the media contain COECs in the future, based on an understanding of the chemical migration pathways? Are the contaminated media accessible to potential receptors by the exposure pathways being evaluated? In ERAs, the particular feeding habits of the receptor are important for evaluating whether the exposure pathway is complete. For example, the evaluation of incidental sediment ingestion intake route by dabbling waterfowl (e.g., mallard) is appropriate; the evaluation of incidental sediment ingestion by pisciverous (fish-eating) waterfowl (e.g., common merganser) is not appropriate.

EXHIBIT 10

CHEMICAL AND PHYSICAL PROPERTIES

AND THEIR ROLE IN FATE AND TRANSPORT

Water Solubility (S). This property indicates the degree to which a chemical is soluble in water. High water solubility suggests that the chemical will readily dissolve into water and is likely to be retained in surface water or groundwater. Low water solubility indicates that the chemical will dissolve only slightly in water and is less likely to be found in surface water or groundwater.

Vapor Pressure (VP). This property indicates the readiness with which a chemical volatilizes to air. Chemicals with a low vapor pressure will more readily volatilize from surface soil or surface water to the air and are, therefore, less likely to be retained in water or soil for prolonged periods of time.

Henry's Law Constant (H). This value is, in essence, an air/water partition coefficient, comparing the water solubility (S) and the vapor pressure (VP) of a chemical. It is expressed in several different ways, the most common being in atm-m^3/mol, but it is also expressed as a unitless concentration form. This value indicates the readiness with which a chemical will volatilize from water to air. A high H value is associated with a higher diffusion rate from water.

Octanol/Water Partition Coefficient (K_{ow}). This partition coefficient indicates the tendency of a chemical to partition to either octanol or water. While octanol is of little consequence in environmental situations, it is a reasonably good surrogate for describing the tendency for chemicals to bind to (or be taken up by) other environmental media, such as soil and lipids. The larger the K_{ow} value, the more likely a chemical is to be accumulated in biota tissue or to bind to soil and sediments. Other more specific measures (K_{oc} and BCF) can also be used to describe these tendencies.

Organic Carbon/Water Partition Coefficient (K_{oc}). This partition coefficient describes the tendency of a chemical to partition to either organic carbon or water. It is useful as an indicator of whether a chemical will bind strongly to soils or sediments or will leach/migrate to interstitial water. The higher the K_{oc} value, the more strongly the chemical will bind to organic carbon in soil or sediment and the less likely it will partition to water.

Bioconcentration Factor (BCF). This value is a measured value describing the accumulation of a chemical from a water column to biota tissue. The actual BCF factor for a chemical depends upon the experimental design or field conditions, the biota tissue being considered, and other factors. Higher BCF values indicate a greater tendency for the chemical to accumulate in biota. BCFs are often approximated from a chemical's log K_{ow} value by the application of published regression equations.

Bioaccumulation Factor (BAF). This value is a measured value describing the net accumulation by an organism as a result of uptake from all routes of exposure. Organic chemicals with log K_{ow} coefficients greater than 4.3 to 5 are likely to have significant food-chain input to accumulation by fish.

Biomagnification Factor (BMF). This value is a measured or modeled value describing the net magnification of a chemical through dietary accumulation to the highest level in a food web. Biomagnification is the phenomenon by which chemicals occur at higher concentrations in organisms at higher trophic levels. Mercury and the organochlorine pesticides are generally recognized for their strong tendency to biomagnify through terrestrial food webs; selenium has recently been recognized to biomagnify through aquatic food webs (Lemly 1993).

EXHIBIT 11

DETERMINATION OF CURRENT AND FUTURE LAND USE

The identification of current and future land use will impact the potential exposure pathways that may be plausible for a site and also the potentially exposed receptors and the magnitude and frequency of their exposure. One or several land uses may be appropriate for assessing potential risks under current and future exposures.

Common types of land use include:

- Agricultural.
- Residential.
- Commercial.
- Industrial.
- Recreational.
- Mining.
- Mixed.
- Unused.

In many cases, land use of an area is mixed. In these cases, multiple current land uses, including the more conservative land use (i.e., the one that results in the highest degree of potential exposure), can be assumed for the assessment.

Current land use can be determined through observation. More detail may be obtained from zoning maps, aerial photographs, and land use reports. When selecting a current land use, that land use should be valid for the exposure period being assessed, e.g. 30 years. If the current use is anticipated to change within the exposure period, the newer land use, or both, should be assessed.

Future land use can often be inferred by the current site use and use of land surrounding the site. Land use projections from the local planning commission and census projections can provide information on potential future land use. The current owners or users should be questioned regarding their intended future use of the land, and about the length of time in which their current ownership/usership extends. In some cases, such as on Federal lands, long-term ownership and the control of future land use can be controlled.

The assumption of future residential use of a site, while certainly conservative, is not necessarily the most appropriate assumption, if information exists to support a more likely alternate future land use. However, assumed future residential use may be appropriate if there are no compelling reasons to assume an alternate use. If the future land use is unclear, or if different future land uses are equally plausible, assessment of the different options can be performed. In these cases, it is necessary to comprehensively discuss the reasons for the plausibility (and implausibility) of each assessed option.

EXHIBIT 12

POTENTIAL EXPOSURE PATHWAYS AND ROUTES

TERRESTRIAL ECOSYSTEMS

Direct Exposure		
Exposure to Surface Water	•	Ingestion by wildlife
	•	Uptake by plants
	•	Dermal contact by (submergent) wildlife
Exposure to Sediments	•	Incidental ingestion
	•	Uptake (sediment solution) by plants
Exposure to Soils	•	Dermal contact by soil-dependent organisms
	•	Ingestion by invertebrates
	•	Incidental ingestion
	•	Dermal contact by burrowing wildlife
	•	Uptake (soil solution) by plants
Exposure to Air	•	Inhalation of volatile surface water components
	•	Inhalation of volatile sediment components
	•	Inhalation of entrained sediment particles (if dry)
	•	Inhalation of volatile soil components
	•	Inhalation of entrained soil particles
	•	Deposition on or uptake by plants
	•	Active or passive uptake by plants
Indirect Exposure		
	•	Ingestion of food or prey items

AQUATIC RECEPTORS

Direct Exposure		
Surface Water	•	Dermal contact/bioconcentration by aquatic organisms
Sediments	•	Dermal contact/bioconcentration by sediment (benthic) dwelling organisms
	•	Ingestion by sediment dwelling organisms
Indirect Exposure		
	•	Ingestion of food or prey items

EXHIBIT 13

GENERAL FACTORS TO CONSIDER

WHEN DERIVING EXPOSURE POINT CONCENTRATIONS

- Exposure point estimates should be based on *the appropriate form of the medium* that is likely to be contacted. Unfiltered water samples should be used for assessing animal intake. If plant consumption by herbivores is being assessed (Tier II), data on the unwashed leafy portion of the plant should be used rather than washed, whole plant samples.
- The exposure point estimate should reflect *the exposure area* that is potentially contacted by the receptor. In some instances, it may be appropriate to use all available site data (exclusive of background and/offsite data); in other instances, a subset of the data may be more appropriate. Chemical data from an area of the site that is impacted should not always be combined with data from unimpacted areas, particularly if the impacted area is discrete (i.e., if it is localized). If contamination is widespread spatially, but some sampling locations within the widely contaminated area are reported as nondetected, these data can be combined, since they reflect the variation of chemical concentrations within the impacted area.
- The exposure point estimate should reflect the actual *depth or interval of the medium* that is relevant to the exposure pathway. Exposure point concentrations for soil and sediments should reflect the depth interval and location that are potentially available for contact, and should not combine data results from depths or areas that are not likely to be contacted. For example, dabbling waterfowl (e.g., mallards) generally feed in the more shallow or nearshore areas of a water body. Sediment samples below 2 inches or those from the deeper portions of the lake should not be included in the calculation of direct sediment ingestion. Likewise, burrowing mammals are limited in the depth to which they burrow (typically less than 5 feet). These depths will vary according to ecoregion and soil type. Chemical data from samples collected at depths greater than 5 feet are probably not appropriate for use in calculating exposure concentrations for such receptors in any ecoregion.
- The exposure point estimate should consider *temporal changes* in the chemical concentration over the exposure period. Certain chemicals may decrease in concentration over time in a specific medium, or migrate to another medium, as a result of its fate and transport characteristics. In such instances, estimation of the chemical concentration decline with time is appropriate.
- Exposure point concentrations should be developed *for COECs only.*
- Exposure point concentrations should *not include results from Laboratory QA/QC samples.* Laboratory duplicate/replicate analysis, spikes, and blanks should not be combined with site data. Results of spikes and blanks are not relevant to the site. The original sample results and field duplicates should not both be used as inclusion may skew the average toward concentrations at locations where duplicate analyses were collected by representing these locations more than once. Generally, either the higher or the average of the two quantitations is used.

EXHIBIT 14

CALCULATION OF THE 95% UPPER CONFIDENCE LIMIT

As part of several aspects of data review and interpretation (examination of precision, estimation of average and upper bound chemical concentrations) an assumption must be made regarding the frequency distribution of the data. Application of statistical tests, such as the "W" test, can test for normality or log-normality (Gilbert 1987). In some cases, presentation of the data graphically as frequency histograms may be sufficient to identify a reasonable frequency distribution.

EPA has indicated that, in the absence of information supporting a normal or other frequency distribution, a log-normal distribution should be assumed (EPA 1992h). Summary statistics for the data should be derived by performing a log transformation of the data and averaging to derive the geometric mean and 95% UCL on the arithmetic mean, as described in the EPA directive (EPA, 1992h)

$$UL_{1-\alpha} = \exp\left(y + 0.5s_y^2 + \left[\frac{(s_y H_{1-\alpha})}{(n-1)^{1/2}}\right]\right)$$

where

$UL_{1-\alpha}$	=	the upper confidence limit (where α is 0.05, the 95% upper confidence limit)
y	=	the mean of the log-transformed data (Σy_i, where $y_i = \ln x_i$) (where exp(y) = sample mean)
s_y	=	the standard deviation of the log-transformed data
s^2_y	=	the variance of the log-transformed data
$H_{1-\alpha}$	=	the "H" statistic (Tables A10-A13 of Gilbert [1987])
n	=	number of samples

If a normal distribution can be demonstrated by application of the "W" test, frequency histograms, or other method, the 95% UCL can be calculated using the student's "t" distribution.

$$UCL_{1-\alpha} = x + \left(\frac{t_{1-\alpha}}{2, n-1}\right)\left(\frac{s}{n^{1/2}}\right)$$

where

x	=	arithmetic mean of the data
$t_{1-\alpha/2, n-1}$	=	"t" statistic at n-1 degrees of freedom (Table A2 in Gilbert [1987])
n	=	number of samples
s	=	sample standard deviation

EXHIBIT 15

ALLOMETRIC EQUATIONS FOR DETERMINING WILDLIFE FEEDING AND DRINKING RATES

FOOD INGESTION RATES

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)	
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 equals the body weight (wet) of the animal in grams (g) or kilograms (kg) as indicated. For more accurate estimates of food requirements, EPA recommends using estimates of free-living (or field) metabolic rate (FMR), dietary composition, and assimilation efficiency (AE) for the species of interest as outlined in EPA's *Wildlife Exposure Factors Handbook* (EPA 1993e).

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)	
FI (g/day) = 0.621 $Wt^{0.564}$ (g)	Rodents
FI (g/day) = 0.577 $Wt^{0.727}$ (g)	Herbivores

EPA (1988k) 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

Reptiles and Amphibians

Nagy (1987) developed the following equations for calculating FI rates (in grams dry matter per day):

FI (g/day) = 0.019 $Wt^{0.841}$ (g)	Herbivores
FI (g/day) = 0.013 $Wt^{0.773}$ (g)	Insectivores

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

EXHIBIT 15

(Concluded)

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:

$$WI\ (g/g\text{-}day) = WI\ (kg/kg\text{-}day),\ or$$

$$= WI\ (L/day)/Wt\ (kg)$$

In general, birds drink less water than do mammals of equivalent body weights. Because of their relatively high metabolic rates, the quantity of metabolic water produced by birds is greater in relationship to body size than that produced by other vertebrates (Bartholomew and Cade 1963).

Mammals

Calder and Braun (1983) developed the following allometric equation for drinking water ingestion (WI) for mammals:

$$WI\ (L/day) = 0.099\ Wt^{0.90}\ (kg) \qquad \text{All mammals}$$

where Wt equals 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 (1988k) also provides the following equations for this calculation:

$$WI\ (L/day) = 0.10\ (Wt)^{0.7377}\ (kg) \qquad \text{Laboratory mammals}$$

$$WI\ (L/day) = 0.009\ (Wt)^{1.2044}\ (kg) \qquad \text{Mammals, moist diet}$$

$$WI\ (L/day) = 0.093\ (Wt)^{0.7584}\ (kg) \qquad \text{Mammals, dry diet}$$

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:

$$NWI\ (g/g\text{-}day) = WI\ (kg/kg\text{-}day),\ or$$

$$= WI\ (L/day)/Wt\ (kg)$$

Reptiles and Amphibians

Allometric equations relating body weight to drinking water ingestion rates are not available from EPA for reptiles and amphibians. The water balance of these groups is complex, in part because they can absorb water through their skin as well as drink water and extract water from their food. The relative contribution of these three routes of water intake depends on the species, habitat, temperature, and body surface area. In general, the skin of reptiles is less permeable than that of amphibians. Aquatic turtles (e.g., snapping turtle, painted turtle) also may ingest large amounts of water when feeding on aquatic plants and animals; however, the magnitude of such ingestion has not been quantified. For further discussion of water balance for these groups, see EPA (1993e).

EXHIBIT 16

GENERAL FACTORS TO CONSIDER WHEN SELECTING EXPOSURE FACTORS

- Select site-specific values when available. To best describe the ecological risks posed by chemicals at a specific area, exposure factors that best describe the actual or potential exposure conditions should be used. EPA has recently published the *Wildlife Exposure Factors Handbook* (EPA 1993e) which provides data, references, and guidance for conducting exposure assessments for wildlife species exposed to toxic chemicals in their environment. Site-specific factors that influence exposure or intake factors (chemical type, exposure frequency, degree of site access) should be considered whenever possible.
- Select values appropriate to the exposure pathway. The exposure factors selected should best reflect the exposure pathways being assessed. For example, if the contaminated site occupies only a small portion of the animal's home range, then appropriate exposure modifying factors should be applied to the intake equation to account for area use or exposure frequency.
- Select values appropriate to the medium being assessed. The conditions or state of the environmental medium being contacted should be considered. For example, earthworms may not be present at a site due to soil or climatic conditions. Direct ingestion of fine, silty, soil particles as grit for birds is much less likely than ingestion of larger sized particles; grit ingestion would be unlikely where soil is covered with dense vegetation. Some modification of the amount of soil ingested may thus be appropriate.
- Select values appropriate to the receptor being assessed. Receptor-specific factors should be considered in relation to site-specific conditions. Receptor-specific contact (intake) rate factors need to be applied for each specific abiotic (water, soil, sediment) or biotic (food) media. Intake and exposure modifying factors for different life stages (adult and young) may need to be assessed for some receptors.

EXHIBIT 17

TOXICITY EQUIVALENCY FACTORS (TEFs) FOR POLYCHLORINATED DIBENZO-p-DIOXINS (PCDDs) AND DIBENZOFURANS (PCDFs)

PCDDs			PCDFs		
	TEFs			TEFs	
Congener	EPA (1989m)	Safe (1990)	Congener	EPA (1989m)	Safe (1990)
2,3,7,8-TCDD	1	1	2,3,7,8-TCDF	0.1	0.1
1,2,3,7,8-PeCDD	0.5	0.5	2,3,4,7,8-PeCDF	0.5	0.5
1,2,3,4,7,8-HxCDD	0.1	0.1	1,2,3,7,8-PeCDF	0.05	0.1[(1)]
1,2,3,6,7,8-HxCDD	0.1	0.1	1,2,3,4,7,8-HxCDF	0.1	0.1
1,2,3,7,8,9-HxCDD	0.1	0.1	2,3,4,6,7,8-HxCDF	0.1	0.1
1,2,3,4,6,7,8-HpCDD	0.01	0.01	1,2,3,6,7,8-HxCDF	0.1	0.1
OCDD	0.001	0.001	1,2,3,7,8,9-HxCDF	0.1	0.1
Other PCDDs	0	N/L	1,2,3,4,6,7,8-HpCDF	0.01	0.1[(1)]
			1,2,3,4,7,8,9-HpCDF	0.01	0.1[(1)]
			OCDF	0.001	0.001
			Other PCDFs	0	N/L

Sources:

EPA (1995b)

Safe (1990) — NATO/CCMS TEFs from Tables 10 and 13.

[(1)] Recommended adjustment of NATO/CCMS TEF by Safe (1990).

N/L = Not Listed

EXHIBIT 18

TIERED APPROACH TO ASSESSMENT OF SEDIMENT QUALITY AND CHARACTERIZATION OF RISK TO AQUATIC LIFE

The characterization of ecological risk due to sediment contamination is highly complex, as many site-specific parameters need to be considered. Such factors include bioavailability; sorption kinetics; sediment characteristics; sediment deposition, erosion, and compaction; bioturbation; and temporal and spatial differences (Adams, Kimberle, and Barnett 1992). Due to this complexity, a tiered approach to assessing environmental risk from contaminated sediments should be used, allowing for periodic decision-making. This exhibit presents an example of how the four-tiered USACE ERA approach may be implemented to assess sediment quality. A flow diagram of this process is shown in Figure 5-1.

Tier I - Preliminary Ecological Risk Assessment

The purpose of Tier I is to provide a rapid screen for potential impacts and thereby eliminate the need for further testing, if possible. In the Tier I decision sequence, the first possibility is that more information is required to identify potential COECs in sediments or to determine compliance with identified ARARs. In some situations, biological effects-based criteria (bioassays) are required to determine the presence of COECs, to assess impacts on appropriate sensitive marine organisms, and to determine limiting permissible concentrations (40 CFR, Part 227.13, Federal Regulations on Ocean Dumping of Dredged Sediments).

Assessment of ecological risks related to sediments may also begin in Tier I by using available sediment criteria or derived sediment assessment values (SAVs) to evaluate site-related chemical concentrations in sediments. SAVs may be obtained by employing a variety of methods, such as the equilibrium partitioning (EP) approach for nonionic (nonpolar) organics, AVS normalization method for metals, cation exchange capacity (CEC) or critical micelle concentration methods for ionic organics, AET approach, or the biological effects-based, sediment quality triad (SQT) approach (biological tests are considered Tier II methods).

EPA (1989m) has published analysis of current methods available to assess sediment quality in *Sediment Classification Methods Compendium*. Newer methods are also published in recent literature. 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. A comparison of various methods for assessing sediment quality (Adams, Kimberle, and Barnette 1992) is shown in Table 5-1.

If the SAVs are exceeded by the sediment chemical concentrations, indicating potential for significant ecological risk, then additional assessment of the sediment may be appropriate and a Tier II ERA would be initiated. A Tier II ERA may also be initiated if the sediments standards are slightly less or slightly greater than sediment chemical concentrations, but the margin of safety is deemed too small (HI < 10), in order to adequately characterize risk. The decision to proceed with a Tier II ERA to address sediments may also be made early in the Tier I ERA process, when suitable SAVs are determined to be unavailable or inadequate for characterizing site-specific risks from the COECs. Tier II toxicity testing may also be recommended when synergistic effects are suspected between the contaminants. After consideration of all information available at the end of Tier I, one of the following conclusions is reached:

- Existing information provides a sufficient basis for characterizing and interpreting ecological risk, and is relevant to the choice of remedial actions or other decisions.
- Existing information on the sediment and associated biota provides neither the sufficient basis for characterizing and interpreting ecological risk nor the ability to determine whether the ecological effects are relevant to the choice of remedial actions or other decisions. In this case, further evaluation in Tiers II, III, and/or IV is appropriate.

EXHIBIT 18

(Continued)

Tier II - Focused Biological Evaluation and Sampling

Where the margin of safety is small, or no standards are available, limited aquatic toxicity testing, biota community characterization, or bioaccumulation estimation and testing may be desired. As part of this assessment, the determination is made whether the sediments contain chemicals in amounts toxic to aquatic organisms or whether chemicals with a high potential to bioaccumulate are below levels of concern. Tier II testing would typically include lethality as the measurement endpoint because lethality is easily interpreted and quantified, and is inexpensive. Tier II bioassays are primarily acute tests using organisms representative of the water-column and benthic environments at the site such as minnows and daphnia (water fleas) in freshwater. Tier II bioaccumulation tests may be used to more fully evaluate potential adverse effects on food webs. Tier II bioaccumulation tests may include such procedures as the EPA and USACE (EPA 1991g) 10-day (metals) or 28-day (organic or organometallic compounds) exposure test on benthic organisms for assessing bioaccumulation and toxicity potential.

Additional chemical or biological (bioassay) testing may be required to define the zone or magnitude of the area that is impacted by the COECs. If the area is determined to be larger than expected, then additional sampling or testing (Tier III) would be considered. If the impacted area is small, and an adequate risk characterization may be performed, then no additional tiers would be required and remediation could be performed, if necessary.

Tier III - Expanded Sampling Program

Where significant impacts are suspected, additional in-depth testing may be needed to confirm long-term effects of chemical exposure on aquatic life populations or to delineate the movement of chemicals through the food web to other organisms. Tier III might include the performance of a variety of tests, including multispecies chronic toxicity tests, spiked sediment bioassays, infaunal investigations, bioaccumulation/bioconcentration measurements, and toxicity identification evaluations (Adams, Kimberle, and Barnett 1992). Tier III testing might also include an AET evaluation or a SQT analysis, and calculation of a site-specific sediment quality criterion, when appropriate. In any case, because of the limited availability of standardized and appropriate procedures for Tier III, tests should be carefully selected to address site-specific issues. Whatever the Tier III test, evaluative criteria should be determined in advance and should be agreed upon by all involved parties.

The Tier III tests and bioassays should measure sensitive indicators of long-term effects of clear ecological importance, such as survival, reproduction and, perhaps, the time to onset of reproduction. Tier III tests may be longer and more expensive than the Tier II tests, and might simulate exposure conditions at the contaminated site and reference area. Tier III tests should also maximize exposure to sediment-associated contaminants by focusing on infaunal organisms.

Tier IV - Monitoring Program

Depending on project planning strategy and objectives, a more long-term, effort-intensive Tier IV ERA may be desired. The Tier IV ERA could include performance of chronic bioassays with a diverse array of marine or freshwater organisms over longer durations than used in Tier II or Tier III. Tier IV testing may also be appropriate when data are needed to evaluate long-term, steady-state, bioaccumulation potentials for a variety of COECs and biota. As was the case in Tiers II and III, tests should be carefully selected to address site-specific issues.

EXHIBIT 18

(Concluded)

The need to test for effects at the ecosystem level may also necessitate a Tier IV effort. Tests of toxic effects at the ecosystem level include field or laboratory tests of interactions between species, or microcosm and mesocosm tests. Microcosms are laboratory systems that are intended to physically simulate an ecosystem or a major subsystem of an ecosystem, while permitting control of conditions and replication of treatments at reasonable cost (Suter 1993). Mesocosms are outdoor experimental systems that offer more realism than microcosms, but are less convenient, more expensive, and more subject to catastrophic agents such as extreme weather (Suter 1993). Tier IV planning objectives and data needs could also require the development of mathematical ecosystem models to examine ecosystem perturbations that cannot be addressed experimentally, due to either the severity of the expected impacts or to the scale of the necessary experiment (Suter 1993). A variety of such mathematical ecosystem models are available or are currently under development. Such models are designed to address such attributes as energy flow, material cycling, and food web assembly (Suter 1993). Development of such models could also include additional validation and calibration for chemical and/or biological sampling.

EXHIBIT 19

AN EXAMPLE OF DEVELOPMENT OF REMEDIATION LEVELS

FOR TERRESTRIAL RECEPTORS

The baseline risk assessment for a site has indicated that lead in sand at this remote beach site may pose unacceptable ecological risks to the endangered albatross. Calculation of the remediation level (RL) at the site (i.e., the anticipated RTV or no-effect chemical concentration in the sand expressed as mg-chemical/kg-sand) uses the NOEL dose (mg-lead/kg-bw/day), albatross body weight (kg), sand intake factor (kg/day), exposure modifying factors (the exposure modifying factors are area use and exposure frequency), a sand matrix effects factor (MEF) in the following equation:

No-Effect Concentration = [(RTV) (Body Weight)]/ [(Sand Intake)(EMF)(MEF)]

The basis for factors used in the preceding equation are as follows:

Body Weight of Albatross: Adult = 2.8 kg Chick = 1.4 kg

Sand Ingestion by Albatross:

Data on sand ingestion rates for albatross are lacking. Estimates of sand ingestion rates for the albatross must therefore be made on the basis of ecological and behavioral information. Direct ingestion of sand by seabirds is likely to be limited to incidental ingestion during activities such as burrowing, preening, and nesting., Since piscivorous seabirds do not have functional gizzards, they do not ingest grit and therefore do not routinely ingest sand. Albatross chicks, however, may ingest sand incidental to pecking at small items near their nest site. Because the albatross is unlikely to feed in nearshore water or along the beach, it is very unlikely that they would ingest any sand containing lead incidental to feeding activities. In view of these behavior patterns, potential ingestion of sand by the albatross is limited to the time spent nesting on the beach.

Food intake rates for piscivorous birds such as the albatross are approximately 20% of body weight or 0.56 kg and 0.28 kg, respectively, for the adult and chick albatross. Experts on albatross behavior estimate sand ingestion by adult or chick albatross to be less than 1 gram per day (approximately 0.2 to 0.4 percent of food intake). For this assessment, a maximum sand ingestion rate of 1 gram/day is assumed.

Exposure Modifying Factors:

Exposure Frequency: The adult albatross spends 40% of its time on this beach; the chick albatross is assumed to have an exposure frequency of 100%.

Sand Matrix Effects Factor (MEF):

It is unknown what percentage of lead in sand is tightly bound to the sand due to matrix effects and consequently is not absorbed by an albatross ingesting the sand. Lead is likely to be strongly absorbed onto soils (Eisler 1988) and the bioavailable fraction is likely to be 50% or less depending on factors such as percent organic carbon in soil, size of soil particles, and soil pH, among others. The sand at this beach has a low percentage of organic carbon (0.3%); therefore it may be conservatively assumed that 75% of the lead attached to the sand is bioavailable.

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(Concluded)

Reference Toxicity Value (RTV) for Lead:

A wide range of NOEL and LOEL doses for birds has been reported in the literature and is summarized in Eisler (1988). In view of the large number of studies of lead toxicity to birds and the wide range of sensitivities of birds to lead, the NOEL dose selected for lead in the albatross is 2.0 mg/kg-bw/d. This conservative NOEL dose is based on the reported chronic (5 months) NOEL diet of 10 mg/kg metallic lead for the American kestrel (Franson et al. 1983). The NOEL dietary value of 10 mg/kg for the American kestrel is converted to a NOEL dose value of 2 mg/kg-bw/d by assuming the kestrel's diet is 20% of its body weight; e.g., NOEL dose = NOEL diet x (food intake/body weight). The selected NOEL dose is not multiplied by an uncertainty factor because of the large number of data available for birds (Newell, Johnson, and Allen 1987) and the fact that 2.0 mg/kg-bw/d is one of the lowest reported NOEL doses (Eisler 1988).

Remedial Level Calculation:

Using the above algorithm and intake factors, the lead remedial level for this site is calculated as follows:

RL for albatross adult = [(2.0 mg/kg-bw/d)(2.8 kg-bw)]/
[(0.001 kg-sand/day) (0.4)(0.75)] = 18,666 mg/kg lead

RL for albatross chick =[(2.0 mg/kg-bw/d)(1.4 kg-bw)]/
[(0.001 kg-sand/day) (1)(0.75)] = 3733 mg/kg lead

Note that regulatory values, if available and considered as an ARAR, may take precedence over risk-based remedial level. This is one example of how risk assessment interacts with risk management decisions.

EXHIBIT 20

DEVELOPMENT OF REMEDIATION GOALS FOR AQUATIC-BASED WILDLIFE RECEPTORS

Water criteria for the protection of avian and mammalian wildlife that utilize water of the Great Lakes System as a drinking and/or foraging source have been recently published by EPA (1995b) as part of the GLWI. These criteria as well as the process used in the development of the wildlife protective water concentrations can be applied in the derivation of remediation goals for sites where there are similar avian and mammalian wildlife. Five Great Lakes basin wildlife species representative of avian and mammalian species resident in the Great Lakes basin which are likely to experience significant exposure to contaminants through the aquatic food web were identified. These species are the bald eagle, osprey, belted kingfisher, mink, and river otter. A wildlife value (WV) (safe concentrations of a given pollutant) is calculated for each of these species and then the geometric mean of these values within each taxonomic class is determined. The Great Lakes Water Criterion (GLWC) is the lower of two class-specific means.

To derive the WVs from which the GLWC is determined, scientific literature for the toxicant of concern is reviewed for mammalian and avian toxicity studies that meet the minimum toxicity database requirements. The equation used to calculate the WV, and ultimately the GLWC, has both a hazard and exposure component. The hazard component contains the NOAEL--the highest tested dose of a substance which does not result in an observed adverse effect. The exposure routes considered in this derivation are food and water ingestion. The intake level is dependent on organism size and therefore it is scaled to body weight. The total toxicant intake through these exposure routes is determined and then set equal to the NOAEL as follows:

$$\text{Chemical intake from drinking water} = (WV \times WI)/BW \quad (1)$$

$$\text{Chemical intake from food} = (WV \times FI \times BAF)/BW \quad (2)$$

where

WV = safe wildlife value in mg/L

W = water intake for the most sensitive species (L/d)

BW = body weight for the most sensitive species (kg)

FI = food intake by the most sensitive species (kg/d)

BAF = aquatic life bioaccumulation factor for wildlife (L/kg)

Equations 1 and 2 are combined to yield:

$$NOAEL > (WV \times WI)/BW + (WV \times FI \times BAF)/BW$$

where

NOAEL = no observed adverse effects level in milligrams of substance per kilogram of body weight per day (mg-chem/kg-bw/d) as derived from mammalian and avian toxicity studies.

Factoring and rearranging equations

$$WV < (NOAEL \times BW) / [WI + (FI \times BAF)]$$

To account for difference in toxicity among species the NOAEL is multiplied by a species sensitivity (uncertainty) factor (SSF). The final equation for the wildlife water criterion is

$$WV = [(NOAEL \times SSF) \times BW] / [WI + (FI \times BAF)]$$

EXHIBIT 21

A CASE EXAMPLE STUDY FOR RISK ASSESSMENT IN REMOVAL ACTION DECISION-MAKING

Site XYZ, an IRP site on the proposed NPL, has an onsite landfill containing an unknown number of drums. A shallow drum was uncovered which contained high concentrations of trichloroethene, other VOCs, barium, and mercury. The basis for the NPL is both human health and environment. EPA suggested that there was a concern for groundwater (GW) migration to offsite residential wells; it also suggested that there was a concern for the surface runoff and shallow groundwater discharge to an adjacent stream, a river tributary. EPA felt that although drinking water intake is over 100 miles away, it was concerned about the impact of the GW discharge to aquatic species.

A Screening Risk Assessment. Environmental mapping, literature search, and consultation with a local university uncovered the following: moderate resources for aquatic species (sunfish); two species of ecological concern (one endangered and one threatened; both listed by the State); both fish may contact and ingest sediments; no fish kill episodes (in fact fishing has been good in that stretch of the river mile); VOCs could quickly dissipate or be diluted by forces of the stream and river flow; metals, however, will settle and adsorb to stream and river sediments; purposive groundwater seep samples (one round) by the streambank indicated that there was some exceedences of the Federal AWQC and the State criteria for the one VOC and mercury. The seep samples also had exceeded some human health criteria (the Maximum Contaminant Level).

Risk Management Decision-Making. At this early project phase, the decisions to be made are: "Should the site be eliminated or should removal action be taken to quickly reduce the principal threat to human health and the environment?" Since the site was scored above 28.5 with the revised HRS, and the ecological pathway was a substantial contributor to the site scoring, the customer decided that some action would be appropriate to address site risk. The anticipated option (preferred by the customer) is to eventually cap the landfill (a presumptive remedy) and limit the remedial investigation and work plan preparation (both are costly activities). The removal actions considered were drum removal; provision of bottled water to offsite residents; surface water diversion away from the stream or channels leading to the streams; capping the landfill; site groundwater and groundwater seep monitoring; installation of groundwater capture wells onsite; and installation of GAC (granulated activated carbon) water treatment systems at all potentially affected downgradient residential homes. Other options include further sampling, RI, no removal, and NFA.

Removal Action Implementation and Strategy Development. The customer is committed to certain removal action because it is consistent with the final remedy for similar site types and has the potential benefit of narrowing the scope of the RI and reduce site risk risks. Based on EE/CA and a qualitative risk evaluation of potential removal actions, the risk manager (PM in this case), the risk assessors (human health and ecological), and other project team members (chemist, engineer, geologist, ecologist, compliance specialist, etc.) decided to recommend these options to the customer: (1) performing limited drilling/excavation and sample collection; and (2) testing the drum contents and contaminated soil for chemistry, reactivity, and explosivity. If testing indicated there is not a potential risk of explosion, excavation/drum removal would be conducted to remove the source of contamination. Four groundwater monitoring wells will be installed to determine groundwater quality to ascertain plume direction and quality. The site will be regraded after drum removal to divert surface water runoff away from the stream.

Summary. The removal action will remove the primary contamination source, monitor site condition, and substantially reduce both the human health and ecological threats. The customer has determined that the site cannot be eliminated, and may need further evaluation. Since the anticipated remedy will reduce the degree of exposure to ecological species and direct contact of the site soils by humans (and terrestrial receptors), this interim remedial action is taken and will also become the final remedy. The customer could have chosen further evaluation of the impact by, for example, development of benchmark toxicity values (for the sunfish) or laboratory and(or) in-situ bioassays; the customer felt that the cost of capping was not considered to be unacceptable, particularly when compared with the costs of the baseline ERA and uncertainty of such evaluations for this small site.

EXHIBIT 22

A CASE EXAMPLE STUDY FOR SCREENING RISK ANALYSES

OF RESIDUAL RISKS FS OR CMS RISK MANAGEMENT DECISION-MAKING

Site XYZ (a Federal site with EPA-Customer IAG only) had an onsite landfill containing an unknown number of drums. Removal actions had been taken at this site which included excavation of drums containing trichloroethene and other VOCs, mercury, and barium. Periodic perimeter well groundwater/groundwater seep monitoring and surface water diversion away from the site have also been instituted as part of the removal action. The groundwater plume intersects a stream which is a tributary to a river, a favorite fishing spot for the local residents. The lower aquifer is not threatened by the onsite plume. Groundwater seep samples (4 rounds) indicated that there were sporadic exceedences of seep water with the Federal AWQC and the state criteria for the river mile for the VOCs and mercury for all rounds. The fish, which is primarily bluegill sunfish, commonly caught for recreational purposes are found in the stream and in the river. However, two aquatic species, the bluehead shiner (*Notropis hubbsi*), a feeder of zooplankton along the shoreline, and Longnose sucker (*Catostomus catostomus*), a bottom feeder, have been found in the river downstream from the tributary/river confluence. The former is on the state endangered species list while the latter is a state threatened species. Bluegill sunfish is considered by the state as an aquatic resource of moderate value, and the benthic macroinvertebrates are classified as of limited resource value. A comparison between the upstream (reference) and downstream locations indicated no significant difference in abundance, size, and age between these two locations. However, samples of sediments and macroinvertebrates indicated an increased level of mercury immediately downstream of the site location.

Potential Remedial Alternatives Being Evaluated. Capping the landfill to minimize leaching of COECs from the impacted subsurface soils to groundwater; installation of groundwater capture wells onsite to create a cone of hydraulic depression to keep the plume from migrating offsite plus air stripping/metal precipitation of the captured groundwater; and no-further action/monitoring only. The remedial objective was to protect aquatic ecological receptors of concern in the river.

Screening Analyses of Alternatives. The following findings were presented to the risk manager for selection of proposed remedies:

Alternative	% Risk Reduction (in terms of %COEC Removed from GW)	Residual Risk	Permanence (fraction remaining)
Clay cap and revegetation	95% (5% estimated infiltration)	5%	Cap replacement in 25 years
Capture well/air stripping	80% of GW VOC	20%	Equipment replacement in 15 to 20 years
No further action/ monitoring only	0% for metals; some for VOCs due to natural attenuation	100-90%	NA; quarterly sampling and $300/seep sample

Analysis. The onsite clay cap will reduce the volume of seep, i.e., loading of COECs to the stream. The capture well plus air stripping-metal precipitation can also afford protection via removal of VOCs and metals. On a mass loading per unit time basis, this alternative does not reduce mass to the same extent as the clay cap (in fact 200 times higher). The last alternative could cost in excess of $120,000 in today's (1995) dollar value, assuming 4 seep samples are collected and analyzed. Although the removal efficiency of VOCs and metals in the water treatment of captured groundwater could be improved by recirculation (multiple path treatment), the cost per unit volume treated (treatment chemicals and maintenance of equipment) is considerably higher than the first alternative, although the initial costs for both alternatives are comparable. The time to replacement for the second alternative is also shorter. The uncertainties associated with the risk reduction and cost analyses are comparable in all three alternatives.

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(Concluded)

Risk Management Decision. Based on the RI and baseline ERA information, the ecological receptors of concern are the state endangered and threatened species. Since these species are not on the Federal list and the state is not a party in the IAG, protection of these species has not been explicitly specified. In other words, EPA and the customer are the risk management decision-makers. Since these species are not sport fish species and the sunfish population has not been impacted, there should be little stakeholders' concern. However, the sediment and macroinvertebrate do have higher mercury contents that would bioconcentrate. The endangered and threatened species co-occur with toxic sediment and could be adversely impacted. The water quality criterion for mercury is one of the lowest; moreover, groundwater seep samples indicate that some samples have exceeded this criterion. The risk management decision made after the RI was that remedial action or corrective action is warranted, despite the fact that protection of the state endangered and threatened species is not legally required. The customer would like to project an image that it is in compliance with Executive Order 12580 (Superfund Implementation). The degree of risk reduction by mass loading basis is highest for the capping/revegetation alternative. This alternative also requires less costly maintenance when compared to the second alternative. Finally, although the initial investment is higher, the benefit over no further action/monitoring is evident. Mercury is a highly toxic and bioaccumulative chemical; the customer feels that it is prudent to take action to reduce risk to two ecological receptors, and project an image of good citizen at a reasonable cost.

Appendix A
References

Bibliographic references (some annotated) on Information Sources (Procedures. Guidance, Methodologies) related to the conduct of an Ecological Risk Assessment are presented in Appendix B.

Adams, Kimberle, and Barrett 1992
Adams, W. J., Kimberle. R. A., and Barnett, J. W., Jr. 1992. "Sediment Quality and Aquatic Life Assessment." *Environ. Sci. Technol.* Vol. 26, No. 10, pp. 1864-1875.

Agency for Toxic Substances and Disease Registry (ATSDR) 1989
Agency for Toxic Substances and Disease Registry (ATSDR). 1989. *Toxicological Profile for Polycyclic Aromatic Hydrocarbons.* Draft. U.S. Department of Health and Human Services, Public Health Service. Pre pared by Clement Associates, Inc. Contract No. 205-88-0608. October.

Agency for Toxic Substances and Disease Registry (ATSDR) 1993
Agency for Toxic Substances and Disease Registry (ATSDR). 1993, *Toxicological Profile for 1,1,1-Trichloroethane.* U.S. Public Health Service. Atlanta, GA.

Alloway 1990
Alloway, B. J. 1990. *Heavy Metals in Soils.* John Wiley and Sons, Inc., New York. 339p.

Amdur, Doull, and Klaasen 1991
Amdur, M. 0., Doull, J., and Klaasen, C. D. (Eds.). 1991. *Casarett and Doull's Toxicology: The Basic Science of Poisons.* 4th Ed. Pergamon Press. New York.

American Petroleum Institute (API) 1993
American Petroleum Institute ***(API).*** 1993. *A Critical Review of Toxicity Values and an Evaluation of the Persistence of Petroleum Products for Use in Natural Resource Damage Assessments.* Washington, DC.

American Society for Testing and Materials (ASTM) 1995
American Society for Testing and Materials (ASTM). 1995. *Cleanup Criteria for Contaminated Soils and Groundwater.* Ed.: Anthony J. Buonicore. ASTM Data Series DS64.

Anderson, Doos, and Rose 1982
Anderson, R. S., Doos, J. E., and Rose, F. L. 1982. "Differential Ability of *Ambystoma tigrinum* Hepatic Microsomes to Produce Mutagenic Metabolites from Polycyclic Aromatic Hydrocarbons and Aromatic Amines." *Cancer Lett.* Vol. 16, pp. 33-41. *In* Eisler 1987.

Ankley, Lodge, Call, Baker, Brooke, Cook, et al. 1992
Ankley, G. T., Lodge, K., Call, D. J., Baker, M. D., Brooke, L. T., Cook, P. M., et al. 1992. "Integrated assessment of contaminated sediments in the Lower Fox River and Green Bay, Wisconsin." *Ecotoxicol. Environ. Safety* 23:46-63.

Barnthouse, Suter, and Rosen 1990
Barnthouse, L. W., Suter, G. W., and Rosen, A. E. 1990. "Risks of Toxic Contaminants to Exploited Fish Populations: Influence of Life History, Data Uncertainty, and Exploitation Intensity." *Environmental Toxicology and Chemistry.* Vol. 9, pp. 297-311. In Hull and Suter 1993.

Barnthouse, Suter, Bartell, Beauchamp, Gardener, Linder, O'Neill, and Rosen 1986
Barnthouse, L. W., Suter, G. W., Bartell, S. M., Beauchamp, J. J., Gardener, R. H., Linder, E., O'Neill, R. V., and Rosen, A. E. 1986. *User's Manual for Ecological Risk Assessment.* Environmental Division. Prepared for Office of Research and Development, EPA. Washington, DC. Publication No. 2679. ORNL-6251.

Bartholomew and Cade 1963
Bartholomew, G. A., and Cade, T. J. 1963. 'The Water Economy of Land Birds." *Auk.* Vol. 80, pp. 504-539. *In* EPA 1993e.

Beyer 1990
Beyer, W. N. 1990. *Evaluating Soil Contamination.* Biological Report. 90(2). U.S. Department of the Interior, Fish and Wildlife Service. Washington. DC.

Beyer and Stafford 1993
Beyer, W. N., and Stafford, C. 1993. "Survey and Evaluation of Contaminants in Earthworms and in Soils Derived from Dredged Material at Confined Disposal Facilities in the Great Lakes Region." *Environmental Monitoring and Assessment.* Vol. 24, pp. 151-165.

Beyer, Stafford, and Best 1993
Beyer, W. N., Stafford, C., and Beat, D. 1993. "Survey and Evaluation of Contaminants in Earthworms from Confined Disposal Facilities for Dredged Material in the Great Lakes." *Environmental Monitoring Assessment.* Vol. 24. pp. 151-165. *In* EPA 1993g.

Beyer, Connor, and Gerould 1994
Beyer, W. N., Connor, E. E., and Gerould, S. 1994. "Estimates of Soil Ingestion by Wildlife." *Journal of Wildlife Management.* Vol. 58. No. 2. pp. 375-382.

Briggs, Bromilow, and Evans 1982
Briggs, G. G.. Bromilow, R. H., and Evans, A. A. 1982. "Relationship Between Lipophilicity and Root Uptake and Translocation of Nonionized Chemicals by Barley." *Pesticide Science.* Vol. 13. pp. 495-504. *In* Hull and Suter 1993.

Burmaster and Anderson 1994
Burmaster, E., and Anderson, P. D. 1994. "Principles of Good Practice for the Use of Monte Carlo Techniques in Human Health and Ecological Risk Assessments." *Risk Analysis.* Vol. 14. No. 4. pp. 4055-419.

Burrows, Rosenblatt, Mitchell, and Partner 1989
Burrows, E. P., Rosenblatt, D. H., Mitchell. W., and Parmer, D. 1989. *Organic Explosives and Related Compounds: Environmental and Health Considerations.* Technical Report 8901. U.S. Army Medical Bioengineering Research and Development Lab, Fort Detrick. Frederick. MD.

Calder III and Braun 1983
Calder III, W. A., and Braun, E. J. 1983. "Scaling of Osmotic Regulation in Mammals and Birds." *American Journal of Physiology.* Vol. 244. pp. 601-606.

Calderbank 1989
Calderbank, A. 1989. 'The Occurrence and Significance of Bound Pesticide Residues in Soil." *Reviews of Environmental Contamination and Toxicology,* Vol. 108. Springer-Verlag. Inc. New York. pp. 71-103.

California Department of Toxic Substances Control (CAL EPA) 1994
California Department of Toxic Substances Control (CAL EPA). 1994. *Guidance for Ecological Risk Assessment at Hazardous Waste Sites and Permitted Facilities.* Part A: Overview: Part B: Scoping Assessment; State of California, California Environmental Protection Agency.

Callahan, Shirazi, and Neuhauser 1994
Callahan, C. A., Shirazi, M. A., and Neuhauser, E. F. 1994. "Comparative Toxicity of Chemicals to Earthworms." *Environmental Toxicology and Chemistry.* Vol. 13. No. 2. pp. 291-298.

Canada Council of Ministers of the Environment (CCME) 1995
Canada Council of Ministers of the Environment (CCME). 1995. *Protocol for the Derivation of Canadian Sediment Quality Guidelines for the Protection of Aquatic Life.* Guidelines Division, Evaluation and Interpretation Branch, Environment Canada, Ottawa. Report CCME-98E. March.

Cataldo, Harvey, and Fellows 1990
Cataldo, D. A., Harvey, S. D., and Fellows, R. J. 1990. *An Evaluation of the Environmental Fates and Behavior of Munitions Material (TNT, RDX) in Soil and Plant Systems.* Project No. 88PP8853. Pacific Northwest Laboratory. Richland, WA.

Chapman 1989
Chapman, P. M. 1989. "Current Approaches to Developing Sediment Quality Criteria." *Environmental Toxicology and Chemistry.* Vol. 8. pp. 589-599.

Clayton and Clayton 1981
Clayton, G. D., and Clayton, F. E., (Eds.). 1981. *Patty's Industrial Hygiene and Toxicology: Volume 2B - Toxicology.* 3rd Ed. John Wiley and Sons. New York.

Cohen 1978
Cohen, J. E. 1978. *Food Webs and Niche Space.* Princeton University Press. Princeton, NJ.

Connell 1989
Connell, D. W. 1989. *Bioaccumulation of Xenobiotic Compounds.* CRC Press. Boca Raton, Florida. *In* Suter 1993.

Conover, Strong, Hickey, and Sander 1985
Conover, S., Strong, K. W., Hickey, T. E., and Sander, F. 1985. "An Evolving Framework for Environmental **Impact** Analysis. I-Methods." *Journal of Environmental Management.* Vol. 21. pp. 343-358.

Debinski and Brussard 1992
Debinski, D. M., and Brussard, P. F. 1992. "Biological Diversity Assessment in Glacier National Park, Montana: I. Sampling Design." *In* McKenzie et al. 1992.

Dietz et al. 1991
Dietz, D. D.. et al. 1991. '"Toxicity Studies of Acetone Administered in the Drinking Water of Rodents." *Fundam. Appl. Toxicol.* 17:347-360. *In* ATSDR 1993.

Duinker, Hillebrand, and Boon 1983
Duinker, J. C., Hillebrand, M. T. J., and Boon, J. P. 1983. "Qrganochlorines in Benthic Invertebrates and Sediments from the Dutch Wadden Sea; Identification of Individual PCB Components." *Neth. J. Sea Res* 17:19-38 (in Eisler 1986).

Dunbabin and Bowmer 1992
Dunbabin, J. *S.*, and Bowmer, K. H. 1992. *Potential Use of Constructed Wetlands for Treatment of Industrial Wastewaters Containing Metals: The Science of the Total Environment* Vol. III.

Edwards 1983
Edwards, N. T. 1983. "Polycyclic Aromatic Hydrocarbons (PAHs) in the Terrestrial Environment - A Review." *J. Environ Qual.* Vol. 12. pp. 427-441. In ATSDR 1989.

Eisler 1986
Eisler, R. 1986. *Polychlorinated Biphenyl Hazards to Fish, Wildlife, and Invertebrates: A Synoptic Review.* U.S. Department of the Interior Fish and Wildlife Service. Biological Report No. 85(1.7). Contaminant Hazard Reviews. Report No. 11. May.

Eisler 1987
Eisler, R. 1987. *Polycyclic Aromatic Hydrocarbon Hazards to Fish. Wildlife, and Invertebrates: A Synoptic Review.* USFWS. Biological Report No. 85(1.11). Contaminant Hazard Reviews. Report No. 11. May.

Eisler 1988
Eisler, R. 1988. *Lead Hazards to Fish, Wildlife. and Invertebrates: A Synoptic Review.* USFWS Biological Report 85(1.14) Contaminant Hazard Reviews, Report No. 14, April.

Environment Canada 1994
Environment Canada 1994. *A Framework for Ecological Risk Assessment at Contaminated Sites in Canada: Review and Recommendations.* Authors: C. Gaudot (EVS) and ESSA Environmental and Social Systems Analysts. Environmental Quality Division, Evaluation and Interpretation Branch. Ecosystem Conservation Directorate ISBN 0-662-22156-7.

Executive Order 11990 (Presidential Document) May 24, 1977
Executive Order 11990 (Presidential Document). May 24, 1977. Protection of Wetlands. 42 FR 26961.

Executive Order 11988 (Presidential Document) May 24, 1977
Executive Order 11988 (Presidential Document). May 24, 1977. Floodplain Management. 42 FR 26951.

Executive Order 12088 (Presidential Document) October 13, 1978
Executive Order 12088 (Presidential Document). October 13, 1978. Federal Compliance with Pollution Control standards. 43 FR 47707.

Executive Order 12498 (Presidential Document) January 8, 1985
Executive Order 12498 (Presidential Document). January 8, 1985. Regulatory Planning Process. 50 FR 1036.

Executive Order 12580 (Presidential Document) January 29, 1987
Executive Order 12580 (Presidential Document). January 29, 1987. Superfund Implementation. 52 FR 2923.

Executive Order 12777 (Presidential Document) 1991
Executive Order 12777 (Presidential Document). 1991. Implementation of Section 311 of the Federal Water Pollution Control Act of October 18, 1972 and the Oil Pollution Act of 1990.

Executive Order 12898 (Presidential Document) February 16, 1994
Executive Order 12898 (Presidential Document). February 16, 1994. Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations. 59 FR No. 32.

Executive Order 11988 (Presidential Document) 1977
Executive Order 11988 (Presidential Document). 1977. Floodplain Management.

Executive Order 11990 (Presidential Document) 1977
Executive Order 11990 (Presidential Document). 1977. Protection of Wetlands.

Federal Focus Inc. 1994
Federal Focus Inc. 1994. *A Blueprint for Constructing a Credible Environmental Risk Assessment Policy in the 104th Congress.* Washington, DC.

Fordham and Reagan 1991
Fordham, C. L., and Reagan, D. P. 1991. "Pathways Analysis Method for Estimating Water and Sediment Criteria at Hazardous Waste Sites." *Environ. Toxicol. and Chemistry.* Vol. 10. No. 7. pp. 949-960.

Franson, Sileo, Pattee, and Moore 1983
Franson, J. C., Sileo, L., Pattee, O. H., and Moore, J. F. 1983. "Effects of Chronic Dietary Lead in American Kestrels *(Falco sparverius)." J. Wildlife Dig.* 19:100-113. In Eisler 1988.

Gilbert 1987
Gilbert, R. O. 1987. *Statistical Methods for Environmental Pollution Monitoring.* Van Nostrand Reinhold. New York.

Gile, Collins, and Gillet 1982
Gile, J. D., Collins, J. C., and Gillet, J. W. 1982. "Fate and Impact of Wood Preservatives in a Terrestrial Microcosm." *J. Agric. Food Chem.* Vol. 30. pp. 295-301. *In* ATSDR 1989.

Goon, Hatou, Klan, Jernigan, and Farmer 1991
Goon, D., Hatou, N. S., Klan, M. J., Jernigan, J. D., and Farmer, R. G. 1991. "Oral Bioavailability of "Aged" Soil-adsorbed Benzo(a)pyrene (BaP) in Rats." Society of Toxicology Annual Meeting Abstracts #1356.

Cough, Shacklette, and Case 1979
Gough, L. P., Shackle & H. T., and Case, A. A. 1979. *Element Concentrations Toxic to Plants, Animals and Man.* U.S. Geologic Survey Bulletin No. 14. United States Government Printing Office. Washington, DC.

Halvorson 1984
Halvorson, ***C.*** H. 1984. *Long-term Modeling of Small Vertebrates: A Review with Suggestions.* In Morrison 1988.

Henny, Blus, Krynitsky, and Bunck 1984
Henny, C. J., Blus, L. J., Krynitsky, A. J., and Bunck, C. M. 1984. "Current impact of DDE on Black-Crowned Night-Herons in the Intermountain West." *J. Wildl. Manage.* 48:1-13. In Eisler 1986.

Hill 1965
Hill, A. B. 1965. *The Environment and Disease: Association or Causation?* Proceedings of the Royal Society of Medicine. 58:295-300.

Hull and Suter 1993
Hull, R. N., and Suter, G. W. 1993. *Decreasing the Risk of an Unacceptable Ecological Risk Assessment.* Oak Ridge National Laboratory. Environmental Sciences Division, Oak Ridge, TN; and David A. Belluck, Minnesota Pollution ControI Agency, St. Paul, MN.

Hulzebros, Adema, and Dirven-Van Breemen 1993
Hulzebros, E. M., Adema, D. M. M., and Dirven-Van Breemen, E. M. 1993. "Phytotoxicity Studies with *Latuca Sativa* in Soil and Nutrient Solution." *Environmental Toxicology and Chemistry.* Vol. 12. pp. 1709-1094.

Johnson, Huggins, and DeNoyelles, Jr. 1991
Johnson, M. L., Huggins, D. G., and DeNoyelles, F., Jr. 1991. "Ecosystem Modeling with LISREL: A New Approach for Measuring Direct and Indirect Effects." *Ecological Applications.* Vol. 1. No. 4. pp. 383-398.

Jorschgen 1970
Jorschgen, L. J. 1970. "Soil-Food Chain-Pesticide Wildlife Relationships in Aldrin-Treated Fields." *Journal of Wildlife Management.* Vol. 34. No. 1.

Kabata-Pendias and Pendias 1984
Kabata-Pendias, A., and Pendias, H. 1984. *Trace Elements in Soils and Plants.* CRC Press. Boca Raton, FL.

Karr, Fausch, Angermeier, Yant, and Schlosser 1986
Karr, J. R., Fausch, K. D., Angermeier, P. L., Yant, P. R., and Schlosser, I. J. 1986. "Assessing Biological Integrity in Running Waters: A Method and Its Rationale." *Illinois Natural History Survey.* Special Publication No. 5.

Keith 1983
Keith, L. B. 1983. "Role of Food in Hare Populations Cycles." *Oikos* 40: 385-395. In Morrison 1988.

Kimball and Levin 1985
Kimball, K. D., and Levin, S. A. 1985. "Limitations of Laboratory Bioassays: The Need for Ecosystem-Level Testing." *BioScience.* Vol. 35. No. 3.

Layton, Mallon, Mitchell, Hall, et al. 1987
Layton, D., Mallon, B., Mitchell, W., Hall, L., et al. 1987. *Conventional Weapons Demilitarization: A Health and Environmental Effects Data Base Assessment.* Produced by Lawrence Livermore National Laboratory for U.S. Army Medical Research and Development Command, Fort Detrick, Federick, MD. AD/UCRL-21109.

Lemly 1993
Lemly, A. D. 1993. "Guidelines for Evaluating Selenium Data from Aquatic Monitoring and Assessment Studies." *Environmental Monitoring and Assessment* 28:83-100.

Long and Morgan 1990
Long, E. R., and Morgan, L. G. 1990. *The Potential for Biological Effects of Sediment-Sorbed Contaminants Tested in the National Status and Trends Program.* NOAA Technical Memorandum NOS OMA 52. Seattle, WA.

Long, MacDonald, Smith, and Colder 1995
Long, E. R., MacDonald, D. D., Smith, S. L.. and Calder. F. D. 1995. *Incidence of Adverse Biological Effects within Ranges of Chemical Concentrations in Marine and Estuarine Sediments.* Environmental Management, Vol. 19, No. 1, pp. 81-97.

Ludwig and Reynolds 1988
Ludwig, J. A., and Reynolds, J. F. 1988. *Statistical Ecology*. John Wiley and Sons. New York.

MacDonald, Matta, Field, Cairncross, and Munn 1992
MacDonald, D. A., Matta M. B.. Field, L. J.. Cairncross, C., and Munn, M. (EVS Consultants). December 1992. *The Coastal Resource Coordinator's Bioassessment Manual.* NOAA/Hazard Materials Response and Assessment Division (HMRAD), Report No. HAZMAT 93-l. Seattle, WA.

MacDonald 1994
MacDonald, D. D. 1994. *Approach to the Assessment of Sediment Quality in Florida Coastal Waters.* Vol. I: Developmental Evaluation of Sediment Quality Assessment Guidelines. Vol. II: Application of the Sediment Quality Assessment Guidelines. Vol. III: Supporting Documentation: Biological Effects Database for Sediments. Vol. IV: Supporting Documentation: Regional Biological Effects Database for Sediments. Prepared for Florida Dept. of Environmental Rot&ion. Tallahassee, FL. November.

MacIntosh, Suter, and Hoffman 1994
MacIntosh, L., Suter II, G. W., and Hoffman, F. O. 1994. "Uses of Probabilistic Exposure Models in Ecological Risk Assessments of Contaminated Sites." *Risk Analysis.* Vol. 14, No. 4, pp. 405-418.

Massachusetts Department of Environmental Protection (MDEP) 1994
Massachusetts Department of Environmental Protection (MDEP). 1994. *Environmental Risk Characterization Guidance.* January.

Maughan 1993
Maughan. J. T. (1993). *Ecological Assessment of Hazardous Waste Sites.* Van Nostrand Reinhold, New York. **352** p.

McDowell 1992
McDowell, L. R. 1992. *Minerals in Animal and Human Nutrition.* Academic Press, San Diego, CA. 524 pp.

McKenzie, Hyatt, and McDonald 1992
McKenzie, L. D., Hyatt, D., and McDonald, V.. (Eds). 1992. *Ecological Indicators.* Vols. I and II. Elsevier Applied Science. New York.

Morrison 1988
Morrison, M. 1988. '"The Design and Importance of Long-Term Ecological Studies: Analysis of vertebrates in the Inyo-White Mountains, California." In: *Management of Amphibians, Reptiles. and Small Mammals in North America.* Proceedings of Symposium, Flagstaff, Arizona, July 19-21 (1988). U.S. Forest Service, Rocky Mountain Forest and Range Experiment Station, CO.

Mouat, Fox, and Rose 1991
Mouat, D. A., Fox, C. A., and Rose, M. R. 1992. "Ecological Indicator Strategy for Monitoring Arid Ecosystems." *In* McKenzie et al. 1992.

Mueller-Dombois and Ellenberg 1974
Mueller-Dombois, D., and Ellenberg, H. 1974. *Aims and Methods of Vegetation Ecology.* John Wiley and Sons. New York.

Nagy 1987
Nagy, K. A. 1987. "Field Metabolic Rate and Food Requirement Scaling in Mammals and Birds." Ecological Society of America. *Ecological Monographs.* Vol. 57. No. 2. pp. 111-128. Arizona State University, Tempe, AZ.

National Academy of Sciences (NAS) 1980
National Academy of Sciences (NAS). 1980. *Mineral Tolerance of Domestic Animals.* Subcommittee on Mineral Toxicity in Animals. Committee on Animal Nutrition, National Research Council.

National Institute for Occupational Safety and Health (NIOSH) 1987
National Institute for Occupational Safety and Health (NIOSH). 1987. *Registry of Toxic Effects of Chemical Substances (RTECS).* R. J. Lewis and R. L. Tolkin (Eds.). U.S. Department of Health and Human Services, Center for Disease Control. Publ. No. 79-100.

Nationat Oceanic and Atmospheric Administration NOAA) 1992
National Oceanic and Atmospheric Administration ***(NOAA).*** 1992. *The Coastal Resource Coordinator's Bioassessment Manual.* Authors: MacDonald, D. A., M. B. Matta L. J. Field, C. Cairncross, and M. Munn (EVS Consultants). NOAA/Hazard Materials Response and Assessment Division (HMRAD), Report No. HAZMAT 93-l. Seattle, WA.

National Research Council (NRC) 1983
National Research Council (NRC). 1983. *Risk Assessment in the Government: Managing the Process.* National Academy Press/National Academy of Science. Washington, DC.

National Research Council (NRC) 1993
National Research Council (NRC). 1993. *Science and Judgement in Risk Assessment.* National Academy Press/ National Academy of Science. Washington, D.C.

National Research Council (NRC) 1994
National Research Council (NRC). 1994. *Issues in Risk Assessment.* National Academy Press/National Academy of Science, Washington, DC.

National Toxicology Program (NTP) 1991
National Toxicology Program (NV). 1991. *National Toxicology Program - Technical Report No. 3: Toxicity Studies of Acetone in F344/N Rats and B6C3FI Mice (Drinking Water Studies).* NIH PB91-3122. Research Triangle Park, NC. U.S. Department of Health and Human Services, Public Health Service, National Institute of Health. *In* ATSDR 1993.

Neptune
Neptune, D. (w/EPA). no date. *Streamlining Superfund Soil Studies: Using the Data Quality Objectives Process for Scoping.*

New York Department of Environmental Conservation **(NYDEC) 1991**
New York Department of Environmental Conservation (NYDEC). 1991. *Fish and Wildlife Impact Analysis for Inactive Hazardous Waste Sites.* June.

Newell, Johnson, and Allen 1987
Newell, A. J., Johnson, D. W.. and Allen, L. K. 1987. *Niagara River Biota Contamination Project: Fish Flesh Criteria for Piscivorous Wildlife.* New York State, Dept. of Environmental Conservation Tech. Report 87-3.

Newsted, Giesy, Ankley, Tillitt, et al. 1995
Newsted, J. L., Giesy, J. P., Ankley, G. T.. Tillitt, D. E., et al. 1995. *Development of Toxic Equivalency Factors for PCB Congeners and the Assessment of TCDD and PCB Mixtures in Rainbow Trout.* Environmental Toxicology and Chemistry, Vol. 14, No. 5, pp. 861-872.

Norheim and Kjos-Hanssen 1984
Norheim, G., and Kjos-Hanssen, B. 1984. "Persistent Chlorinated Hydrocarbons and Mercury in Birds Caught off the West Coast of Spitzbergen." *Environ. Pollut.* 33A:143-152 *(In* Eisler 1986).

Norton, McVey, Colt, Durda, and Hegner 1988
Norton, S., McVey, M., Colt, J., Durda, J., and Hegner, R. 1988. *Review of Ecological Risk Assessment Methods.* Prepared for USEPA, Office of Planning and Evaluation, ICF, Inc., Fairfax, VA.

Ness 1990
Ness, R. F. 1990. "Indicators for Monitoring Biodiversity: A Hierarchical Approach." EPA. *In* Mouat et al. 1992.

O'Conner 1989
O'Connor, G. A. 1989. *Degradation, Crop Uptake, and Risk of Micropollutants in Sewage Sludge.* Proceedings of Sewage and Sludge Conference (Qual. Aspects and Risk in Connection with Land Application). Swedish Water and Wastewater Association. April.

O'Conner, Chaney, and Ryan 1990
O'Conner, G. A., **Chaney,** R. L., and Ryan, J. A. 1990. "Bioavailability to Plants of Sludge-Borne Toxic Organics." *In* Ware 1991.

Oak Ridge National Laboratory (ORNL) 1994
Oak Ridge National Laboratory (ORNL). 1994. *Toxicological Benchmarks.* Includes the six following reports: (see Appendix B).

Suter and Mabrey 1994
Suter, G. W.. and Mabrey, J. B. 1994 (revision). *Toxicological Benchmark for Screening Potential Contaminants of Concern for Effects on Aquatic Biota.* ORNL Environmental Restoration Program ES/ER/TM-96/R1.

Opresko, Sample, and Suter 1994
Opresko, D. M., Sample, B. E., and Suter G. W. 1994 (revision). *Toxicological Benchmarks for Wildlife.* ORNL Environmental Restoration Program. ES/ER/TM-886/Rl.

Will and Suter II 1994
Will, M. E.. and Suter II. G. W. 1994 (revision). *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Terrestrial Plants.* ORNL Environmental Restoration Program. ES/ER/TN-85/R1.

Will and Suter II 1994
Will, M. E., and Suter II, G. W. 1994. *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Soil and Litter Invertebrates and Heterotrophic Processes.* ORNL Environmental Restoration Program. ES/ER/TM-126.

Hull and Suter II 1994
Hull, R. N., and Suter II, G. W. 1994 (revision). *Toxcological Benchmarks for Screening Contaminants of Potential Concern for Effects on Sediment-Associated Biota*. ORNL Environmental Restoration Program ES/ER/TM-95/R1.

ORNL 1994
ORNL. 1994. *Manual for PC-Data Base Screening Benchmarks for Ecological Risk Assessment*. Environmental Sciences Division, Health Sciences Research Division. ORNL/TM-12898.

Outridge and Noller 1991
Outridge, P. M., and Noller. B. N. 1991. "Accumulation of Toxic Trace Elements by Freshwater Vascular Plants." *In* Ware 1991.

Overcash and Pal 1979
Overcash, M. R.. and Pal, D. 1979. *Design of Land Treatment System for Industrial Wastes - Theory and Practice.* Ann Arbor Science Publishers, Inc. Ann Arbor, ML

Parkburst, Bergmann, Marcus, Creger, Warren-Hicks, Olem, Boelter, and Baker 1990
Parkhurst, B. R., Bergmann, H. L., Marcus, M. D.. Creger. C. S., Warren-Hicks, W., Olem, H., Boelter, A., and Baker, J. P. 1990. *Evaluation of Protocols for Aquatic Ecological Risk Assessment and Risk Management.* Prepared for WPCF Research Foundation, Technology Assessment Dept., Alexandria, VA.

Pastorok and Sampson 1990
Pastorok, R. J.. and Sampson, J. R. 1990. *Review of Ecological Risk Assessment Methods to Develop Numerical Criteria for Cleanup of Hazardous Waste Sites.* Prepared for Washington Dept. of Ecology.

Pennsylvania Department of Environmental Resources (DER) 1991
Pennsylvania Department of Environmental Resources (DER). 1991. *Risk Assessment Guidelines for Facilities Burning Hazardous Waste.*

Persaud, Jaugumagi, and Hayton 1992
Persaud. D., Jaugumagi. R., and Hayton, A. 1992. *Guidelines for the Protection and Management of Aquatic Sediment Quality in Ontario.* Water Resources Branch. Ontario Ministry of the Environment, 1 St. Clair Ave. W., Toronto, Ontario. January.

Pielou 1975
Pielou, E. C. 1975. *Ecological Diversity.* John Wiley and Sons. New York.

Pye 1993
Pye, L. H. 1993. "Decision Analysis/Risk Analysis (DARA) Methodology for Evaluating Ecological Risk at Federal Facilities." Presentation at 14th Annual Meeting of Society of Environmental Toxicology and Chemistry. Houston, Texas.

Rand and Petrocelli 1985
Rand, G. M., and Petrocelli. S. R. 1985. Fundamentals of Aquatic Toxicology, Methods and Applications. Hemisphere Publishing Corp., New York, 666 p.

Ross 1989
Ross, D. A. 1989. *Amphibians and Reptiles in the Diets of North American Raptors.* Bureau of Endangered Resources, Wisconsin Department of Natural Resources. **Madison,** WI.

Royce, Fletcher, and Risser 1984
Royce, C. L., Fletcher, J. S., and Risser, P.G. 1984. Phytotox: A Database Dealing with the Effect of Organic Chemicals on Terrestrial Vascular Plants." *Journal of Chemical Information and Computer Sciences.* Vol. 24. pp. 7-10.

Safe 1990
Safe, S. 1990. "Polychlorinated Biphenyls (PCBs), Dibenzo-p-dioxins (PCDDs), Dibenzofurans (PCDFs), and Related Compounds: Environmental and Mechanistic Considerations Which Support the Development of Toxic Equivalency Factors (TEFs)." *Critical Reviews in Toxicology.* Vol. 21. No. 1. pp. 51-71.

Sawhney 1988
Sawhney, B. L. 1988. "Chemistry and Properties of PCBs in Relation to Environmental Effects." *In* Waid. 1990.

Shu, Paustenbach, Murray, Marple, Brunck, Dei Rossi, and Teitelbaum 1988
Shu, H., Paustenbach, D., Murray, F. J., Marple, L. Brunck, B., Dei Rossi, D., and Teitelbaum P. 1988. "Bioavailability of Soil-Bound TCDD: Oral Bioavailability in the Rat." *Fundam. Appl. Toxicol.* 10:648-654.

Sims and Overcash 1983
Sims, R. C., and Overcash, R. 1983. "Fate of Polynuclear Aromatic Compounds (PNAs) in Soil-Plant Systems." *Residue Rev.* Vol. 88. pp. 1-68. *In* Eisler 1987.

Stakhiv 1988
Stakhiv, E. Z. 1988. "An Evaluation Paradigm for Cumulative Impact Analysis." *Environmental Management.* Vol. 12. No. 5. pp. 725-748.

Stewart, Haynes, and Martinez 1992
Stewart, A. J., Haynes, G. J., and Martinez, M. I. 1992. "Fate and Biological Effects of Contaminated Vegetation in a Tennessee Stream." *Environmental Toxicology and Chemistry.* Vol. 2.

Strek, Weber, Shea, Mrozek, and Overcash 1981
Strek. H. J.. Weber, J. B., Shea P. J., Mrozek, E. J., and Overcash, R. 1981. "Reduction of Polychlorinated Biphenyl Toxicity and Uptake of Carbon-14 Activity by Plants Through the Use of Activated Carbon." *Journal of Agricuture and Food.* Vol. 29.

Suter 1993
Suter, G.W. 1993. *Ecological Risk Assessment.* Lewis Publishers. Chelsea, MI.

Tiffin 1977
Tiffin, L. O. 1977. "The Form and Distribution of Metals in Plants: An Overview." *Proceedings of the Fifteenth Annual Hanford Life Sciences Symposium - Biological Implications of Metals in the Environment.* Richland, Washington. Sept. 29 to Oct. 1, 1975. Published by Technical Information Center, Energy Research and Development Administration.

Topp, Scbenert, Attar, Korte, and Korte 1986
Topp, E., Schenert, I., Attar, A., Korte, A., and Korte, F. 1986. "Factors Affecting the Uptake of C^{14}-Labelled Organic Chemicals by Plants from Soil." *Ecotoxicol. Environ. Saf* Vol. 11. P. 219. *In* Suter 1993.

Travis and Arms 1988
Travis, C. C., and Arms, A. D. 1988. "Bioconcentration of Organics in Beef, Milk, and Vegetation." *Environ. Sci. Technol.* Vol. 22. pp. 271-274. *In* Suter 1993.

U.S. Air Force (USAF) 1989
U.S. Air Force (USAF). 1989. *The Air Force Installation Restoration Program Management Guidance.* Washington, DC.

U.S. Air Force (USAF) 1990
U.S. Air Force (USAF). 1990. *General Guidance for Ecological Risk Assessment at Air Force Installations.* Prepared for Human Systems Division/IRP Program Oftice. Brooks Air Force Base, TX. Authors: DeSesso and Price.

U.S. Air Force (USAF) 1991
U.S. Air Force (USAF). 1991. *The Air Force Hazardous Waste Management Policy HQ USAF.* Washington, DC.

U.S. Air Force (USAF) 1992
U.S. Air Force (USAF). 1992. *FY 93/94/95 DERA Eligibility and Programming Guidance.* HQUSAF. Washington, DC.

U.S. Army (USA)
U.S. Army (USA). Army Regulation 420-74. Natural Resources-Land, Forest, and Wildlife Management.

U.S. Army Corps of Engineers (USACE) 1987
U.S. Army Corps of Engineers (USACE). 1987. *Wetlands Evaluation Technique (WET). Volume II: Methodology.*

U.S. Army Corps of Engineers (USACE) 1990
U.S. Army Corps of Engineers (USACE). 1990 (October 31). *USACE HTRW Management Plan*. OM 10-1-1. Washington, DC.

U.S. Army Corps of Engineers (USACE) 1992
U.S. Army Corps of Engineers (USACE). 1992. *Environmental Compliance Assessment System (ECAS) Assessment Protocols.* Construction Engineering Research Laboratories (CERL). Per AR 200-1.

U.S. Army Corps of Engineers (USACE) 1995a
U.S. Army Corps of Engineers (USACE). 1995a. *Risk Assessment Handbook: Volume I - Human Health Evaluation (EM 200-1-4).*

U.S. Army Corps of Engineers (USACE) 1995b
U.S. Army Corps of Engineers (USACE). 1995b. *Technical Project Planning - Guidance for HTRW Data Quality Design.* EM 200-1-2.

U.S. Army Corps of Engineers (USACE) 1995c
U.S. Army Corps of Engineers (USACE). 1995c. *Engineering and Design, Chemical Data Quality Management for Hazardous, Toxic, and Radioactive Waste Remedial Activities.* ER 1110-1-263. October 1.

U.S. Army Edgewood Research, Development, and Engineering Center (USAERDEC) 1994
U.S. Army Edgewood Research, Development, and Engineering Center (USAERDEC). 1994. *Procedural Guidelines for Ecologicat Risk Assessments at U.S. Army Sites.* Wentsel, R.S.. T.W. LaPoint. M. Simini, R. Checkai, D. Ludwig and L. Brewer. U.S. Army Environmental Center, Aberdeen Proving Ground, MD, 21010.

U.S. Dept. of Agriculture (USDA) 1983
U.S. Dept. of Agriculture (USDA). 1983. *Land Treatment of Hazardous Wastes.* J. F. Parr, P. M. Marsh, and J. M. Kla. (Eds.). Agricultural Environmental Quality, Agricultural Research Service. Beltsville, MD.

U.S. Department of the Army (USA) 1988
U.S. Department of the Army (USA). 1988 (December). Army Regulation 200-2, Environmental Effects of Army Actions.

U.S. Department of the Army (USA) 1990
U.S. Department of the Army (USA). 1990 (April 23). Army Regulation 200-1. Environmental Quality, Environmental Protection, and Enhancement.

U.S. Department of the Army (USA) 1991
U.S. Department of the Army (USA). 1991 (February 25). *Health Risk Assessment Guidance for the Installation Restoration Program and Formerly Used Defense Sites.* Pamphlet 40-578. Washington, DC.

U.S. Department of Defense (DoD) 1973
U.S. Department of Defense (DoD). 1973. Directive 5100.50, Protection and Enhancement of Environmental Quality. May.

U.S. Department of Defense (DoD) 1977a
U.S. Department of Defense (DoD). 1977a. Directive 5030.41, Oil and Hazardous Substances Pollution Prevention and Contingency Program. June.

U.S. Department of Defense (DoD) 1977b
U.S. Department of Defense (DoD). 1977b. Directive 4120.14, Environmental Pollution, Prevention, Control, and Abatement August.

U.S. Department of Defense (DoD) 1978
U.S. Department of Defense (DoD). 1978. Directive 6230.1, Safe Drinking Water. April.

U.S. Department of Defense (DoD) 1979a
U.S. Department of Defense (DOD). 1979a. Directive 6050.1, Environmental Effects in the United States of Department of Defense Actions. July 30.

U.S. Department of Defense (DoD) 1979b
U.S. Department of Defense (DOD). 1979b. Directive 6060.7. Environmental Effects Abroad of Major Department of Defense Actions. March 31.

U.S. Department of Defense (DoD) 1993
U.S. Department of Defense (DoD). 1993. Memorandum from the Deputy. Secretary of Defense to Addressees; Subj: Fast Track Cleanup at Closing Installations. Washington, DC. September 9.

U.S. Department of Defense (DoD) 1994a
U.S. Department of Defense (DoD). 1994a Memorandum from the Deputy Secretary of Defense to Addressees; Subj: Fast Track Cleanup - Finding of Suitability to Transfer (FOST) for BRAC Property. Washington, DC.

U.S. Department of Defense (DoD) 1994b
U.S. Department of Defense (DoD). 1994b. *Relative Risk Site Evaluation Primer.* Interim Edition. Washington, DC.

U.S. Department of Energy (DOE) 1984
U.S. Department of Energy (DOE). 1984. *A Review and Analysis of Parameters for Assessing Transport of Environmentally Released Radionuclides Through Agriculture.* C. F. Baes III, R. D. Sharp, A. J. Sjoreen, and R. W. Shor (Eds.). Prepared by Oak Ridge National Laboratory. ORNL-5786. September.

U.S. Department of the Interior (USDOI) 1991
U.S. Department of the Interior (USDOI). 1991. *Final Environmental Statement: Vegetation Treatment on BLM Lands in Thirteen Western States.* Bureau of Land Management (BLM).

U.S. Department of the Navy 1992
U.S. Department of the Navy. 1992. *The Navy and Marine Corps Installation Restoration (IR) Program Manual.* Chief of Naval Operations (CNO). Washington, DC.

U.S. Department of the Navy 1994
U.S. Department of the Navy (DON). 1994 (November 1). *Environmental and Natural Resources Program Manual.* OPNAVINST 509O.1B. Washington, DC.

U.S. Environmental Protection Agency (EPA) 1980
U.S. Environmental Protection Agency (EPA). 1980. *Ambient Water Quality Criteria for Polychlorinated Biphenyls.* USEPA Report 440/5-80-068. 211 p.

U.S. Environmental Protection Agency (EPA) 1982
U.S. Environmental Protection Agency (EPA). 1982. *Water Quality Assessment: A Screening Procedure for Toxic and Conventional Pollutants - Part 1.* EPA-600/6 82/004a.

U.S. Environmental Protection Agency (EPA) 1983
U.S. Environmental Protection Agency (EPA). 1983. *Hazardous Waste Land Treatment.* Office of Solid Waste and Emergency Response. Washington, DC. SW-874. April.

U.S. Environmental Protection Agency (EPA) 1985
U.S. Environmental Protection Agency (EPA). 1985. *Rapid Assessment of Exposure to Particulate Emissions from Surface Contamination Sites.* EPA/600/8-85/002. February.

U.S. Environmental Protection Agency (EPA) 1986a
U.S. Environmental Protection Agency (EPA). 1986a. *RCRA Facility Assessment Guidance.* EPA/530-SW-86-053.

U.S. Environmental Protection Agency (EPA) 1986b,
U.S. Environmental Protection Agency (EPA). 1986b. *Quality Criteria for Water*. Office of Water Regulations and Standards. EPA 440/5-86/001.

U.S. Environmental Protection Agency (EPA) 1986c
U.S. Environmental Protection Agency (EPA). 1986c *Hazard Evaluation Division, Standard Evaluation Procedure, Ecological Risk Assessment.* Office of Pesticide Programs. EPA/540/9-85/001. June.

U.S. Environmental Protection Agency (EPA) 1986d
U.S. Environmental Protection Agency (EPA). 1986d. *Superfund Remedial Design and Remedial Action Guidance.* Office of Emergency Response and Remedial Design, Washington, DC. OSWER Directive 9355.0-4A. June.

U.S. Environmental Protection Agency (EPA) 1987a
U.S. Environmental Protection Agency (EPA). 1987a. *Selection Criteria for Mathematical Models Used in Exposure Assessments: Surface Water Models.* EPA/600/8 87/042. July.

U.S. Environmental Protection Agency (EPA) 1987b
U.S. Environmental Protection Agency (EPA). 1987b. *Superfund Selection of Remedy.* Office of Solid Waste and Emergency Response. August.

U.S. Environmental Protections Agency (EPA) 1988a
U.S. Environmental Protection Agency (EPA). 1988a. *Guidance for Conducting Remedial Investigations and Feasibility Studies under CERCLA.* Interim Final. OSWER Directive 9355.3-01.

U.S. Environmental Protection Agency (EPA) 1988b
U.S. Environmental Protection Agency (EPA). 1988b. *RCRA Corrective Action Interim Measures Guidance.* EPA/530-SW-88-029.

U.S. Environmental Protection Agency (EPA) 1988c
U.S. Environmental Protection Agency (EPA). 1988c. *CRA Corrective Action Plan.* EPA/530-SW-88-028.

U.S. Environmental Protection Agency (EPA) 1988d
U.S. Environmental Protection Agency (EPA). 1988d *Federal Facilities Compliance Strategy.* Office of Federal Activities, Office of External Affairs, Washington, DC. 20460. November.

U.S. Environmental Protection Agency (EPA) 1988e
U.S. Environmental Protection Agency (EPA). 1988e. *Enforcement Actions Under RCRA and CERCLA at Federal Facilities.*

U.S. Environmental Protection Agency (EPA) 1988f
U.S. Environmental Protection Agency (EPA). 1988f. *Evaluation Process for Achieving Federal Facility Compliance.*

U.S. Environmental Protection Agency (EPA) 1988g
U.S. Environmental Protection Agency (EPA). 1988g. *Estimating Toxicity of Industrial Chemicals to Aquatic Organisms Using Structure Activity Relationships.* Office of Substances. EPA/560/6-88/001.

U.S. Environmental Protection Agency (EPA) 1988h
U.S. Environmental Protection Agency (EPA). 1988h. *Superfund Exposure Assessment Manual.* OSWER Dir. 9285.5-1. EPA/540/1-88/001. April.

U.S. Environmental Protection Agency (EPA) 1988i
U.S. Environmental Protection Agency (EPA). 1988i. *A Workbook of Screening Techniques for Assessing Impacts of Toxic Air Pollutants.* EPA-450/4-88-009. September.

U.S. Environmental Protection Agency (EPA) 1988j
U.S. Environmental Protection Agency (EPA). 1988j. *Selection Criteria for Mathematical Models Used in Exposure Assessments: Ground-Water Models*. EPA/600/8-88/075. May.

U.S. Environmental Protection Agency (EPA) 1988k
U.S. Environmental Protection Agency (EPA). 1988k. *Recommendations for and Documentation of Biological Values for Use in Risk Assessment.* Environmental Criteria and Assessment, Office of Research and Development. EPA/600/6-87/008. February.

U.S. Environmental Protection Agency 1988l
U.S. Environmental Protection Agency. 1988l. *Guidance on Remedial Actions for Contaminated Groundwater at Superfund Sites.* Office of Emergency and Remedial Response, Washington, D.C. EPA/540/G-88/003.

U.S. Environmental Protection Agency 1988m
U.S. Environmental Protection Agency. 1988m. *Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-dioxins and Dibenzofioans (CDDs and CDFs).* Update. Risk Assessment Forum. EPA/625/3-89/016. March.

U.S. Environmental Protection Agency (EPA) 1989a
U.S. Environmental Protection Agency (EPA). 1989a. *Risk Assessment Guidance for Superfund. Volume II (RAGS II): Environmental Evaluation Manual (RAGS II).* Interim Final. Office of Emergency and Remedial Response. EPA/540/1-89/001. March.

U.S. Environmental Protection Agency (EPA) 1989b
U.S. Environmental Protection Agency (EPA). 1989b. *RCRA Facility Investigation (RFI) Guidance.* Development of an RFI Work Plan and General Considerations for RCRA Facility Investigations. Waste Management Division, Office of Solid Waste. Interim Final G-89-00075.

U.S. Environmental Protectho Agency (EPA) 1989c
U.S. Environmental Protection Agency (EPA). 1989c. *Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference.* Office of Research and Development. EPA/600/3-89/013. March.

U.S. Environmental Protection Agency (EPA) 1989d
U.S. Environmental Protection Agency (EPA). 1989d. *Federal Facilities Negotiations Policy.* Office of Emergency and Remedial Response, Washington, DC. OSWER Directive 9992.3.

U.S. Environmental Protection Agency (EPA) 1989e
U.S. Environmental Protection Agency (EPA). 1989e. *Policy and Program Requirements to Implement the Quality Assurance Program.* Washington, DC. Office of the Administrator. EPA Order 5366.1. April 17.

U.S. Environmental Protection Agency (EPA) 1989f
U.S. Environmental Protection Agency (EPA). 1989f *Risk Assessment Guidance for Superfund. Volume I (RAGS I): Human Health Evaluation Manual (RAGS I).* EPA/540/1-89/002. December.

U.S. Environmental Protection Agency (EPA) 1989g
U.S. Environmental Protection Agency (EPA). 1989g. *Statistical Analysis of Ground-water Monitoring at RCRA Facilities.* Interim Final Guidance. Office of Solid Waste, EPA/530-SW-89-026.

U.S. Environmental Protection Agency (EPA) 1989h
U.S. Environmental Protection Agency (EPA). 1989h. *Air/Superfund National Technical Guidance Study Series. Volume II - Estimation of Baseline Air Emissions from Cleanup Activities at Superfund Sites.* EPA-450/1-89-002.

U.S. Environmental Protection Agency (EPA) 1989i
U.S. Environmental Protection Agency (EPA). 1989i. *Air/Superfund National Technical Guidance Study Series. Volume III - Estimation of Baseline Air Emissions from Cleanup Activities at Superfund Sites.* EPA-450/1-89-003.

U.S. Environmental Protection Agency (EPA) 1989j
U.S. Environmental Protection Agency (EPA). 1989j. *Rapid Bioassessment Protocols for Use in Streams and Rivers: Benthic Macroinvertebrates and Fish.* Office of Water (WH-553). EPA/444/4-89/001.

U.S. Environmental Protection Agency (EPA) 1989k
U.S. Environmental Protection Agency (EPA). 1989k. *Ecological Risk Assessment Methods: A Review and Evaluation of Past Practices in the Superfund and RCRA Programs,* EPA/600/8-89/043. Office of Policy Planning and Evaluation. June.

U.S. Environmental Protection Agency (EPA) 1989l
U.S. Environmental Protection Agency (EPA). 1989l. *CERCLA Compliance with Other Laws Manual Parts I and II.* Office of Emergency and Remedial Response: OSWER Directive 9234.1-01.

U.S. Environmental Protection Agency (EPA) 1989m
U.S. Environmental Protection Agency (EPA). 1989m. *Sediment Classification Methods Compendium.* Draft Final. Watershed Protection Division, Washington, DC.

U.S. Environmental Protection Agency (EPA) 1990a
U.S. Environmental Protection Agency (EPA). 1990a (March **8).** *National Oil and Hazardous Substances Pollution Contingency Plan.* Final Rule. 55 FR 8660.

U.S. Environmental Protection Agency (EPA) 1990b
U.S. Environmental Protection Agency (EPA). 1990b. *The Revised Hazard Ranking System: Background Information.* OSWER Directive 9320.7-03FS. 55 FR 51532-51667. December 14.

U.S. Environmental Protection Agency (EPA) 1990c
U.S. Environmental Protection Agency (EPA). 1990c *Federal Facilities Hazardous Waste Compliance Manual.* **Office of Waste Programs Enforcement, Washington, DC.** OSWER Directive 9992.4.

U.S. Environmental Protection Agency (EPA) 1990d
U.S. Environmental Protection Agency (EPA). 1990d. *Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions.* Office of Health and Environmental Assessment. EPA/600/6-90/003.

U.S. Environmental Protection Agency (EPA) 1990e
U.S. Environmental Protection Agency (EPA). 1990e. *Interim Methods for Development of Inhalation Reference Concentrations. Review Draft.* Office of Research and Development. EPA/600/890/066A.

U.S. Environmental Protection Agency (EPA) 1990f
U.S. Environmental Protection Agency (EPA). 1990f. *Superfund Emergency Response Actions.* A summary of Federally funded removals, fourth annual report, fiscal year 1989. Office of Research and Development. Washington, DC. EPA/540/8-89-014.

U.S. Environmental Protection Agency (EPA) 1991a
U.S. Environmental Protection Agency (EPA). 1991a *Guidance for Performng Preliminary Assessments Under CERCLA.* Office of Emergency and Remedial Response, EPA/600/6-91/010. OSWER Directive 9345.0-01A.

U.S. Environmental Protection Agency (EPA) 1991b
U.S. Environmental Protection Agency (EPA). 1991b. *Regional Guidance for Conducting Ecological Assessments.* Region VI.

U.S. Environmental Protection Agency (EPA) 1991c
U.S. Environmental Protection Agency (EPA). 1991c. *Streamlining Superfund Studies: Using the Data Quality Objective Process for Soil Scoping.* Quality Assurance and Management Staff, Office of Research and Development.

U.S. Environmental Protection Agency (EPA) 1991d
U.S. Environmental Protection Agency (EPA). 1991d. *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions.* Memorandum from Don R. Clay, the Assistant Administrator to Regional Division Directors. OSWER Directive 9355.0-30. Washington, DC. April 22.

U.S. Environmental Protection Agency (EPA) 1991e
U.S. Environmental Protection Agency (EPA). 1991e. *Assessment and Control of Bioconcentratable Contaminants in Surface Water.* Office of Research and Development, Office of Water, Washington, DC.

U.S. Environmental Protection Agency (EPA) 1991f
U.S. Environmental Protection Agency (EPA). 1991f. *Technical Guidance on Chemical Concentration Data Near the Detection Limit.* Region III Technical Guidance Manual. November.

U.S. Environmental Protection Agency (EPA) 1991g
U.S. Environmental Protection Agency (EPA). 1991g. *Evaluation of Dredged Material Proposed for Ocean Dumping*. Office of Marine and Estuarine Protection, EPA and Dept. of the Army, USACE. EPA/503/B92/001. February.

U.S. Environmental Protection Agency (EPA) 1992a
U.S. Environmental Protection Agency (EPA). 1992a. *Framework for Ecological Risk Assessment. Risk Assess*ment Forum. EPA/630/R-92/001.

U.S. Environmental Protection Agency (EPA) 1992b
U.S. Environmental Protection Agency (EPA). 1992b. *Guidance for Performing Site Inspections Under CERCLA.* Interim Final. Office of Emergency and Remedial Response, Washington, D.C. OSWER Directive 9345.0-05.

U.S. Environmental Protection Agency (EPA) 1992c
U.S. Environmental Protection Agency (EPA). 1992c. *Hazard Ranking System Guidance.* Interim Final.

U.S. Environmental Protection Agency (EPA) 1992d
U.S. Environmental Protection Agency (EPA). 1992d *Guidance for Data Useability in Risk Assessment.* Part A. Publication No. 9285.7-09A. PB92-963356. April.

U.S. Environmental Protection Agency (EPA) 1992e
U.S. Environmental Protection Agency (EPA). 1992e. *Guidance/or Data Useability in Risk Assessment. Part B.* Publication No. 9285.7-09B. PB92-963362. May.

U.S. Environmental Protection Agency (EPA) 1992f
U.S. Environmental Protection Agency (EPA). 1992f. *Regional Guidelines for Conducting Ecological Assessments.* Region V. April.

U.S. Environmental Protection Agency (EPA) 1992g
U.S. Environmental Protection Agency (EPA). 1992g. *Guidance on Risk Characterization for Risk Managers and Risk Assessors.* Memorandum from F. Henry Habicht, Deputy Administrator. February 26.

U.S. Environmental Protection Agency (EPA) 1992h
U.S. Environmental Protection Agency (EPA). 1992h. *Supplemental Guidance to RAGS: Calculating the Concentration Term.* Office of Solid Waste and Emergency Response. OSWER Directive 9285.7-081. May.

U.S. Environmental Protection Agency (EPA) 1992i
U.S. Environmental Protection Agency (EPA). 1992i. *AirlSuperfund National Technical Guidance Study Series. Volume I - Overview of Air Pathway Assessments for Superfund Sites (Revised).* EPA-450/1-89-001a.

U.S. Environmental Protection Agency (EPA) 1992j
U.S. Environmental Protection Agency (EPA). 1992j. *Interim Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals.* Office of Science and Technology, Health and Ecological Criteria Division. May.

U.S. Environmental Protection Agency (EPA) 1992k
U.S. Environmental Protection Agency (EPA). 1992k. *Health Effects Assessment Summary Tables, Annual FY 92.* Prepared by Environmental Criteria and Assessment Office for Office of Emergency and Remedial Response. OERR 9200.6-303. Cincinnati, OH. March.

U.S. Environmental Protection Agency (EPA) 1992l
U.S. Environmental Protection Agency (EPA). 1992l. *Dermal Exposure Assessment: Principles and Applications.* Interim Report Office of Research and Develop ment. EPA/600/8-91/001B.

U.S. Environmental Protection Agency (EPA) 1992m
U.S. Environmental Protection Agency (EPA). 1992m. *RCRA Corrective Action Stabilization Technologies - Proceedings.* Office of Research and Development, Washington, DC. EPA/625/R-92/014.

U.S. Environmental Protection Agency (EPA) 1992n
U.S. Environmental Protection Agency (EPA). 1992n. *Superfund Accelerated Cleanup Model (SACM).* Office of Solid Waste and Emergency Response, OSWER Directive 9203.1-01, April 7. (Also see OSWER Directive 9203-1-03, July 7, 1992, *Guidance on the Implementation of the SACM* under CERCLA).

U.S. Environmental Protection Agency (EPA) 1992o
U.S. Environmental Protection Agency (EPA). 1992o. *Estimation of Air Impacts for the Excavation of Contaminated Soil.* EPA-450/1-92-004.

U.S. Environmental Protection Agency (EPA) 1992p
U.S. Environmental Protection Agency (EPA). 1992p. *Guidance on Setting Priorities for NPL Candidate Sites.* OSWER Directive 9203.1-06. October 28.

U.S. Environmental Protection Agency (EPA) 1993a
U.S. Environmental Rot&ion Agency (EPA). 1993a. *Superfund Program Checklist for Ecological Assessment/ Sampling.* Emergency Response Branch, OSWER. January.

U.S. Environmental Protection Agency (EPA) 1993b
U.S. Environmental Protection Agency (EPA). 1993b. *Guideline for Deriving Site-Specific Sediment Quality Criteria for the Protection of Benthic Organisms.* EPA/822/R/93/017.

U.S. Environmental Protection Agency (EPA) 1993c
U.S. Environmental Protection Agency (EPA). 1993c. *Guidance Document on Dissolved Criteria, Expression of Aquatic Life Criteria for Metals.* Proceedings to Water Mtg. Div. Dir. Washington, DC.

U.S. Environmental Protection Agency (EPA) 1993d
U.S. Environmental Protection Agency (EPA). 1993d. *Air/Superfund National Technical Guidance Study Series. Volume IV - Guidance for Ambient Air Monitoring at Superfund Sites (Revised).* EPA-451/R-93-007.

U.S. Environmental Protection Agency (EPA) 1993e
U.S. Environmental Protection Agency (EPA). 1993e. *Wildlife Exposures Factors Handbook.* Office of Research and Development. 2 Volumes. EPA/600/R93/187a&b. December.

U.S. Environmental Protection Agency (EPA) 1993f
U.S. Environmental Protection Agency (EPA). 1993f. *A Review of Case Studies from a Risk Assessment Perspective.* Risk Assessment Forum, Washington, DC. EPA/630/R92/005.

U.S. Environmental Protection Agency (EPA) 1993g
U.S. Environmental Protection Agency (EPA). 1993g. *Water Quality Standards Handbook.* Office of Water. EPA-823-B-93-002 (Second Edition: August 1994).

U.S. Environmental Protection Agency (EPA) 1993h
U.S. Environmental Protection Agency (EPA). 1993h. *Interim Report on Data and Methods to Assessment of 2. 3, 7, 8-Tetrachlorodibenzo-p-dioxin Risks to Aquatic Life and Associated Wildlife.* Office of Research and Development, Washington, D.C. EPA/600/R-93/005.

U.S. Environmental Protection Agency (EPA) 1993i
U.S. Environmental Protection Agency (EPA). 1993i. Initiative by EPA Official (Denit).

U.S. Environmental Protection Agency (EPA) 1993j
U.S. Environmental Protection Agency (EPA). 1993j. *Technical Basis for Deriving Sediment Quality Criteria for Nonionic Organic Contaminants for the Protection of Benthic Organisms by Using Equilibrium Partitioning.* Washington, DC., Office of Water. EPA/822/R-931001.

U.S. Environmental Protection Agency (EPA) 1994a
U.S. Environmental Protection Agency (EPA). 1994a. "Role of the Ecological Risk Assessment in the Baseline Risk Assessment." Memorandum from Elliott Laws, Assistant Administrator. OSWER Directive No. 9285.7-17.

U.S. Environmental Protection Agency (EPA) 1994b
U.S. Environmental Protection Agency (EPA). 1994b. *Interim Ecological Risk Assessment Guidelines.* Region III. July.

U.S. Environmental Protection Agency (EPA) 1994c
U.S. Environmental Protection Agency (EPA). 1994c. *Laboratory Data Validation, Functional Guidelines for Evaluating Inorganics Analyses.* EPA Hazardous Site Evaluation Division, Data Review Work Group. July 1.

U.S. Environmental Protection Agency (EPA) 1994d
U.S. Environmental Protection Agency (EPA). 1994d. *Laboratory Data Validation, Functional/ Guidelines for Evaluating Organics Analyses.* EPA Hazardous Site Evaluation Division, Data Review Work Group.

U.S. Environmental Protection Agency (EPA) 1994e
U.S. Environmental Protection Agency (EPA). 1994e. *Sediment Quality Criteria.* Notice of Availability and Request for Comment on Sediment Quality Criteria and Support Documents. 59 FR 2652, Vol. 59, No. 11.

U.S. Environmental Protection Agency (EPA) 1994f
U.S. Environmental Protection Agency (EPA). 1994f. *Evaluating and Identifying Contaminants of Concern for Human Health.* EPA Region VIII Superfund Tech. Guidance RA-03.

U.S. Environmental Protection Agency (EPA) 1994g
U.S. Environmental Protection Agency (EPA). 1994g. *Workshop on the Use of Available Data and Methods for Assessing Ecological Risks of 2,3.7,8-Tetrachlorodibenzo-p-dioxin to Aquatic Life and Associated Wildlife.* Risk Assessment Forum. Office of Research and Development, Washington, DC. EPA/63O/R-94/002.

US. Environmental Protection Agency (EPA) 1995a
U.S. Environmental Protection Agency (EPA). 1995a. "EPA Risk Characterization Program" and "Policy for Risk Characterization at USEPA." Memo from C. Browner. March 21.

U.S. Environmental Protection Agency (EPA) 1995b
U.S. Environmental Protection Agency (EPA). 1995b. *Final Water Quality Guidance for the Great Lakes System.* Final Rule. Federal Register. Vol. 60. No. 56. March 23. p. 15366. (See supporting documentation: *Great Lakes Water Quality Criteria Documents for the Protection of Wildlife.)*

U.S. Environmental Protection Agency (EPA) 1995c
U.S. Environmental Protection Agency (EPA). 1995c. Personal communication with M. Sprenger, EPA Headquarters Environmental Response Team (ERT). June 12.

U.S. Environmental Protection Agency (EPA) 1995d
U.S. Environmental Protection Agency (EPA). 1995d *Guidance for Risk Characterization.* (Attachment to C. Browner Memorandum, 1995). Science Policy Council. February.

U.S. Environmental Protection Agency (EPA) 1995e
U.S. Environmental Protection Agency (EPA). 1995e. *Land Use in CERCLA Remedy Selection Process.* OSWER Directive No. 9355.7-04.

U.S. Environmental Protection Agency (EPA) 1995f
U.S. Environmental Protection Agency (EPA). 1995f. *Water Quality Standards: States Compliance - Revision of Metals Criteria Interim* Final Rule. 60 FR 22229.

U.S. Environmental Protection Agency (EPA) 1995g
U.S. Environmental Protection Agency (EPA). 1995g. *Air/Superfund National Technical Guidance Study Series. Volume V - Procedures for Air Dispersion Modeling at Superfund Sites.* EPA-454/R-95-003.

U.S. Fish and Wildlife Service (USFWS) 1985-1994
U.S. Fish and Wildlife Service (USFWS). 1985-1994. *Contaminant Hazard Review Series.* See: R. Eisler.

U.S. Fish and Wildlife Service (USFWS) 1987
U.S. Fish and Wildlife Service (USFWS). 1987. *Type B Technical Information Document: Guidance on Use of Habitat Evaluation Procedures, and Suitability Index Models for CERCLA Application.* National Technical Information Service. PB88-100151.

US. Fish and Wildlife Service (USFWS) 1990
U.S. Fish and Wildlife Service (USFWS). 1990. *Evaluating Soil Contamination.* Biological Report 90(2). Author: W. N. Beyer. USDOI. Washington, DC. 25 p.

Van Gestel and Ma 1988
Van Gestel, C. A. M., and Ma, W. C. 1988. "Toxicity and Bioaccumulation of Chlorophenols in Earthworms in Relation to Bioavailability in Soil." *Ecotoxicol. Environ. Saf. Vol.* 15. pp. 289-297. *In* Suter 1993.

Van Leeuwen, Van Der Zandt, Aldenberg, Verhaar, and Hermens 1992
Van Leeuwen. C. J., Van Der Zandt, P. T., Aldenberg, T.. Verhaar, H. J., and Hermens, J. L. 1992. "Application of QSARs, Extrapolation and Equilibrium Partitioning in Aquatic Effects. Assessment I - Narcotic Industrial Pollutants." *Environ. Tox. and Chem.* Vol. 2. pp. 267-282.

Vaughn 1984
Vaughn, B. E. 1984. "State of Research: Environmental Pathways and Food Chain Transfer." *Environ. Health Perspect.* pp. 353-371. *In* ATSDR 1989.

Waid 1990
Waid, J. J. (Ed.). 1990. *PCBs and the Environment.* Vol. 1. CRC. Boca Raton, FL.

Ware 1991
Ware. ***G.*** W. (Ed.). 1991. *Reviews of Environmental Contamination and Toxicology.* Vol. 121.

Washington State Department of Ecology 1991
Washington State Department of Ecology. 1991. *Sediment Management Standards.* Chapter 173-204 WAC (April) and *Summary of Criteria and Guidelines for Contaminated Freshwater Sediments.* Sediment Management Unit (September). Olympia, WA.

Water Environmental Research Foundation (WERF) 1994
Water Environmental Research Foundation (WERF). 1994. *Methodology for Aquatic Ecological Risk Assessment.* Draft Final Report. April 25. Prepared by B. R. Parkhurst, W. Warren-Hicks, and R.D. Cardwell. WERF, Alexandria, VA.

Whaley 1995
Whaley, J., Dr., USACHPPM. Personal communication, 1995.

Wheatley and Hardman 1968
Wheatley, G. O., and Hardman, J. O. 1968. "Organochlorine Insecticide Residue in Earthworms from Arable Soils." *J. Sci. Food Agric.* Vol. 19. pp. 219-229. *In Suter* 1993.

Wiemeyer, Lamont, Bunck, et al. 1984
Wiemeyer, S. N.. Lamont, T. G., Bunck, C. M., et al. 1984. Organochlorine pesticide, polychlorobiphenyl, and mercury residues in bald eagles - 1966-1979 - and their relationship to shell thinning and reproduction. Arch. Environ. Contam. Toxicol. 13:529-549 *(In* Eisler 1986).

Winter and Streit 1992
Winter. S.. and Streit, B. 1992. "Organochlorine Compounds in a Three-Step Terrestrial Food Chain." *Chemosphere.* Vol. 24. No. 12. pp. 1765-1774.

Zar 1984
Zar, J.H. 1984. *Statistical Analysis.* Prentice-Hall Inc. Englewood Cliffs, NJ. 718 p.

Appendix B
Information Sources for Ecological Risk Assessment

B.1 Procedural and Guidance Documents

Canada Council of Ministers of the Environment (CCME). 1995. *Protocol for the Derivation of Canada Sediment Quality Guidelines for the Protection of Aquatic Life.* Guidelines Division, Evaluation and Interpretation Branch, Environment Canada, Ottawa, Canada. Report CCME EPC-98E. March.

Department of Energy (DOE). 1991. *Natural Resource Trusteeship and Ecological Evaluation for Environmental Restoration at Department of Energy Facilities.* DOE/EH-0192.

Department of Energy (DOE). 1993. *Policy Framework and Implementation Plan for Using Ecological Risk Assessment at DOE Facilities.* DOE/RL/01830-H16.

Department of Energy (DOE). 1993. *Remedial InvestigationlFeasibility Study (RI/FS) Process and Techniques Guidance.* 3/93.

Department of Energy (DOE). 1994. *Ecological Risk Assessment Guidance for Preparation of Remedial InvestigationlFeasibility Study Work Plans.* DOE/EH-0338.

Department of the Navy. 1994. *Environmental and Natural Resources Program Manual.* OPNAVINST 5090.1B. Washington, D.C. 11/l/94.

DeSesso, J. M., and Price, F. T. 1990. *General Guidance for Ecological Risk Assessment at Air Force Installations.* Human Systems Division IRP Program Office. 12 pp. and Appendix: Terrestrial Toxicity Test Methods (3 pp.)

Environment Canada. 1994. *A Framework for Ecological Risk Assessment at Contaminated Sites in Canada. Review and Recommendations.* Ecosystem Conservation Directorate, Evaluation and Interpretation Branch, Ottawa, Ontario. Scientific Series No. 199.

Proposed framework for conduct of ERAs at contaminated sites in Canada. This proposed framework is similar to others developed for various regulatory programs.

EPA. 1984. *Policy and Program Requirements to Implement the Mandatory Quality Assurance Program.* EPA Order 5360.1.

EPA. 1989. *Risk Assessment Guidance for Superfund - Volume II: Environmental Evaluation Manual (RAGS II).* Interim Final. Office of Emergency and Remedial Response. EPA/540/1-89/001, 3/89.

The guidance consists of two parts: (1) a guidance manual that established a general framework for understanding the ecological principles of a Superfund ERA and discusses the performance of the assessment, and (2) a compendium method handbook, "Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference."

EPA. 1990. *Water Quality Standards for Wetlands - National Guidance.* Office of Water. EPA 440/2-90-011.

EPA. 1990. *Guidance on Remedial Actions for Superfund Sites with PCB Contamination. Office of Emergency and Remedial Response.* EPA/540/G-90/007.

EPA. 1992. *Framework for Ecological Risk Assessment (Framework).* Risk Assessment Forum. EPA/630/R92/001,2/92.

Presents the guiding principles and structure for the conduct of an ERA.

EPA. 1992. *Supplemental Guidance to RAGS: Calculating the Concentration Term.* Intermittent Bulletin Publication 9285.7-081. Office of Solid Waste and Emergency Response.

Although written as a supplement to RAGS I, this bulletin is also applicable to ecological risk assessment as it describes the method and reasons for calculating the 95% UCL.

EPA. 1992. *Guidelines for Exposure Assessment.* 57 FR 22888-22938.

Although these guidelines are written for human health assessment, various principles presented are relevant to ecological risk exposure assessments.

EPA. 1993. *Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria.* Memorandum from Office of Water to Water Management Division Directors. 10/1/93.

EPA. 1993. *Implementation of Metals Criteria.* Memorandum from Office of Water to Water Management Division Directors. 4/1/93.

EPA. 1993. *Great Lakes Water Quality Initiative Criteria Documents for the Protection of Wildlife - DDT, Mercury, 2,3,7,8-TCDD, and PCBs.* Office of Water. EPA/822/R-93/007, 4/93.

EPA. 1993. *Wildlife Criteria Portions of the Proposed Water Quality Guidance for the Great Lakes System.* Office of Water. EPA/822/R-93/006, 7/93.

EPA. 1993. *Guidance for Planning for Data Collection in Support of Environmental Decision Making Using the Data Quality Objectives Process.* Interim Final. Quality Assurance Management Staff. EPA QA/G-4.

EPA. 1994. *Interim Guidance on Determination and Use of Water-Effect Ratios (WERs) for Metals.* EPA 823/B/94/001. February.

Presents an effluent-specific approach for calculating a total recoverable metal permit limit from the dissolved metal criterion. Appendix D explains the relationship between WERs for dissolved criteria and WERs for total recoverable criteria.

EPA. 1994. *Equilibrium Approach to Predicting Metal Bioavailability in Sediments and the Derivation of Sediment Quality Criteria for Metals.* Volume I Briefing report to the EPA Science Advisory Board. Office of Water and Office of Research and Development. December.

This document is a compilation of data and analyses from scientific investigation into the bioavailability of metals in sediments to benthic organisms with the intent of proposing an approach to assessing metals contamination of sediments for the protection of benthic organisms.

EPA. 1994. *Water Quality Standards Handbook.* Second Edition. Water Quality Standards Branch. Office of Water. August. EPA-823-B-94-005A.

An annotated list of the major guidance and policy documents on the water quality standards program issued since 1983 is included in the Introduction. Material added to the Second Edition by periodic updates since 1993 is summarized in the Appendix.

The handbook includes chapters on general provisions (40 CFR 131 - Subpart A), designation of uses (40 CFR 131.10). water quality criteria (40 CFR 131.11). antidegradation (40 CFR 131.12). general policies (40 CFR 131.13), procedures for review and revision of water quality standards (40 CFR 131 - Subpart C), and the water quality-based approach to pollution control.

EPA. 1995. *Study of Federal Water Quality Criteria for Metals; Water Quality Standards: States Compliance-Revision of Metals Criteria,* Interim Final Rule. 40 CFR part 131. Federal Register Vol. 60 (May 4) No. 86, p. 22228.

This interim final rule establishes metals criteria that are protective of aquatic life and approximate, better than the 1992 criteria, the biologically available fraction of waterborne metals to aquatic organisms.

EPA. 1995. *Guidance for Risk Characterization.* Science Policy Council. 2/95. 29 pp.

This guidance contains principles for developing and describing EPA risk assessments, with a particular emphasis on human health risk characterization. This guidance does not specifically address ecological risk assessment, although it does present guiding principles for human health risk assessments that are equally applicable to ecological risk assessments.

EPA. 1995. *Policy for Risk Characterization: Memorandum from Carol M. Browner, EPA Administrator.* 3/21/95.

This policy statement and associated guidance for risk characterization (EPA, Science Policy Council, 1995) are designed to ensure that critical information from each stage of a risk assessment is used in forming conclusion about risk and that this information is appropriately communicated from risk assessors to risk managers. This policy provides a basis for greater clarity, transparency, reasonableness, and consistency in risk assessments across Agency programs.

EPA. 1995. *Final Water Quality Guidance for the Great Lakes System.* Federal Register, Volume 60, No. 56. 3/23/95.

Water Quality Criteria for 29 pollutants to protect aquatic life, wildlife and human health and detailed methodologies to develop criteria for additional pollutants. Locations for obtaining supporting documents are listed. EPA is also making a number of documents available in electronic format at no incremental cost to users of the Internet (see Great Lakes Information Network (GLIN).

EPA. *BTAG Forum.* Office of Solid Waste and Emergency Response (OSWER).

BTAG Forum is a bulletin series published primarily to foster communication among biological/ecological technical assistance groups (BTAGs/ETAGs) and to assist EPA site managers in designing, managing, and reviewing ecological assessments of Superfund sites.

EPA. *ECO Updates.* Office of Solid Waste and Emergency Response (OSWER), Hazardous Site Evaluation. Eco Update is a bulletin series on ecological risk assessment of Superfund sites. These bulletins serve as supplements to Risk Assessment Guidance for Superfund, Volume II: Environmental Evaluation Manual (EPA/540-l-89/001).

The Role of Natural Resource Trustee in the Superfund Process. Vol. 1, No. 3. 1992. Publ. 9345.0-051.

Developing a Work Scope for Ecological Assessments. Vol. 1, No. 4. May 1992. Publ. 9345.0-051.

Using Toxicity Tests in Ecological Risk Assessment. Vol. 2, No. 1. September 1994.

Catalogue of Standard Toxicity Tests for Ecological Risk Assessment. Vol. 2, No. 2. September 1994.

Field Studies for Ecological Risk Assessment. Vol. 2., No. 3. September 1994.

Selecting and Using Reference Information in Superfund Ecological Risk Assessments. Vol. 2, No. 4. September 1994.

EPA. OSWER DIRECTIVES

Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions. 1991. OSWER Directive 9355.0-30, 4/22/91 (current vs. future land use).

Guidance on Risk Characterization for Risk Managers and Risk Assessors. 1992. OSWER (no number), 5/26/92. Addresses risk assessment vs. risk management.

New Policy on Performance of Risk Assessments during Remedial Investigation/Feasibility Studies (RI/FSs) Conducted by Potentially Responsible Parties (PRPs). 1993. Directive No. 9835.15b.

Role of the Ecological Risk Assessment in the Baseline Risk Assessment. Memorandum from Elliott P. Laws, Assistant Administrator. 1994. OSWER Dir. No. 9285.7-17.

Persaud, D., Jagumagi, R., and Hayton, A. 1992. *Guidelines for the Protection and Management of Aquatic Sediment Quality in Ontario.* Water Resources Branch, Ontario Ministry of the Environment. ISBN 0-7729-9248-7.

Contains protocol for setting sediment quality guidelines and application of the sediment quality guidelines for freshwater systems.

USACE. 1991. *Commander's Guide to Environmental Management.* Author: J.B. Pringle. Prepared for USATHAMA, Aberdeen Proving Ground, MD. CETHA-EC-TR-91036.

U.S. Army Research, Development and Engineering Center (USAERDEC). 1994. *Procedural Guidelines for Ecological Risk Assessment at U.S. Army Sites.* Wentsel, R.S., T.W. La Point, M. Simini, R.T. Checkai, D. Ludwig, and L. Brewer. 2 Volumes.

Volume 1 is designed to enhance an understanding of the ecological risk assessment requirements under CERCLA. Using a three-tiered analysis process, emphasis in this document is placed on the ecological effects-toxicity teat based approach to ERAs. Volume 2 contains information on more than 100 environmental models and test methods.

U.S. Air Force (USAF). 1990. *General Guidance for Ecological Risk Assessment at Air Force Installations.* Prepared for the Human System Division IRP Program Office at Brooks AFB, TX.

Document provides an overview of ERA fundamentals and guidance for the conduct of an ERA. Guidance is provided for assessing the terrestrial, freshwater, and marine habitats.

B.2 Methods Documents and Technical Documents

Barnthouse, L. W., Suter, G. W.; Bartell, S. M., et al. 1986. *User's Manual for Ecological Risk Assessment.* ORNL Oak Ridge, TN: Environmental Sciences Div. Publ. No. 2679.

U.S. Department of the Interior (DOI). 1991. *Plant Toxicity Testing With Sediment and Marsh Soils.* Authors G. E. Walsh. Technical Report NPS/NRWRD/NRTR-91/03.

EPA. 1978. *Quality Assurance Guidelines for Biological Testing: Environmental Monitoring Series.* Environmental Monitoring and Support Laboratory, Office of Research and Development, Las Vegas, NV. EPA-600/4-78-043.

EPA. 1986. *User's Manual for Ecological Risk Assessment.* Barnthouse, L. W., G. W. Suter, S. M. Bartell, J. J. Beauchamp, R. H. Gardener, E. Linder, R. V. O'Neill, and A. E. Rosen. Environmental Sciences Division. Publication No. 2679, ORNL-6251.

EPA. 1986. *Hazard Evaluation Division, Standard Evaluation Procedure, Ecological Risk Assessment.* Office of Pesticide Programs. EPA/540/9-85-001, 6/86.

EPA. 1986. *Review of Ecological Risk Assessment Methods.* EPA Office of Policy, Planning, and Evaluation, 11/86.

EPA. 1988. *Recommendations for and Documentation of Biological Values For Use in Risk Assessment.* Environmental Criteria and Assessment Office, Office of Research and Development. EPA/600/6-87/008, 2/88.

This document consists of an extensive compilation of values gleaned from the published literature sources for lifespan, body weight, food consumption, water consumption, and inhalation volumes for a wide range of predominantly mammalian species.

EPA. 1988. *Estimating Toxicity of Industrial Chemicals to Aquatic Organisms Using Structure Activity Relationships.* Office of Toxic Substances. EPA-560-6-88-001.

EPA. 1989. *Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-dioxins and Dibenzofurans (CDDs and CDFs). Update.* Risk Assessment Forum. EPA/625/3-89/016. March.

EPA. 1989. *Ecological Risk Assessment Methods: A Review and Evaluation of Past Practices in the Superfund and RCRA Programs.* Office of Policy, Planning, and Evaluation. EPA/230/03-89/044, 6/89.

EPA. 1989 to present. *Contaminated Sediment News.* Office of Water. EPA-823-N92-001.

EPA. 1989. *Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference Document.* Office of Research and Development. EPA/600/3-89/013. 3/89.

EPA. 1989. *Guidance Manual: Bedded Sediment Bioaccumulation Tests.* ERN-L, Pacific Ecosystems Branch, Bioaccumulation Team, Newport, OR. EPA/600/X-89/302; ERLN-N111.

EPA. 1991. *Assessment and Control of Bioconcentratable Contaminants in Surface Water.* Office of Water/ Office of Research and Development. March.

EPA. 1991. *Evaluation of Dredged Material Proposed for Ocean Dumping.* Dept. of the Army, USACE. EPA/503/B-92/001.

EPA. 1992. *Sediment Classification Methods Compendium.* Office of Water. EPA-823-R-92-066. 3/92.

Includes chapters on Quality Assurance/Quality Control, Sampling, and Analytical Considerations; Bulk and Spiked-Sediment Toxicity Test Approaches: Tissue Residue Approach: Interstitial Water Toxicity Identification Evaluation Approach: Equilibrium Partitioning Approach, Sediment Quality Triad Approach, Apparent Effects Threshold Approach; Benthic Community Structure Assessments.

EPA. 1992. *Ecological Techniques for the Assessment of Terrestrial Superfund Sites.* Authors: G. Linder, E. Ingham, C. J. Brandt, and G. Henderson. Environmental Research Laboratory, Corvallis, OR. NTIS: PB93-1000865; EPA/600/R-92/183. 3/92. Also titled: Evaluation of Terrestrial Ecological Indicators at Superfund Sites.

EPA. 1992. Fish Field and Laboratory Methods for Measuring Biological Integrity of Surface Water. Office of Research and Development. EPA/600/R-92/111.

Compendium of plant and animal test methods used for the assessment of soil and sediment contamination. Methods which assess soils directly are emphasized here but additional methods applicable to wetlands soils or sediments have also been included to complement those methods readily available for aquatic and sediment toxicity assessment. Tabular guides to the selection of test methods applicable to various habitats and toxicity endpoints are summarized to help potential users select the most appropriate biological assessment tool for the site under consideration.

EPA. 1992. *Higher Plant Accumulation of Organic Pollutants From Soils.* Risk Reduction Engineering Laboratory, Office of Research and Development, Cincinnati, OH. EPA/600/R-92/138.

The purpose of this work was to determine the effect of higher plants on sites polluted by organic chemicals and to discuss the potential of using plants as an in situ cleanup treatment. This work is based primarily on literature review but also includes greenhouse experiments and field testwork.

EPA. 1993. *Interim Report on Data and Methods for Assessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin Risks to Aquatic Life and Associated Wildlife.* Office of Research and Development, Washington, DC. EPA/600/R-93/055.

This report provides an initial base of information and analyses that EPA is planning to use for assessing risks of TCDD to aquatic life and wildlife. The analyses presented specifically address the direct toxic effects of TCDD to aquatic life and wildlife based on uptake from aquatic prey, sediment, and surface water.

EPA. 1993. Wildlife Exposure Factors Handbook. Office of Research and Development. EPA/600/R-93/187a&b,12/93.

Document summarizes literature values for exposure factors for 34 species of buds, mammals, amphibians, and reptiles. Includes chapter on allometric equation that can be used to estimate some of the exposure factors when data are lacking. To obtain a copy, call the Center for Environmental Research Information (CERI) at 513-569-7562.

EPA. 1993. *Superfund Program Checklist for Ecological AssessmentlSampling.* 1/93.

This checklist provides guidance on making observations during an ecological assessment, and is a screening tool for preliminary site evaluation. The checklist is not intended to be used for limited actions nor for purely industrial setting with no discharges, but may be useful in planning more extensive site investigations.

EPA. 1993. *Sediment Quality Criteria for the Protection of Benthic Organisms.* 59 FR 2652. The five proposed sediment criteria documents include Acenaphthene (EPA-822-R-93-013); Dieldrin (EPA-822-R-93-015); Endrin (EPA-822-R-93-016); Fluoranthrene (EPA-822-R-93-012); and Phenanthrene (EPA-822-R-93-014).

To make the task easier for calculating sediment criteria, EPA has prepared Lotus and Excel spreadsheets with organic carbon levels (dry weight or %), fresh and marine sediment criteria values, and confidence limits that will be automatically calculated foe the five draft criteria compounds. Spreadsheets are located on the Nonpoint Source Program electronic bulletin board (301)589-0205. EPA employees or contractors can download file (SQCCALC.ZIP). Final chronic values and K_{ow}s may be slightly different from those contained in current draft criteria documents.

EPA. 1993. *Technical Basis for Deriving Sediment Quality Criteria for Nonionic Organic Contaminants for the Protection of Benthic Organisms by Using Equilibrium Partitioning.* Washington, D.C. Office of Water. EPA/822/R-93/001.

EPA. 1994. *Ecological Risk Assessment Issue Papers.* Risk Assessment Forum. Office of Research and Development, Washington, DC. EPA/630/R-94/009.

EPA's issue papers and case studies are intended to provide scientific arguments for the appropriate use of ecological concepts at varying levels of ecological organization. The issue papers were prepared to provide a bridge between the skeletal structure provided by the Framework Report and the more fully developed concepts needed for Agency-wide risk assessment guidelines. Document presents issue papers on (1) Defining the Significance of Ecological Change, (2) Societal and Ecological Values. (3) Criteria for Determining Ecological Significance,

(4) The Ecological Significance Framework, and (5) Ecological Significance Inputs to Decision Making.

EPA. 1994. *Peer Review Workshop Report on Ecological Risk Assessment Issue Papers.* Office of Research and Development. Washington, D.C. EPA/630/R-94/008.

EPA. 1994. *Representative Sampling Guidance Document.* Volume 3; Ecological. Washington, DC Oftice of Emergency and Remedial Response.

EPA. 1994. *EPA's Contaminated Sediment Management Strategy.* Washington, D.C.

Strategy describes the cross-program policy framework in which EPA intends to promote consideration and reduction of ecological and human health risks posed by sediment contamination. Goals of the strategy are: (1) to develop consistent methodologies for assessing contaminated sediments: (2) to prevent ongoing contamination of sediments that may cause unacceptable ecological or human health risks; (3) to clean up existing sediment contamination that causes significant effects on human health or the environment; and (4) to ensure that sediment dredging and the disposal of dredged material continue to be managed in an environmentally sound manner.

Food and Drug Administration (FDA). 1993. *Guidance Documents for Metals in Shellfish: Arsenic, Chromium, Cadmium, Lead, and Nickel* (5 volumes). Center for Food Safety and Applied Nutrition, Washington, DC.

The references in the back of these documents are also quite useful for ecological risk assessments for coastal and marine environments. Also, FDA's seafood list (ISBN 0-16-042999-4) identifies scientific, common, and vernacular names for the seafood.

Layton, D., Mallon, B., Mitchell, W., Hall, L., et al. 1987. *Conventional Weapons Demilitarization: A Health and Environmental Effects Data Base Assessment.* Final Report, Phase II for Lawrence Livermore National Laboratory and U.S. Army Medical Research and Development Laboratory, Ft. Detrick, MD. December. AD-A220-588; UCRL - 21109.

To support studies of environmental risks and byproducts, this report provides data on factors that influence transport and fate of explosives and co-contaminants in environmental media (e.g., soils, water). Information on dose-response relationships for various toxic effects in laboratory animals is evaluated. Toxic effects on plants and aquatic species are also addressed.

Long, E. R., and Morgan, L. G. 1990. *The Potential for Biological Effects of Sediment Sorbed Contaminants Tested in the National Status and Trends Program.* NOAA (Seattle, Washington) Technical Memorandum NOS OMA 52.

NOAA's screening levels for chemical concentrations in marine sediments, based on studies at multiple sites. The screening levels, known as "effects range-low" (ER-Ls) and "effects range-median (ER-Ms), represent the 10th and 50th percentile, respectively, of the chemical mixture concentration at which effects were observed."

Long, E. R., MacDonald, D. D., Smith, S. L., and Calder, F. D. 1995. *Incidence of Adverse Biological Effects within Ranges of Chemical Concentrations in Marine and Estuarine Sediments.* Environmental Management, Vol. 19, No.1, pp. 81-97.

Paper presents approach and guidelines for use in sediment quality assessments. This method is being used as a basis for developing National sediment quality guidelines for Canada and informal, sediment quality guidelines for Florida. While these methods and guidelines presented in this report do not necessarily represent NOAA or Florida policy, they are commonly used as screening criteria for aquatic systems.

MacDonald, D. D. 1994. *Approach to the Assessment of Sediment Quality in Florida Coastal Waters. Vol. II: Application of the Sediment Quality Assessment Guidelines. Vol. HI: Supporting Documentation: Biological Effects Database for Sediments. Vol. IV: Supporting Documentation: Regional Biological Effects Database for Sediments.* Prepared for Florida Department of Environmental Protection. Tallahassee. FL. November.

MacDonald, D., Matta, K., Field, L., Cairncross, C., and Munn, M. 1992. *The Coastal Resource Coordinator's Bioassessment Manual.* NOAA/Hazardous Material Response and Assessment Division, Seattle, WA.

This manual was designed for use by NOAA's Coastal Resource Coordinators as an introduction to and a general guide for using bioassessment techniques for evaluating conditions at hazardous waste sites and is a ready reference to evaluate proposed ecological work plans for those sites. Chapters

include: Role of Bioassessment in the Remedial Process; Toxicity Tests: Bioaccumulation; Biomarkers; Benthic Community Studies; Study Design and Statistical Analysis: Recommended Bioassay Protocols for Soil, Water Column and Sediments.

National Research Council (NRC). 1986. *Ecological Knowledge and Environmental Problem-Solving: Concepts and Case Studies.* National Academy Press, Washington, D.C.

Oak Ridge National Laboratory (ORNL). 1984. *A Review and Analysis of Parameters for Assessing Transport of Environmentally Released Radionuclides Through Agriculture*. Authors: Baes, C. F.. R. D. Sharp, A. L. Sjoreen, and R. W. Shor. Prepared for Dept. of Energy. ORNL-5786. 150 p.

Oak Ridge National Laboratory (ORNL). 1990. *Integrating NEPA and CERCLA Requirements During Responses at DOE Facilities.* Authors: M. B. Levine, E. Smith, F. Sharples, G. Eddleman. ORNL/TM-11564.

Oak Ridge National Laboratory (ORAL). 1994. *Toxicological Benchmarks.* Includes the following reports:

Suter, G. W., and Mabrey, J. B. 1994 (revision). *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Aquatic Biota.* ORNL Environmental Restoration Program ES/ER/TM-96/R1.

Opresko, D. M., Sample, B. E., and Suter, G. W. 1994 (revision). *Toxicological Benchmarks for Wildlife.* ORNL Environmental Restoration Program ES/ER/TM-886/R1.

Will, M. E., and Suter II, G. W. 1994 (revision). *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Terrestrial Plants.* ORNL Environmental Restoration Program ES/ER/TN-85/R1.

Will, M. E.. and Suter II, G. W. 1994 (revision). *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Soil and Litter Invertebrates and Heterotrophic Processes.* ORNL Environmental Restoration Program ES/ER/TM-126.

Office of Health and Environmental Assessment (OHEA). no date. *Exposure Models Library with the Integrated Model Evaluation System (EML/IMES).*

U.S. Fish and Wildlife Service (USFWS). 1979. *Classification of Wetlands and Deepwater Habitats of the United States Biological Services Program.* Authors: L. M. Cowardin, V. Carter, F. C. Galet, and E. T. LaRoe. FWS/OBS-79/31. December.

U.S. Fish and Wildlife Service (USFWS). 1985 to 1994. *Contaminant Hazard Review Series.* Series by R. Eisler, USFWS, Dept. of Interior.

Between 1985 and 1989 USFWS published the Contaminant Review Series by Eisler for a number of chemicals of ecological concern. These documents summarize the chemical's environmental chemistry, background concentrations in biological and nonbiological samples, and lethal and sublethal effects in terrestrial plants, invertebrates, aquatic biota, birds, and mammals. The documents also propose health-based criteria or doses for these species. In the Biological Report 90(2), USFWS also summarized data on soil toxicity for screening assessments of terrestrial systems (Evaluating Soil Contamination, Beyer 19%). Copies of individual reviews may be obtained from FWS, 1849 C Street N.W.. Mail Stop 130-ARLSQ, Washington, DC 20240, or through the National Technical Information Service.

U.S. Fish and Wildlife Service (USFWS). 1987. *Guidance on Use of Habitat Evaluation Procedures, and Suitability index Models for CERCLA Application.* Type B Technical Information Document. PB88-100151.

U.S. Fish and Wildlife Service (USFWS). 1989. *Annotated Bibliography of Ecological Cumulative Impacts Assessment.* Authors: S.C. Williamson and K. Hamilton. National Biological Ecology Research Center, Ft. Collins, CO. Biological Report 89(11).

Water Environmental Research Foundation. 1994. *Methodology for Aquatic Ecological Risk Assessment.* Draft Final Report. Prepared for Water Environment Research Foundation, Alexandria, VA.

Document is intended for use by members of the regulated or regulatory communities who need to estimate the effects of toxic chemicals on aquatic communities from (1) new or nonpoint sources of chemicals, (2) improved wastewater treatment, (3) increase/decrease in discharge from an existing wastewater treatment facility, (4) more/less stringent numerical water quality standard, (5) hazardous waste site cleanup or remediation.

B.3 Additional EPA Documents

EPA. 1983. *Testing of Environmental Effects Under the Toxic Substances Control Act.* Environmental Effects Branch, Office of Toxic Substances.

EPA. 1987. *Risk Assessment Guidelines of 1986.* EPA/600/8-87/045, 8/87 (principally human health).

EPA. 1988. *State Water Quality Standards Summaries.* Office of Water. EPA 440/5-88-031, 9/88.

EPA. 1988. *Superfund Exposure Assessment Manual.* EPA/540/1-88/001,4/88.

EPA. 1989. *Screening Study for Wildlife Criteria Development.* Office of Water/Office of Water Regulations and Standards. September.

EPA. 1989. *Summary of Ecological Risks, Assessment Methods, and Risk Management Decisions in Superfund and RCRA.* Office of Policy Analysis, Planning and Evaluation. EPA-230-03-89-046.

EPA. 1990. *National Oil and Hazardous Substances Pollution Contingency Plan.* Final Rule 55 FR 8660, 3/8/90.

EPA. 1991. *Peer Review Workshop Report on a Framework for Ecological Risk Assessment.* EPA/625/3091/022.

EPA. 1991. *Technical Support Document for Water Quality-Based Toxic Control.* Office of Water. EPA/505/2-90-001. PB91-127415. March.

EPA. 1991. *Summary Report on Issues in Ecological Risk Assessment.* Risk Assessment Forum. EPA/625/3-91/018.

EPA. 1991. Hazard Profiles - *Selected Heavy Metals.* Ecological Effects Branch, Office of Toxic Substances. August 1991.

EPA. 1992. *Guidelines for Exposure Assessment.* Federal Register. 57: 22888-22938 (May 29).

EPA. 1992. *Peer Review Workshop Report on a Framework for Ecological Risk Assessments.* Risk Assessment Forum. EPA/625/3-91/022.

EPA. 1992. *Report on the Ecological Risk Assessment Guidelines Strategic Planning Workshop.* EPA/630/R-92/002.

EPA. 1992. *Interim Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals.* Office of Science and Technology, Health and Ecological Criteria Division. 5/92.

EPA. 1993. *A Review of Ecological Assessment Case Studies from a Risk Assessment Perspective.* 1993. Risk Assessment Forum. EPA/630/R-92/005, 5/93.

EPA. 1993. *Data Quality Objectives Process for Superfund.* Office of Emergency and Remedial Response, Washington, DC. EPA/540/R-93/078.

EPA. 1994. *A Review of Ecological Assessment Case Studies from a Risk Assessment Perspective.* Risk Assessment Forum. EPA/630/R-94/003.

Presents five case studies which address a broader understanding of the ERA process.

EPA. 1994. *Workshop on the Use of Available Data and Methods for Assessing the Ecological Risks of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin to Aquatic Life and Associated Wildlife.* Office of Research and Development. Washington, DC. EPA/630/ZR-94/002.

B.4 State and Regional EPA Guidance Documents

California

California Dept. of Toxic Substances Control (California EPA). *Guidance for Ecological Risk Assessment at Hazardous Waste Sites and Permitted Facilities.* 1994. 2 Parts. Part A: Overview. Part B: Scoping Assessment.

Florida

Approach to the Assessment of Sediment Quality in the Florida Coastal Waters. Florida Dept. of Environmental Protection.

Massachusetts

Massachusetts Department of Environmental Protection. 1994. *Environmental Risk Characterization Guidance.* January (Draft).

New York

New York Department of Environmental Conservation (NYDEC). 1991. *Fish and Wildlife Impact Analysis for Inactive Hazardous Waste Sites.* June.

NYDEC. 1992. *Technical and Administrative Guidance Memorandum: Determination of Soil Cleanup Objectives and Cleanup Levels.*

Pennsylvania

Pennsylvania Dept. of Environmental Resources (1991). *Risk Assessment Guidelines for Facilities Burning Hazardous Waste* (Draft). Includes ERA guidelines.

Region III - EPA

Interim Ecological Risk Assessment Guidelines. July 27, 1994. Prepared by Robert S. Davis, Biologist, Technical Support Section, Superfund Program Branch, HWMD, Philadelphia, PA. 12 PP. Includes attachments on Data Presentation and Basic Surface Water and Sediment Parameters.

Chemical Concentration Data Near the Detection Limit. November 1991. Region III Technical Guidance Manual. EPA/903/8-91/001.

Hazard Evaluation Handbook: A Guide to Removal Actions. Third Edition. Guide for risk-based removal activities.

Region IV - EPA

New Interim Region IV Guidance. February 1992. Primarily for human health, document provides adopted toxicity equivalency factors (TEFs) for PAHs; sample RME calculation. 9 pp.

Rapid Bioassessment Protocols for the Evaluation of Terrestrial Indicators. (Draft).

Region V - EPA

Regional Guidance for Conducting Ecological Assessments. June 25, 1992. Final version. 9 pp. USEPA, Region V, Chicago, IL.

Region VI - EPA

Regional Guidance for Conducting Ecological Assessments. 1991.

Region 6 Standardized Ecological Risk Format. 1992. 2 pp.

Region VIII - EPA

Region 8 Superfund Technical Guidance. 1994. *Calculating the Concentration Term for Risk Assessment: Use of One "C" Term to Estimate a Lower Average and an Upper RME Risk Range.* No. RA-02: Concentration Term.

This regional guidance is intended to help clarify the proper calculation and use of the Concentration Term for Super-fund risk assessments. the correct determination and use of this term is essential to comply with EPA policy (H. Habicht. Feb. 1992) that both average and RME risk estimates be provided in risk assessments. These two risk estimates are based upon one average Concentration Term, which is currently defined as the 95% UCL of the mean.

Region X - EPA

Region 10 is expected to publish ecological risk guidance by November 1995.

B.5 Professional Organizations

American Society for Testing and Materials (ASTM). ASTM is a not-for-profit organization which provides a forum for producers, users, ultimate consumers, and those having a general interest (representatives of government and academia) to meet on common ground and write standards for materials, products, systems, and services. ASTM continues to develop standards relevant to the ecological risk assessment practice. Contact ASTM, 1916 Race Street, Philadelphia, PA 19103, tel. 215-299-5454.

Ecological Society of America (ESA). ESA provides for the certification of professional ecologists based on specitied minimum standards of education and credentials. The primary objective of the ESA Certification Program is to provide public and private clients and employees more positive access to professional advice in matters

concerning ecological relationships and resources. Contact ESA, Duncan Patten (business manager), tel. 602-965-3000.

Society for Environmental Toxicology and Chemistry (SETAC). SETAC is a nonprofit, professional society established to provide a forum for individuals and institutions engaged in the study of environmental problems, management and regulation of natural resources, education, research and development, and manufacturing and distribution. Contact SETAC, 1010 North 12th Ave., Pensacola, FL 32501, tel. 904469-1500.

Publications Smithsonian Press. The Smithsonian Institute offers publications on a variety of topics relevant to ecological risk assessment, e.g., amphibian sampling guidance, etc., tel. 202-287-3738 (see Internet).

B.6 Recent Books

Calabrese, E. J., and Baldwin, L. A. 1993. *Performing Ecological Risk Assessments.* Lewis Publishers, Boca Raton, FL. 288 pp.

Dallinger, R., and Rainbow, P. S. 1993. *Ecotoxicology of Metals in Invertebrates.* CRC Press, Lewis Publishers, Boca Raton. FL.

Forbes, V. E., and Forbes, T. L. 1994. *Ecotoxicology in Theory and Practice*. *Chapman* and Hall, London, England. 247 pp.

Hoffman, D. J. 1994. *Handbook of Ecotoxicology.* CRC Press, Lewis Publishers, Boca Raton, FL.

Kendall, R. J., and Lather, T. E., Jr. 1994. *Wildlife Toxicology and Population Modeling.* CRC Press, Boca Raton, FL. 576 p.

Maughan, J. T. 1993. *Ecological Assessment of Hazardous Waste Sites.* Van Nostrand Reinhold, NY. 352 pp.

Newman, M. C. 1994. *Quantitative Methods in Aquatic Ecotoxicology.* CRC Press, Lewis Publishers, Boca Raton, FL.

Suter, G. W., Barnthouse, L. W., Bartell, S. M., Mill, T., Mackay, D., and Patterson, S. 1993. *Ecological Risk Assessment.* Lewis Publishers, Boca Raton, FL . 560 pp.

B.7 Electronic Resources

Keeping informed and being able to access current information resources is becoming increasingly important in many fields including ecological risk assessment. State and Federal agencies (EPA, USFWS, DOE) and universities are providing increasing amounts of information on the Internet relevant to the conduct of ERAS. Regulatory agency news (EPA, USFWS, DoD, DOE, USACE), new guidance, government documents, university libraries and herbaria. and natural history museums are all accessible via the Internet. Updated endangered and threatened plant and animal lists, habitat information, on-line herbaria and museums, plant images, state biota collecting regulations can be readily consulted for information applicable to site-specific ecological risk assessments. Ecotoxicological contaminant information will also be available on the Internet in the near future. The following is a small sampling of relevant agencies and databases accessible on the Internet:

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR):

Internet Address:
http://atsdrl.atsdr.cdc.gov:8080/atsdrhome.html
Provides access to on-line databases such as *HazDat, ToxFAQs* and ATSDR's toxicological profiles.

ENVIRONMENT CANADA

Internet Address: http://www.doe.calenvhome
Environment Canada provides a Green Lane (environmental information domain within the www) for interactive access to Environment Canada Services, products, information holdings, programs, regulations, and policies.

NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION (NOAA)

Internet Address: http://www.noaa.gov
NOAA's Coastal Resource Coordinators (CRC) are based in Seattle, WA. CRC is a branch of NOAA's Hazard Materials and Response (HAZMAT) Division, which is a major unit in NOAA's Office of Ocean Resources Conservation and Assessment (ORCA). ORCA is one of four major line organizations of the National Ocean Service, within NOAA (U.S. Dept. of Commerce). ORCA's three other units (based in Silver Spring, MD) include: (1) the

Coastal Monitoring and Bioeffects Assessments Division (CMBAD) which includes the *National Status and Trends (NS&T) Program* (Mussel Watch Project, Benthic Surveillance Project, Bioeffects Surveys. Specimen Banking, and Coastal Contamination Assessments), (2) the Damage Assessment Center (DAC) which provides scientific and economic expertise as one component of NOAA's Damage Assessment and Restoration Program (DARP) and recovers funds for restoration of NOAA trust resources, and (3) the Strategic Environmental Assessments (SEA) Division which conducts a comprehensive national assessment program focusing on the characterization of coastal and ocean resources (includes the GeoCOAST, geographic information systems facility).

U.S. ARMY CENTER FOR HEALTH PROMOTION AND PREVENTATIVE MEDICINE (USACHPPM)

Internet Address: http://chppm-www.apgea.army.mil
Provides access to USACHPPM's Entomological Sciences Program, Hazardous and Medical Waste Program, the Health Hazard Assessment Program, as well as other remote environmental-military www servers.

U.S. ARMY CORPS OF ENGINEERS

Internet Address: http://www.cecer.army.mil:80/welcome.
Construction Engineering Research Laboratories (USACERL) and Defense Environmental Network and Information Exchange (DENIX) USACERL developed the Defense Environmental Network and Information Exchange (DENIX). an electronic bulletin board accessible throughout DOD. DENIX is the fast DECIM migration system to be fielded. It is based on the Army's Defense Environmental Electronic Bulletin Board System, which was also developed at USACERL. DENIX went online in August 1993. This bulletin board allows users to: (1) read online environmental publications (proprietary or DOD-specific); (2) send and receive mail electronically on the DENIX host computer or across the Internet; (3) exchange environmental information via managed discussion forums based on a subject area; (4) send and receive required reporting data through the chain of command: (5) peruse and request environmental training courses and seminars; (6) access the DENIX directory service database; and (7) upload and download files from DENIX to and from a personal computer. DENIX provides DOD environmental managers with a central communications platform from which to obtain timely access to environmental legislative, compliance, restoration, cleanup, and DOD unique information.

USACERL Points of Contact (POCs) are Mr. Calvin Corbin, COMM 217-373-6731, and Mr. Steve Luzzi, COMM 217-352-6511, ext. 446. Both can be reached toll-free at 800-USA-CERL, ATTN: CECER-ECD, P.O. Box 9005 Champaign, IL 61826-9005.

U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA)

Internet Address: www.epa.gov
EPA's WWW server provides access to a number of online resources including policy documents, regulations, software, and databases. Most regions currently have Public Access Information servers accessible through the main web homepage.

Multimedia Exposure and Ecological Risk Assessment
ftp://ftp.epa.gov/epa-ceam/wwwhtml/ceam_softvare_products.html
The Center for Exposure Assessment Modeling provides current multimedia exposure and ecological risk assessment software programs such as Qual2eu,, Fgets, Multimed, Plumes, Minteq, Femwater, and Przm2.

EPA Online Library System
Telnet_ epaibm.rtpnc.epa.gov, select public access applications menu; EPA National Online Library System.
Extensive databases of EPA document holdings and EPA's endangered species database.

National Listing of Fish Consumption Advisories (NLFCA)
Internet Address: www:epa.gov/OWOW/fishadvice
Database includes all available information (including maps) describing State-issued fish consumption advisories in the U.S. Fish consumption advisories, issued when mean mercury concentrations exceed the FDA limit of 1.0 ppm (0.5 ppm in Florida) have been issued for 10 states: Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana- Mississippi, North Carolina, South Carolina, and Tennessee. For further information, contact Jeffrey Bigler, EPA, at 202-260-1305 (fax: 260-9830).

Field and Laboratory Test Methods and Procedures
WAIS _ wais.epa.gov, database/indexes/ALL, port 210

Field method guides, field operation manuals, laboratory test manuals, quality assurance plans, laboratory method manuals, test procedures, and more.

U.S. FISH AND WILDLIFE SERVICE

Internet Address: http://www.fws.gov
Provides lists of current and proposed listed (and delisted) Endangered and Threatened Wildlife and Plants for each state or territory.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Internet Address: www.fda.gov
FDA provides information on state fish and snapping turtle advisories. Although this information is provided for human health reasons, it can be used for identifying regional anthropogenic contaminant sources. FDA levels in fish and seafood are for interstate commerce.

U.S. GEOLOGICAL SURVEY (USGS)

Internet Address: http://www.usgs.gov
Various databases are available

ALSO SEE:

FEDWORLD INFORMATION NETWORK:

Internet Address: Telnet - fedworld.gov
Provides intemet gateway to wide range of U.S. govemment bulletin board systems, such as

EPA Bulletin Boards
Telnet - fedworld.gov
Access to NOAA, DOI's Office of Environmental Affairs BBS, Clean-Up Information BBS (Superfund Data and other hazardous waste information).

Ohio Environmental Protection Agency
WWW URL - http://arcboy.epa.ohio.gov/oepa.html

Environmental Resource Gophers:

epa.gov
riceinfo.rice.edu
gamet.berkeley.edu 1250
utdallas.edu
ecosys.drdr.virginia.edu

STATE ENVIRONMENTAL AGENCIES:

Most of the State environmental agencies are now on Internet, including:

Washington Dept. of Ecology
California Environmental Resource Evaluation System (CERES)
Oregon Online
Idaho Dept. of Water Resources
Montana Natural Resources Information
Pennsylvania Dept. of Environmental Resources

DIALOG DATABASES (Telnet):

Cambridge Scientific Abstracts: Now available on Internet at www.csa.com.

Enviroline: Provides indexing and abstracting coverage of more than 5000 international primary and secondary source publications reporting on all aspects of the environment.

Environmental Bibliography: Covers the fields of general human ecology, atmospheric studies, energy, land resources, water resources, nutrition, and health.

Pollution Abstracts: Leading resource for references to environment-related literature on pollution, its sources, and its control.

MAJOR EPA ENVIRONMENTAL DATABASES (Telnet):

TOXNET: Toxicology Data Network (Medlars) available through National Library of Medicine (NLM) and EPA's National Computer Center EPPA/NCC); accesses:
Integrated Risk Information System (IRIS)
Hazardous Substances Data Bank (HSDB)
Registry of Toxic Effects of Chemical Substances (RTECS) (also on CIS)

AQUIRE: Aquatic Information Retrieval System (available through CIS)

ASTER: Integration of the AQUIRE and QSAR systems

PHYTOTOX: Biological effects of application of organic chemicals to plants (available through CIS)

ECOTOX:	Combined databases for terrestrial and aquatic organisms, including ASTER, AQUIRE, PHYTOTOX, and TERRETOX

Appendix C
Framework

EPA/63O/R-92/001
February 1992

FRAMEWORK FOR ECOLOGICAL RISK ASSESSMENT

Risk Assessment Forum
U.S. Environmental Protection Agency
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ACKNOWLEGEMENTS

This U.S. Environmental Protection Agency (EPA) report has been developed under the auspices of EPA's Risk Assessment Forum, a standing committee of EPA scientists charged with developing risk assessment guidance for Agency-wide use. An interoffice work group chaired by Susan Norton (Office of Health and Environmental Assessment), Donald Rodier (Office of Toxic Substances), and Suzanne Marcy (Office of Water) led this effort Other members of the work group are Michael Brady. David Mauriello, Anne Sergeant, and Molly Whitworth. William van der Schalie and William Wood of the Risk Assessment Forum staff coordinated the project, which included peer review by scientists from EPA. other Federal agencies, and the private sector.

FOREWARD

Publication of this report, "Framework for Ecological Risk Assessment" (Framework Report), is a first step in a long-term program to develop risk assessment guidelines for ecological effects. EPA has been developing risk assessment guidelines primarily for human health effects for several years. In 1986, EPA issued five such guidelines, including cancer, developmental toxicity, and exposure assessment (51 Federal Register 33992-34054, 24 September 1986). Although EPA had issued guidance for cancer risk assessment 10 years earlier (41 Federal Register 21402, 1976). the 1986 guidelines substantially enlarged the scope of EPA's formal guidance by covering additional health topics and by covering all areas in much greater depth. Each of the guidelines was a product of several years of discussion and review involving scientists and policymakers from EPA, other Federal agencies, universities, industry, public interest groups, and the general public.

Preliminary work on comparable guidelines for ecological effects began in 1988. As part of this work, EPA studied existing assessments and identified issues to help develop a basis for articulating guiding principles for the assessment of ecological risks (U.S. EPA, 1991). At the same time, EPA's Science Advisory Board urged EPA to expand its consideration of ecological risk issues to include the broad army of chemical and nonchemical stressors for which research and regulation are authorized in the environmental laws administered by EPA (U.S. EPA, 1990b). As a result, EPA has embarked on a new program to develop guidelines for ecological risk assessment Like the program for health effects guidance, this activity depends on the expertise of scientists and policy-makers from a broad spectrum and draws principles, information, and methods from many sources.

In May 1991, EPA invited experts in ecotoxicology and ecological effects to Rockville, Maryland, to attend a peer review workshop on the draft Framework Report (56 Federal Register 20223, 2 May 1991). The workshop draft proposed a framework for ecological risk assessment complemented by preliminary guidance on some of the ecological issues identified in the draft. On the basis of the Rockville workshop recommendations (U.S. EPA, 1991). the revised Framework Report is now limited to discussion of the basic framework (see figure l), complemented by second-order diagrams that give structure and content to each of the major elements in the Framework Report (see figures 2 through 4). Consistent with peer review recommendations, substantive risk assessment guidance is being reserved for study and development in future guidelines.

The Framework Report is the product of a variety of activities that culminated in the Rockville workshop. Beginning early in 1990, EPA work groups and the National Academy of Sciences' (NAS) Committee on Risk Assessment Methodology began to study the 1983 NAS risk assessment paradigm (NRC, 1983). which provides the organizing principles for EPA's health risk guidelines, as a possible foundation for ecological risk assessment. Early drafts of EPA's Framework Report received preliminary peer comment late in 1990.

In February 1991, NAS sponsored a workshop in Warrenton. Virginia. to discuss whether any single paradigm could accommodate all the diverse kinds of ecological risk assessments. There was a consensus that a single paradigm is feasible but that the 1983 paradigm would require modification to fulfill this role. In April 1991. EPA sponsored a strategic planning workshop in Miami, Florida The structure and elements of ecological risk assessment were further discussed. Some participants in both of these earlier meetings also attended the Rockville workshop. EPA then integrated information, concepts, and diagrams from these workshop reviews with EPA practices and needs to propose a

working framework for interim use in EPA programs and for continued discussion as a basis for future risk assessment guidelines.

Use of the framework described in this report is not a requirement within EPA, nor is it a regulation of any kind. Rather, it is an interim product that is expected to evolve with use and discussion. EPA is publishing the Framework Report before proposing risk assessment guidelines for public comment to generate discussion within EPA, among Government agencies, and with the public to develop concepts. principles, and methods for use in future guidelines. To facilitate such discussion. EPA is presenting the framework at scientific meetings and inviting the public to submit information relevant to use and development of the approaches outlined for ecological risk assessment in the report

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PREFACE

Increased interest in ecological issues such as global climate change, habitat loss, acid deposition, reduced biological diversity, and the ecological impacts of pesticides and toxic chemicals prompts this Framework Report. This report describes basic elements, or a framework for evaluating scientific information on the adverse effects of physical and chemical stressors on the environment The framework offers starting principles and a simple structure as guidance for current ecological risk assessments and as a foundation for future EPA proposals for risk assessment guidelines.

The Framework Report is intended primarily for EPA risk assessors. EPA risk managers, and persons who perform work under EPA contract or sponsorship. The terminology and concepts described in the report may also assist other regulatory agencies, as well as members of the public who arc interested in ecological issues.

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EXECUTIVE SUMMARY

This report "Framework for Ecological Risk Assessment", is the first step in a long-term effort to develop risk assessment guidelines for ecological effects. Its primary purpose is to offer a simple. flexible structure for conducting and evaluating ecological risk assessment within EPA. Although the Framework Report will serve as a foundation for development of future subject-specific guidelines, it is neither a procedural guide nor a regulatory requirement within EPA and is expected to evolve with experience. The Framework Report is intended to foster consistent approaches to ecological risk assessment within EPA. identify key issues, and define terms used in these assessments.

Ecological risk assessments evaluate ecological effects caused by human activities such as draining of wetlands or release of chemicals. The term "stressor" is used here to describe any chemical, physical, or biological entity that can induce adverse effects on individuals, populations, communities, or ecosystems. Thus, the ecological risk assessment process must be flexible while providing a logical and scientific structure to accommodate a broad array of stressors.

The framework is conceptually similar to the approach used for human health risk assessment, but it is distinctive in its emphasis in three areas. First, ecological risk assessment can consider effects beyond those on individuals of a single species and may examine a population, community, or ecosystem. Second, there is no single set of ecological values to be protected that can be generally applied. Rather, these values are selected from a number of possibilities based on both scientific and policy considerations. Finally, there is an increasing awareness of the need for ecological risk assessments to consider nonchemical as well as chemical stressprs.

The framework consists of three major phases: (1) problem formulation, (2) analysis, and (3) risk characterization Problem formulation is a planning and scoping process that establishes the goals, breadth, and focus of the risk assessment Its end product is a conceptual model that identifies the environmental values to be protected (the assessment endpoints), the data needed, and the analyses to be used.

The analysis phase develops profiles of environmental exposure and the effects of the stressor. The exposure profile characterizes the ecosystems in which the stressor may occur as well as the biota that may be exposed. It also descries the magnitude and spatial and temporal patterns of exposure. The ecological effects profile summarizes data on the effects of the stressor and relates them to the assessment endpoints.

Risk characterization integrates the exposure and effects profiles. Risks can be estimated using a variety of techniques including comparing individual exposure and effects values. comparing the distributions of exposure and effects, or using simulation models. Risk can be expressed as a qualitative or quantitative estimate, **depending** on available data In this step, the assessor also:

- describes the risks in terms of the assessment endpoint;
- **discusses the ecological significance of the effects;**
- summarizes overall confidence in the assessment; and
- discusses the results with the risk manager.

The framework also recognizes several activities that are integral to, but separate from, me risk assessment process as defined in this report. For example, discussions between the risk assessor and risk manager are important. At the initiation of the risk assessment, the risk manager can help ensure that the risk assessment will ultimately provide information that is relevant to making decisions on the issues under consideration, while the risk assessor can ensure that the risk assessment addresses all relevant ecological concerns. Similar discussions of the results of the risk assessment are important to provide the risk manager with a full and complete understanding of the assessment's conclusions, assumptions, and limitations.

Other important companion activities to ecological risk assessment include data acquisition and verification and monitoring studies. New data are frequently required to conduct analyses that are performed during the risk assessment Data from verification studies can be used to validate the predictions of a specific risk assessment as well as to evaluate the usefulness of the principles set forth in the Framework. Ecological effects or exposure monitoring can aid in the verification process and suggest additional data, methods, or analyses that could improve future risk assessments.

1. INTRODUCTION

Public. private, and government sectors of society are increasingly aware of ecological issues including global climate change, habitat loss, acid deposition. a decrease in biological diversity, and the ecological impacts of xenobiotic compounds such as pesticides and toxic chemicals. To help assess these and other ecological problems, the U.S. Environmental Protection Agency (EPA) has developed this report. "Framework for Ecological Risk Assessment", which describes the basic elements. or framework. of a process for evaluating scientific information on the adverse effects of stressors on the environment The term "stressor " is defined here as any physical, chemical, or biological entity that can induce an adverse effect (see box'). Adverse ecological effects encompass a wide range of disturbances ranging from mortality in an individual organism to a loss in ecosystem function.

This introductory section describes the purpose, scope, and intended audience for this report; discusses the definition and application of ecological risk assessment; outlines the basic elements of the proposed framework; and describes the organization of this report.

Physical and Chemical Stressors as a Focus of the Framework

This report does not discuss accidentally or deliberately introduced species, genetically engineered organisms, or organisms used to control horticultural or agricultural pests. While the general principles described in the framework may be helpful in addressing risks associated with these organisms, the capacity of such organisms for reproduction and biological interaction introduces additional considerations that are not addressed in this document

1.1. Purpose and Scope of the Framework Report

An understanding of the finite purpose and scope of this Framework Report is important. EPA. other regulatory agencies, and other organizations need detailed, comprehensive guidance on methods for evaluating ecological risk. However, in discussing tentative plans for developing such guidance with expert consultants (U.S. EPA, 1991; U.S. EPA, in press-a), EPA was advised to first develop a simple framework as a foundation or blueprint for later comprehensive guidance on ecological risk assessment

With this background, the framework (see section 1.4) has two simple purposes, one immediate and one longer term. As a broad outline of the assessment process, the framework offers a basic structure and starting principles for EPA's ecological risk assessments. The process described by the framework provides wide latitude for planning and conducting individual risk assessments in many diverse situations, each based on the common principles discussed in the framework. The process also will help foster a consistent EPA approach for conducting and evaluating ecological risk assessments, identify key issues, and provide operational definitions for terms used in ecological risk assessments.

'The boxes used throughout this document serve several purposes. Some boxes provide additional background and rationale for terms, whereas other boxes expand on concepts described in the text The boxes at the end of each chapter highlight issues that are integral components of the risk assessment process but require more research, analysis, and debate. Further discussion of these issues is reserved for later guidelines.

In addition. the framework offers basic principles around which long-term guidelines for ecological risk assessment can be organized. With this in mind, this report does not provide substantive guidance on factors that are integral to the risk assessment process such as analytical methods. techniques for analyzing and interpreting data, or guidance on factors influencing policy. Rather, on the basis of EPA experience and the recommendations of peer reviewers, EPA has reserved discussion of these important aspects of any risk assessment for future guidelines, which will be based on the process described in this report

1.2. Intended Audience

The framework is primarily intended for EPA risk assessors, EPA risk managers. and other persons who either perform work under EPA contract or sponsorship or are subject to EPA regulations. The terminology and concepts described here also may be of assistance to other Federal, State, and local agencies as well as to members of the general public who are interested in ecological issues.

1.3. Definition and Applications of Ecological Risk Assessment

Ecological risk assessment is defined as a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors. A risk does not exist unless (1) the stressor has the inherent ability to cause one or more adverse effects and (2) it co-occurs with or contacts an ecological component (i.e., organisms, populations, communities. or ecosystems) long enough and at a sufficient intensity to elicit the identified adverse effect Ecological risk assessment may evaluate one or many stressors and ecological components.

Ecological risk may be expressed in a variety of ways. While some ecological risk assessments may provide true probabilistic estimates of both the adverse effect and exposure elements, others may be deterministic or even qualitative in nature. In these cases, the likelihood of adverse effects is expressed through a semiquantitative or qualitative comparison of effects and exposure.

Ecological risk assessments can help identify environmental problems, establish priorities, and provide a scientific basis for regulatory actions. The process can identify existing risks or forecast the risks of stressors not yet present in the environment However, while ecological risk assessments can play an important role in identifying and resolving environmental problems, risk assessments am not a solution for addressing all environmental problems, nor are they always a prerequisite for environmental management. Many environmental matters such as the protection of habitats and endangered species are compelling enough that there may not be enough time or data to do a risk assessment. In such cases, professional judgment and the mandates of a particular statute will be the driving forces in making decisions.

1.4. Ecological Risk Assessment Framework

The distinctive nature of the framework results primarily from three differences in emphasis relative to previous risk assessment approaches. First, ecological risk assessment can consider effects beyond those on individuals of a single species and may examine population. community, or ecosystem impacts. Second, there is no one set of assessment endpoints (environmental values to k protected) that can be generally applied Rather, assessment endpoints am selected from a very large number of possibilities based on both scientific and policy considerations. Finally, a comprehensive

approach to ecological risk assessment may go beyond the traditional emphasis on chemical effects to consider the possible effects of nonchemical stressors.

The ecological risk assessment framework is shown in figure 1. The risk assessment process is based on two major elements: characterization of exposure and characterization of ecological effects. Although these two elements am most prominent during the analysis phase. aspects of both exposure and effects also are considered during problem formulation, as illustrated by the arrows in the diagram. The arrows also flow to risk characterization. where the exposure and effects elements are integrated to estimate risk. The framework is conceptually similar to the National Research Council (NRC) paradigm for human health risk assessments (NRC, 1983).

The first phase of the framework is problem formulation. Problem formulation includes a preliminary characterization of exposure and effects, as well as examination of scientific data and data needs. policy and regulatory issues, and site-specific factors to define the feasibility, scope, and objectives for the ecological risk assessment The level of detail and the information that will be needed to complete the assessment also are determined. This systematic planning phase is proposed because ecological risk assessments often address the risks of stressors to many species as well as risks to communities and ecosystems. In addition there may be many ways a stressor can elicit adverse effects (e.g., direct effects on mortality and growth and indirect effects such as decreased food supply). Problem formulation provides an early identification of key factors to be considered, which in turn will produce a more scientifically sound risk assessment

Relationship of the Framework to a Paradigm for Human Health Risk Assessment

In 1983, NRC published a paradigm that has been used in the development of EPA's human health risk assessment guidelines. The paradigm has four phases: hazard identification, dose-response assessment. exposure assessment, and risk characterization (NRC. 1983). Although the framework's problem formulation phase is not explicitly identified in the NRC paradigm, comparable planning issues are addressed in practice at the beginning of all EPA risk assessments. In the framework's analysis phase, characterization of exposure is analogous to exposure assessment, while characterization of ecological effects includes aspects of both hazard identification and dose-response assesment. (The framework uses the term "stressor response" rather than "dose response" because many Agency programs must address stressors other than chemicals, and dose has been used only for chemicals.) Risk characterization is a similar process in both the framework and the NRC paradigm.

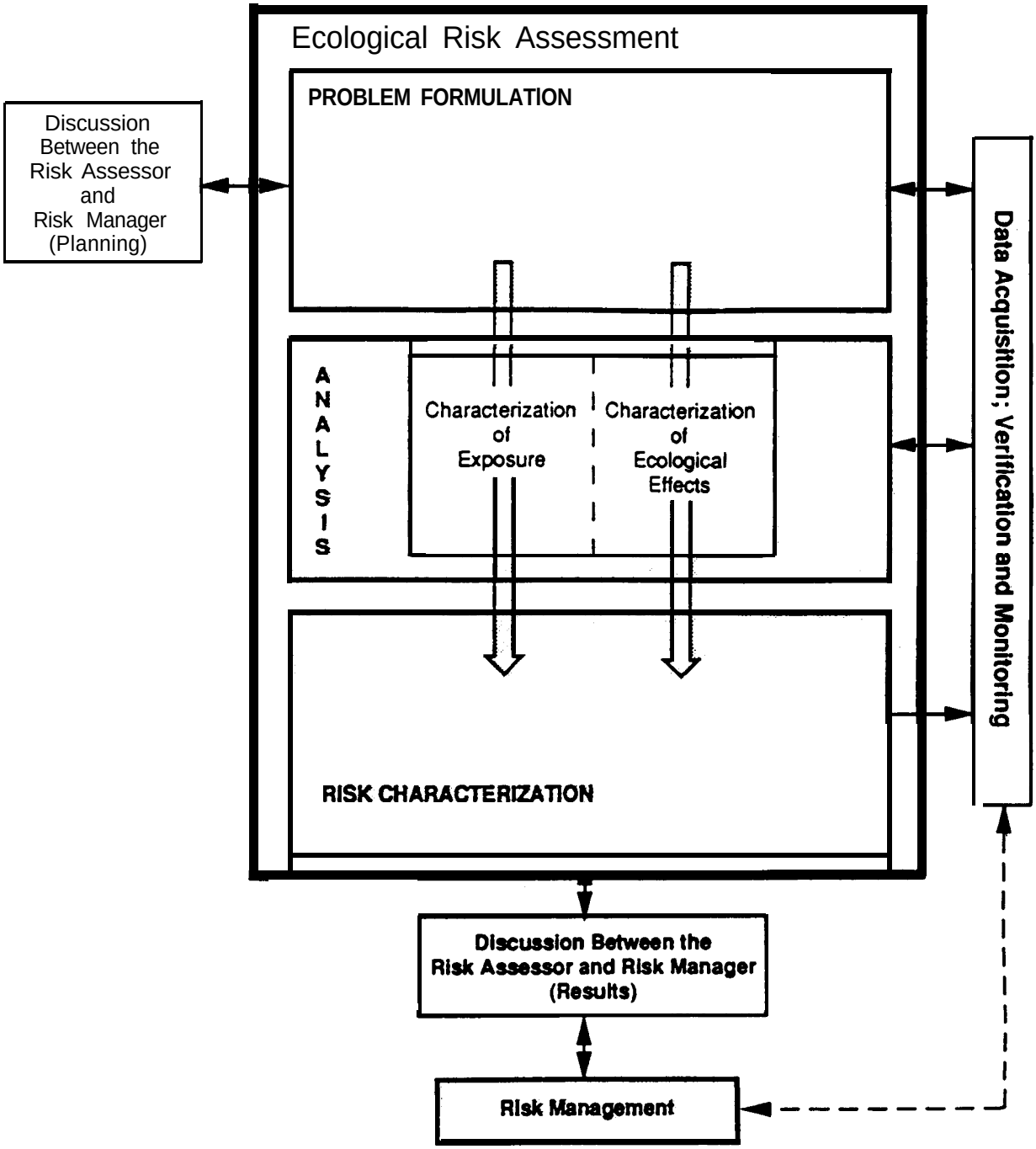

Figure 1. Framework for Ecological Risk Assessment

The second phase of the framework is termed analysis and consists of two activities, characterization of exposure and characterization of ecological effects. The purpose of characterization of exposure is to predict or measure the spatial and temporal distribution of a stressor and its co-occurrence or contact with the ecological components of concern, while the purpose of characterization of ecological effects is to Identify and quantify the adverse effects elicited by a stressor and, to the extent possible, to evaluate cause-and-effect relationships.

The third phase of the framework is risk characterization Risk characterization uses the results of the exposure and ecological effects analyses to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. It includes a summary of the assumptions used, the scientific uncertainties. and the strengths and weaknesses of the analyses. In addition, the ecological significance of the risks is discussed with consideration of the types and magnitudes of the effects, their spatial and temporal patterns, and the likelihood of recovery. The purpose is to provide a complete picture of the analysis and results.

In addition to showing the three phases of the framework, figure 1 illustrates the need for discussions between the risk assessor and risk manager. At the initiation of the risk assessment, the risk manager can help ensure that the risk assessment will ultimately provide information that is relevant to making decisions on the issues under consideration, while the risk assessor can ensure that the risk assessment addresses all relevant ecological concerns. Similar discussions of the results of the risk assessment are important to provide the risk manager with a full and complete understanding of the assessment's conclusions, assumptions, and limitations.

Figure 1 also indicates a role for verification and monitoring in the framework, Verification can include validation of the ecological risk assessment process as well as confirmation of specific predictions made during a risk assessment Monitoring can aid in the verification process and may identify additional topics for risk assessment Verification and monitoring can help determine the overall effectiveness of the framework approach, provide necessary feedback concerning the need for future modifications of the framework

Use of the Term "Exposure"

Some reviewers of earlier drafts of this interim framework proposed that the term "exposure",-which, as used in human health risk assessment generally refers to chemical stressor%-not be used for the nonchemical stressors that can affect a variety of ecological components. Other terms, including "characterization of stress", have been suggested. At this time, WA prefers exposure, partly because characterization of stress does not convey the important concept of the co-occurrence and interaction of the stressor with an ecological component as well as exposure does.

Characterization of Ecological Effects Used Instead of Hazard Assessment

The framework uses characterization of ecological effects rather than hazard assessment for two reasons. First the term "hazard" can be ambiguous, because it has been use in the past to mean either evaluating the intrinsic effects of a stressor (U.S. EPA. 1979) or defining a margin of safety or quotient by comparing a toxicological endpoint of interest with an estimate of exposure concentration (SETAC, 1987). Second. many reviewers believed that hazard is more relevant to chemical than to nonchemical stressors.

help evaluate the effectiveness and practicality of policy decisions, and point out the need for new or improved scientific techniques (U.S. EPA, in press-a).

The interaction between data acquisition and ecological risk assessment is also shown in figure 1. In this report. a distinction is made between data acquisition (which is outside of the risk assessment process) and data analysis (which is an integral part of an ecological risk assessment). In me problem formulation and analysis phases, the risk assessor may identify the need for additional data to complete an analysis. At this point, the risk assessment stops until the necessary data are acquired. When a need for additional data is recognized in risk characterization, new information generally is used in the analysis or problem formulation phases. The distinction between data acquisition and analysis generally is maintained in all of EPA's risk assessment guidelines; guidance on data acquisition procedures are provided in documents prepared for specific EPA programs.

The interactions between data acquisition and ecological risk assessment often result in an iterative process. For example, data used during the analysis phase may be collected in tiers of increasing complexity and cost. A decision to advance from one tier to the next is based on decision triggers set at certain levels of effect or exposure. Iterations of the entire risk assessment process also may occur. For example, a screening-level risk assessment may be performed using readily available data and conservative assumptions; depending on the results. more data then may be collected to support a more rigorous assessment.

1.5. The Importance of Professional Judgment

Ecological risk assessments, like human health risk assessments, are based on scientific data that are frequently difficult and complex, conflicting or ambiguous, or incomplete. Analyses of such data for risk assessment purposes depends on professional judgment based on scientific expertise. Professional judgment is necessary to:

- design and conceptualize the risk assessment;
- evaluate and select methods and models:
- determine the relevance of available data to the risk assessment;
- develop assumptions based on logic and scientific principles to fill data gaps; and
- interpret the ecological significance of predicted or observed effects.

Because professional judgment is so important, specialized knowledge and experience in the various phases of ecological risk assessment is required. Thus, an interactive multidisciplinary team that includes biologists and ecologists is a prerequisite for a successful ecological risk assessment.

1.6. Organization

The next three sections of this report are arranged to follow the framework sequentially. Section 2 describes problem formulation: this section is particularly important for assessors to consider when specific assessment endpoints are not determined a priori by statute or other authority. Section 3 and 4 discuss analysis and risk characterization, respectively. Section 5 defines the terms used in

this report. and section 6 provides literature references. The lists of ecological risk assessment issues at the end of sections 1 through 4 highlight areas for further discussion and research. EPA believes that these issues will require special attention in developing ecological risk assessment guidelines.

Additional Issues Related to the Framework

- Use of the framework for evaluating risks associated with biological stressors.
- Use of the term exposure (versus characterization of stress) for both chemical and nonchemical stressors.
- Use of the term characterization of ecological effects rather than hazard assessment.

2. PROBLEM FORMULATION

Problem formulation is the first phase of ecological risk assessment and establishes the goals. breadth. and focus of the assessment. It is a systematic planning step that identifies the major factors to be considered in a particular assessment, and it is linked to the regulatory and policy context of the assessment.

Entry into the ecological risk assessment process may be triggered by either an observed ecological effect, such as visible damage to trees in a forest, or by the identification of a stressor or activity of concern, such as the planned filling of a marsh or the manufacture of a new chemical. The problem formulation process (figure 2) then begins with the initial stages of characterizing exposure and ecological effects, including evaluating the stressor characteristics, the ecosystem potentially at risk, and the ecological effects expected or observed. Next the assessment and measurement endpoints are identified. (Measurement endpoints are ecological characteristics that can be related to the assessment endpoint) The outcome of problem formulation is a conceptual model that describes how a given stressor might affect the ecological components in the environment The conceptual model also describes the relationships among me assessment and measurement endpoints, the data required, and the methodologies mat will be used to analyze the data. The conceptual model serves as input to the analysis phase of the assessment

2.1. Discussion Between the Risk Assessor and Risk Manager (Planning)

To be meaningful and effective, ecological risk assessments must be relevant to regulatory needs and public concerns as well as scientifically valid. Although risk assessment and risk management are distinct processes, establishing a two-way dialogue between risk assessors and risk managers during the problem formulation phase can be a constructive means of achieving both societal and scientific goals. By bringing the management perspective to the discussion, risk managers charged with protecting societal values can ensure that the risk assessment will provide relevant information to making decisions on the issue under consideration By bringing scientific knowledge to the discussion, the ecological risk assessor ensures that the assessment addresses all important ecological concerns. Both perspectives are necessary to appropriately utilize resources to produce scientifically sound risk assessments that ate relevant to management decisions and public concerns.

2.2. Stressor Characteristics, Ecosystem Potentially at Risk, and Ecological Effects

The initial steps in problem formuladon are the identification and preliminary characterization of stressors, the ecosystem potentially at risk, and ecological effects. Performing this analysis is an interactive process that contributes to both the selection of assessment and measurement endpoints and the development of a conceptual model.

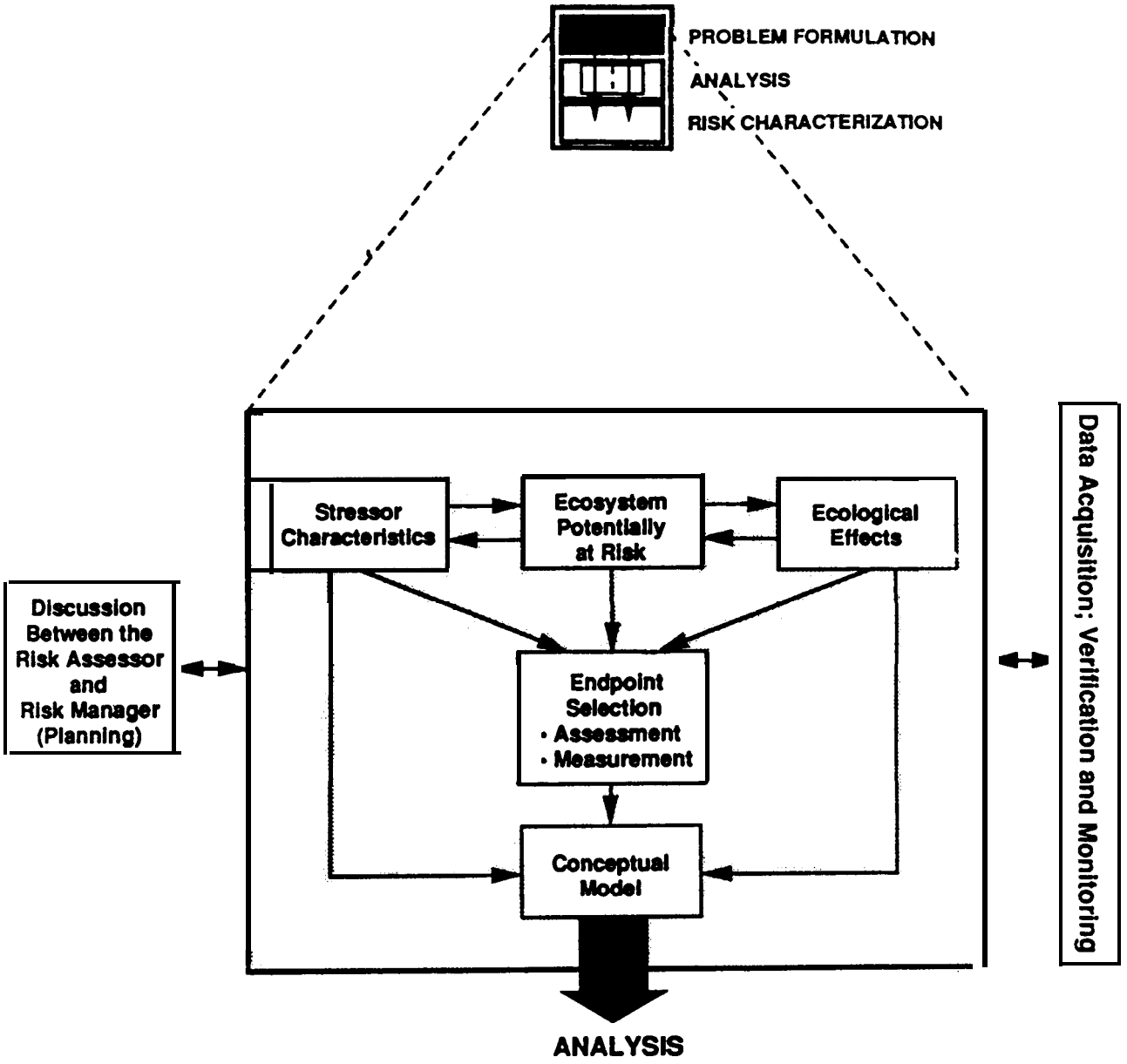

Figure 2. Problem Formulation

2.2.1. Stressor Characteristics

The determination of stressor characteristics begins with the identification of potential chemical or physical stressors. Chemical stressors include a variety of inorganic and organic substances. Some chemicals may result in secondary stressors, as in the case of stratospheric ozone depletion caused by chlorofluorocarbons that could result in increased exposures to ultraviolet radiation. Physical stressors include extremes of natural conditions (e.g.. temperature and hydrologic changes) and habitat alteration or destruction. Stressors that may result from management practices, such as harvesting of fishery or forest resources, also may be considered. Example stressor characteristics are summarized in the box below. Gathering information on the characteristics of a stressor helps define the ecosystems potentially at risk from the stressor as well as the ecological effects that may result.

2.22. Ecosystem Potentially at Risk

The ecosystem within which effects occur provides the ecological context for the assessment Knowledge of the ecosystem potentially at risk can help identify ecological components that may be affected and stressor-ecosystem interactions relevant to developing exposure scenarios. The approach to identifying the ecosystem potentially at risk from a stressor depends in part on how the risk assessment was initiated. If a stressor first was identified, information on the spatial and temporal distribution patterns of the stressor can be helpful in identifying ecosystems potentially at risk. Similarly, if the risk assessment is initiated by observing effects, these effects can directly indicate ecosystems or ecological components that may be considered in the assessment.

Example Stressor Characteristics

Type

Chemical or physical

Intensity

Concentration or magnitude

Duration

Short or long term

Frequency

Single event, episodic, or continuous

Timing

Occurrence relative to biological cycles

Scale

Spatial heterogeneity and extent

A wide range of ecosystem properties may be considered during problem formulation These properties include aspects of the abiotic environment (such as climatic conditions and soil or sediment properties), ecosystem structure (including the types and abundances of different species and their trophic level relationships), and ecosystem function (such as the ecosystem energy source, pathways of energy utilization. and nutrient processing) (U.S. EPA, in press-b). In addition, knowledge of the types and patterns Of historical disturbances may-k helpful in predicting ecological responses to stressors.

The need to evaluate spatial and temporal distribution and variation is inherent in many of these example characteristics. Such information is especially useful for determining potential exposure, that is, where there is co-occurrence of or contact between the stressor and ecological components.

2.23. Ecological Effects

Ecological effects data may come from a variety of sources. Relevant sources of information include field observations (e.g., fish or bird kills, changes in aquatic community structure). field tests (e.g., microcosm or mesocosm tests),-laboratory tests (e.g.. single species or microcosm tests), and chemical structure-activity relationships. Available information on ecological effects can help focus the assessment on specific stressors and on ecological components that should be evaluated.

Many factors can influence the utility of available ecological effects data for problem formulation For example, the applicability of laboratory-based tests may be affected by any extrapolations required to specific field situations, while the interpretation of field observations may be influenced by factors such as natural variability or the possible presence of stressors other than the ones that are the primary focus of the risk assessment.

2.3. Endpoint Selection

Information compiled in the first stage of problem formulation is used to help select ecologically based endpoints that are relevant to decisions made about protecting the environment. An endpoint is a characteristic of an ecological component (e.g., increased mortality in fish) that may be affected by exposure to a stressor (Suter, 1990a). Two types of endpoints axe distinguished in this report. Assessment endpoints are explicit expressions of the actual environmental value that is to be protected. Measurement endpoints are measurable responses to a stressor that are related to the valued characteristics chosen as the assessment endpoints (Suter, 1990a).

Endpoint Terminology

Several reviewers have suggested using the term “indicator" in place of “measurement endpoint”. At this time, measurement endpoint is preferred because it has a specific meaning (a characteristic of an ecological system that can be related to an assessment endpoint), whereas indicator can have several different meanings. For example, indicator has been used at EPA to mean (1) measures of administrative accomplishments (e.g.. number of permits issued), (2) measures of exposure (e.g.. chemical levels in sediments), or (3) measures of ecosystem integrity. These indicators cannot always be related to an assessment endpoint.

Assessment endpoints are the ultimate focus in risk characterization and link the measurement endpoints to the risk management process (e.g.. policy goals). When an assessment endpoint can be directly measured, the measurement and assessment endpoints arc the same. In most cases. however, the assessment endpoint cannot be directly measured, so a measurement endpoint (or a suite of measurement endpoints) is selected that can be related, either qualitatively or quantitatively, to the assessment endpoint. For example, a decline in a sport fish population (the assessment endpoint) may be evaluated using laboratory studies on the mortality of surrogate species, such as the fathead minnow (the measurement endpoint). Sound professional judgment is necessary for proper assessment and measurement endpoint selection, and it is important that both the selection rationale and the linkages between measurement endpoints, assessment endpoints, and policy goals be Clearly stated.

Assessment and measurement endpoints may involve ecological components from any level of biological organization. ranging from individual organisms to the ecosystem itself. In general. the use of a suite of assessment and measurement endpoints at different organizational levels can build greater confidence in the conclusions of the risk assessment and ensure that all important endpoints are evaluated. In some situations, measurement endpoints at one level of organization may be related to an assessment endpoint at a higher level. For example, measurement endpoints at the individual level (e.g., mortality, reproduction, and growth) could be used in a model to predict effects on an assessment endpoint at the population level (e.g., viability of a trout population in a stream).

General considerations for selecting assessment and measurement endpoints are detailed in the following boxes. More detailed discussions of endpoint and selection criteria can be found in Surer (1989, 1990a). Kelly and Harwell (1990), U.S. Department of the Interior (1987). and U.S. EPA (1990a).

Considerations in Selecting Assessment Endpoints

Ecological Relevance

Ecologically relevant endpoints reflect important characteristics of the system and are functionally related to other endpoints. Selection of ecologically relevant endpoints requires some understanding of the structure and function of the ecosystem potentially at risk For example, an assessment endpoint could focus on changes in a species known to have a controlling influence on the abundance and distribution of many other species in its community. Changes at higher levels of organization may be significant because of their potential for causing major effects at lower organizational levels.

Policy Goals and Societal Values

Good communication between the risk assessor and risk manager is important to ensure that ecologically relevant assessment endpoints reflect policy goals and societal values. Societal concerns can range from protection of endangered or commercially or recreationally important species to preservation of ecosystem attributes for functional reasons (e.g., flood water retention by wetlanda) or aesthetic reasons (e.g., visibility in the Grand Canyon).

Susceptibility to the Stressor

Ideally, an assessment endpoint would be likely to be both affected by exposure to a stressor and sensitive to the specific type of effects caused by the stressor. For example, if a chemical is known to bioaccumulate and is suspected of causing eggshell thinning, an appropriate assessment endpoint might be raptor population viability.

Considerations in Selecting Measurement Endpoints

Relevance to an Assessment Endpoint

When an assessment endpoint cannot be directly measured measurement endpoints are identified that are correlated with or can be used to infer or predict changes in the assessment endpoint.

Consideration of Indirect Effects

Indirect effects occur when a stressor acts on elements of the ecosystem that are required by the ecological component of concern. For example. if the assessment endpoint is the population viability of trout, measurement endpoints could evaluate possible stressor effects on trout prey species or habitat requirements.

Sensitivity and Response Time

Rapidly responding measurement endpoints may be useful in providing early warnings of ecological effects, and measurement endpoints also may be selected because they are sensitive surrogates of the assessment endpoint. In many cares, measurement endpoints at lower levels of biological organ&ion may be more sensitive than those at higher levels. Howeva. because of compensatory mechanisms and other factors, a change in a measurement endpoint at a lower organizational level (e.g., a biochemical alteration) may not necessarily be reflected in changes at a higher level (e.g., population effects).

Signal-to-Noise Ratio

If a measurement endpoint is highly variable. the. possibility of detecting stressor-related effects may be greatly reduced even if the endpoint is sensitive to the stressor.

Consistency With Assessment Endpoint Exposure Scenarios

The ecological component of the measurement endpoint should be exposed by similar routes and at similar or greater strcssor levels as the ecological component of the assessment endpoint

Diagnositic Ability

Measurement endpoints that are unique or specific responses to a stressor may be very useful in diagnosing the presence or effects of a stressor. For example, measurement of acetylcholinesterase inhibition may be useful for demonstrating responses to certain types of pesticides.

Practicality Issues

Ideal measurement endpoints are cost effective and easily measured. The availability of a huge database for a measurement endpoint is desirable to facilitate comparisons and develop models.

2.4. The Conceptual Model

The major focus of the conceptual model (figure 2) is the development of a series of working hypotheses regarding how the stressor might affect ecological components of the natural environment (NRC, 1986). The conceptual model also includes descriptions of the ecosystem potentially at risk and the relationship between measurement and assessment endpoints.

During conceptual model development, a preliminary analysis of the ecosystem, stressor characteristics, and ecological effects is used to define possible exposure scenarios. Exposure scenarios consist of a qualitative description of how the various ecological components co-occur with or contact the stressor. Each scenario is defined in terms of the stressor. the type of biological system and principal ecological components, how the stressor will contact or interact with the system, and the spatial and temporal scales.

For chemical stressors, the exposure scenario usually involves consideration of sources, environmental transport. partitioning of the chemical among various environmental media, chemical/biological transformation or speciation processes, and identification of potential routes of exposure (e.g., ingestion). For nonchemical stressors such as water level or temperature changes or physical disturbance, the exposure scenario describes the ecological components exposed and the general temporal and spatial patterns of their co-occurrence with the stressor. For example, for habitat alterations, the exposure scenario may describe the extent and distributional pattern of disturbance, the populations residing within or using the disturbed areas, and the spatial relationship of the disturbed area to undisturbed areas.

Although many hypotheses may be generated during problem formulation, only those that are considered most likely to contribute to risk are selected for further evaluation in the analysis phase. For these hypotheses, the conceptual model describes the approach that will be used for the analysis phase and the types of data and analytical tools that will be needed. It is important that hypotheses that arc not carried forward in the assessment because of data gaps be acknowledged when uncertainty is addressed in risk characterization Professional judgment is needed to select the most appropriate risk hypotheses, and it is important to document the selection rationale.

Additional Issues in Problem Formulation

- o Role of risk management concerns in establishing assessment endpoints.

  Although it is important to consider risk management concerns when assessment endpoints are selected, there is still uncertainty as to how these inputs should influence the goals of the risk assessment, the ecological components to be protected, and the level of protection required.

- o Identifying specific assessment and measurement endpoints for different stressors and ecosystems.

3. ANALYSIS PHASE

The analysis phase of ecological risk assessment (figure 3) consists of the technical evaluation of data on the potential effects and exposure of the stressor. The analysis phase is based on the conceptual model developed during problem formulation Although this phase consists of characterization of ecological effects and characterization of exposure, the dotted line in figure 3 illustrates that the two are performed interactively. An interaction between the two elements will ensure that the ecological effects characterized are compatible with the biota and exposure pathways identified in the exposure characterization . The output of ecological effects characterization and exposure characterization are summary profiles that are used in the risk characterization phase (section 4). Discussion of uncertainty analysis. which is an important part of the analysis phase, may be found in section 4.1.2.

Characterization of exposure and ecological effects often requires the application of statistical methods. While the discussion of specific statistical methods is beyond the scope of this document, selection of an appropriate statistical method involves both method assumptions (e.g., independence of errors, normality, quality of variances) and data set characteristics (e.g., distribution, presence of outliers or influential data). It should be noted that statistical significance does not always reflect biological significance, and profound biological changes may not be detected by statistical tests. Professional judgment often is required to evaluate the relationship between statistical and biological significance.

3.1. Characterization of Exposure

Characterization of exposure (half of the analysis phase shown in figure 3) evaluates the interaction of the stressor with the ecological component Exposure can be expressed as co-occurrence or contact depending on the stressor and the ecological component involved. An exposure profile is developed that quantifies the magnitude and spatial and temporal distributions of exposure for the scenarios developed during problem formulation and serves as input to the risk characterization

3.1.1. Stressor Characterization: Distribution or Pattern of Change

Stressor characterization involves determining the stressor's distribution or pattern of change. Many techniques can be applied to assist in this stressor characterization process. For chemical stressors, a combination of modeling and monitoring data often is used. Available monitoring data may include measures of releases into the environment and media concentrations over space and time. Fate and transport models often arc used that rely on physical and chemical characteristics of the chemical coupled with the characteristics of the ecosystem. For nonchemical stressors such as physical alterations or harvesting, the pattern of change may depend on resource management or land-use practices. Depending on the scale of the disturbance. the data for stressor characterization can be provided by a variety of techniques, including ground reconnaissance, aerial photographs, or satellite imagery.

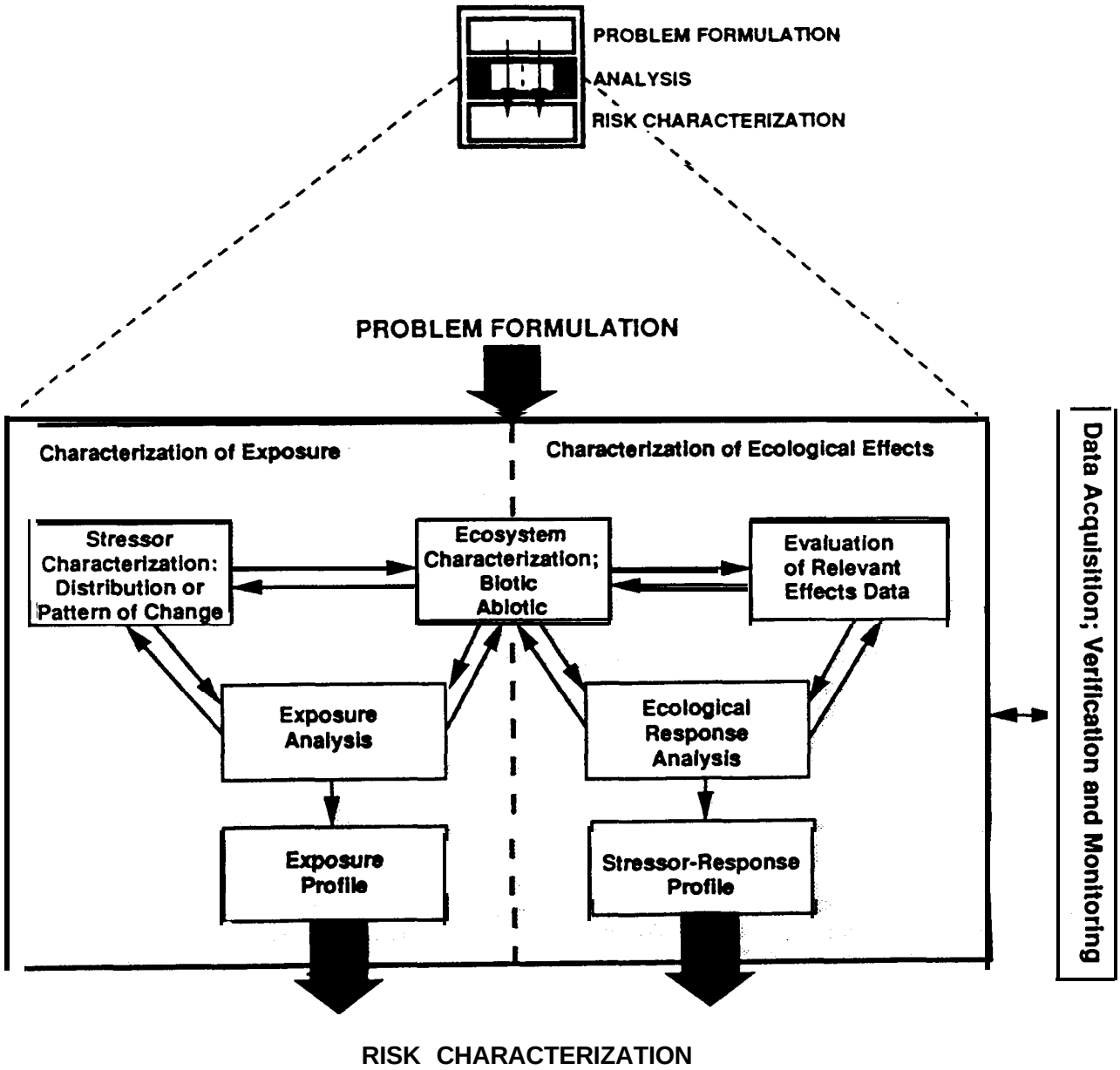

Figure 3. Analysis

During stressor characterization, one considers not only the primary stressor but also secondary stressors that can arise as a result of various processes. For example, removal of riparian (stream-side) vegetation not only alters habitat structure directly, but can have additional ramifications such as increased siltation and temperature rise. For chemicals, secondary stressors can be produced by a range of environmental fate processes.

The timing of the stressor's interaction with the biological system is another important consideration. If the stressor is episodic in nature, different species and life stages may be affected. In addition, the ultimate distribution of a stressor is rarely homogeneous; it is important to quantify such heterogeneity whenever possible.

3.12. Ecosystem Characterization

During ecosystem characterization, the ecological context of the assessment is further analyzed. In particular, the spatial and temporal distributions of the ecological component am characterized, and the ecosystem attributes that influence the distribution and nature of the stressor ate considered.

Characteristics of the ecosystem can greatly modify the ultimate nature and distribution of the stressor. Chemical stressors can be modified through biotransformation by mictobial communities or through other environmental fate processes, such as photolysis. hydrolysis, and sorption. The bioavailability of chemical stressors also can be affected by the environment. which in turn influences the exposure of ecological components.

Physical stressors can be modified by the ecosystem as well. For example, siltation in streams depends not only on sediment volume, but on flow regime and physical stream characteristics. Similarly, nearby wetlands and levees influence water behavior during flood events.

The spatial and temporal distributions of ecological components also are considered in ecosystem characterization. Characteristics of ecological components that influence their exposure to the stressor ate evaluated, including habitat needs, food preferences, reproductive cycles, and seasonal activities such as migration and selective use of resources. Spatial and temporal variations in the distribution of the ecological component (e.g., sediment invertebrate distribution) may complicate evaluations of exposure. When available, species-specific information about activity patterns, abundance, and life histories can be very useful in evaluating spatial and temporal distributions

Another important consideration is how exposure to a stressor may alter natural behavior, thereby affecting further exposure. In some cases. this may lead to enhanced exposure (e.g.. increased preening by birds after aerial pesticide spraying), while in other situations initial exposure may lead to avoidance of contaminated locations or food sources (e.g., avoidance of certain waste effluents or physically altered spawning beds by some fish species).

3.13. Exposure Analyses

The next step is to combine the spatial and temporal distributions of both the ecological component and the stressor to evaluate exposure. In the case of physical alterations of communities and ecosystems. exposure can be expressed broadly as co-occurrence. Exposure analyses of individuals often focus on actual contact with the stressor, because organisms may not contact all of the stressors present in an area For chemical stressors, the analyses may focus further on the amount of chemical that is bioavailable, that is, available for uptake by the organism. Some chemical exposure analyses also follow the chemical within the organism's body and estimate the amount that reaches the target organ. The focus of the analyses will depend on the stressors being evaluated and the assessment and measurement endpoints.

The temporal and spatial scales used to evaluate the stressor need to be compatible with the characteristics of the ecological component of interest. A temporal scale may encompass the lifespan of a species, a particular life stage, or a particular cycle, for example. the long-term succession of a forest community. A spatial scale may encompass a forest, a lake, a watershed, or an entire region Stressor timing relative to organism life stage and activity patterns can greatly influence the occurrence of adverse effects. Even short-term events may be significant if they coincide with critical life stages. Periods of reproductive activity may be especially important, because early life stages often are more sensitive to stressors, and adults also may be more vulnerable at this time.

The most common approach to exposure analysis is to measure concentrations or amounts of a stressor and combine them with assumptions about co-occurrence, contact, or uptake. For example, exposure of aquatic organisms to chemicals often is expressed simply as concentration in the water column; aquatic organisms are assumed to contact the chemical. Similarly, exposures of organisms to habitat alteration often is expressed as because of habitat altered: organisms that utilize the habitat-are assumed to co-occur with the alteration stressor measurements can also be combined with quantitative parameters describing the frequency and magnitude of contact For example, concentrations of chemicals in food items can be combined with ingestion rates to estimate dietary exposure of organisms.

In some situations, the stressor can be measured at the actual point of contact while exposure occurs. An example is the use of food collected from the mouths of nestling birds to evaluate exposure to pesticides through contaminated food (Kendall, 1991). Although such point-of-contact measurements can be difficult to obtain they reduce the need for assumptions about the frequency and magnitude of contact-

Patterns of exposure can be described using models that combine abiotic ecosystem attributes, stressor properties. and ecological component characteristics. Model selection is based on the model's suitability for the ecusystem or component of interest, the availability of the requisite data, and the study objectives. Model choices range. from simple, screening-level procedures that require a minimum of data to more sophisticated methods that describe processes in more detail but require a considerable amount of data

Another approach to evaluating exposure uses chemical, biochemical, or physiological evidence (e.g.. biomarkers) of a previous exposure. This approach has been used primarily for assessing chemical exposures and is particularly useful when a residue or biomarker is diagnostic of exposure to a particular chemical. These types of measurements are most useful for exposure

characterization when they can be quantitatively linked to the amount of stressor originally contacted by the organism. Pharmacokinetic models are sometimes used to provide this Linkage.

3.1.4. Exposure Profile

Using information obtained from the exposure analysis. the exposure profile quantifies the magnitude and spatial and temporal patterns of exposure for the scenarios developed during problem formulation and serves as input to risk characterization The exposure profile is only effective when its results are compatible with the stressor-response profile. For example, appraisals of potential acute effects of chemical exposure may be averaged over short time periods to account for short-term pulsed stressor events. It is important that characterizations for chronic stressors account for both long-term low-level exposure and possible shorter term higher level contact that may elicit similar adverse chronic effects.

Exposure profiles can be expressed using a variety of units. For chemical stressors operating at the organism level, the usual metric is expressed in dose units (e.g., mg/kg body weight/day). For higher levels of organization (e.g.. an entire ecosystem), exposure may be expressed in units of concentration/unit area/time. For physical disturbance, the exposure profile may be expressed in other terms (e.g.. percentage of habitat removed or the extent of flooding/year).

An uncertainty assessment is an integral part of the characterization of exposure. In the majority of assessments, data will not be available for all aspects of the characterization of exposure, and those data that are available may be of questionable or unknown quality. Typically, the assessor will have to rely on a number of assumptions with varying degrees of uncertainty associated with each These assumptions will be based on a combination of professional judgment inferences based on analogy with similar chemicals and conditions and estimation techniques, all of which contribute to the overall uncertainty. It is important that the assessor characterize each of the various sources of uncertainty and carry them forward to the risk characterization so that they may be combined with a similar analysis conducted as part of the characterization of ecological effects.

3.2. Characterization of Ecological Effects

The relationship between the stressor and the assessment and measurement endpoints identified during problem formulation is analyzed in characterization of ecological effects (figure 3). The evaluation begins with the evaluation of effects data that are relevant to the stressor. During ecological response analysis, the relationship between the stressor and the ecological effects elicited is quantified, and cause-and-effect relationships are evaluated. In addition, extrapolations from measurement endpoints to assessment endpoints are conducted during this phase. The product is a stressor-response profile that quantifies and summarizes the relationship of the stressor to the assessment endpoint The stressor-response profile is then used as input to risk characterization.

3.2.1. Evaluation of Relevant Effects Data

The type of effects data that are evaluated depends largely on the nature of the stressor and the ecological component under evaluation. Effects elicited by a stressor may range from mortality and reproductive impairment in individuals and populations to disruptions in community and ecosystem function such as primary productivity. The evaluation process relies on professional judgment

especially when few data are available or when choices among several sources of data are required. If available data are inadequate, new data may be needed before the assessment can be completed.

Data are evaluated by considering their relevance to the measurement and assessment endpoints selected during problem formulation The analysis techniques that will be used also are considered; data that minimize the need for extrapolation are desirable. Data quality (e.g., sufficiency of replications, adherence to good laboratory practices) is another important consideration . Finally, characteristics of the ecosystem potentially at risk will influence what data will be used. Ideally, the test system reflects the physical attributes of the ecosystem and will include the ecological components and life stages examined in the risk assessment

Data from both field observations and experiments in controlled settings can be used to evaluate ecological effects. In some cases, such as for chemicals that have yet to be manufactured. test data for the specific stressor are not available. Quantitative structure-activity relationships (QSARs) are useful in these situations (Auer et al., 1990, Clements et al., 1988; McKim et al., 1987).

Controlled laboratory and field tests (e.g., mesocosms) can provide strong causal evidence linking a stressor with a response and can also help discriminate between multiple stressors. Data from laboratory studies tend to be less variable than those from field studies, but because environmental factors are controlled, responses may differ from those in the natural environment

Observational field studies (e.g., comparison with reference sites) provide environmental realism that laboratory studies lack, although the presence of multiple stressors and other confounding factors (e.g., habitat quality) in the natural environment can make it difficult to attribute observed effects to specific stressors. Confidence in causal relationships can be improved by carefully selecting comparable reference sites or by evaluating changes along a stressor gradient where differences in other environmental factors are minimized. It is important to consider potential confounding factors during the analysis.

3.22. Ecological Response Analyses

The data used in characterization of ecological effects are analyzed to quantify the stressor-response relationship and to evaluate the evidence for causality. A variety of techniques may be used, including statistical methods and mathematical modeling In some cases, additional analyses to relate the measurement endpoint to the assessment endpoint may be necessary.

Stressor-Response Analyses

The stressor-response analysis describes the relationship between the magnitude, frequency, or duration of the stressor in an observational or experimental setting and the magnitude of response. The stressor-response analysis may focus on different aspects of the stressor-response relationship, depending on the assessment objectives, the conceptual model, and the type of data used for the analysis. Stressor-response analyses, such as those used for toxicity tests, often portray the magnitude of the stressor with respect to the magnitude of response. Other important aspects to consider include the temporal (e.g.. frequency, duration, and timing) and spatial distributions of the stressor in the experimental or observational setting. For physical stressors, specific attributes of the environment after disturbance (e.g., reduced forest stand age) can be related to the response (e.g., decreased use by spotted owls) (Thomas et al., 1990).

Analyses Relating Measurement and Assessment Endpoints

Ideally. the stressor-response evaluation quantifies the relationship between the stressor and the assessment endpoint. When the assessment endpoint can be measured, this analysis is straightforward. When it cannot be measured, the relationship between the stressor and measurement endpoint is established first, then additional extrapolations, analyses, and assumptions are used to predict or infer changes in the assessment endpoint The need for analyses relating measurement and assessment endpoints also may he identified during risk characterization after an initial evaluation of risk.

Measurement endpoints are related to assessment endpoints using the logical structure presented in the conceptual model. In some cases, quantitative methods and models arc available, but often the relationship can be described only qualitatively. Because of the lack of standard methods for many of these analyses, professional judgment is an essential component of the evaluation. It is important to clearly explain the rationale for any analyses and assumptions.

Extrapolations commonly used include those between species, between responses, from laboratory to field, and from field to field. Differences in responses among taxa depend on many factors. including physiology. metabolism, resource utilization, and life history strategy. The relationship between responses also depends on many factors, including the mechanism of action and internal distribution of the stressor within the organism. When extrapolating between different laboratory and field settings, important considerations include differences in the physical environment and organism behavior that will alter exposure, interactions with other stressors, and interactions with other ecological components.

Extrapolations and Other Analyses Relating Measurement and Assessment Endpoints

Extrapolation Between Taxa

example: from bluegill sunfish mortality to rainbow trout mortality

Extrapolation Between Responses

example: from bobwhite quail LC_{50} to bobwhite quail NOEL (no observed effect level)

Extrapolation From Laboratory to Field

example: from mouse mortality under laboratory conditions to mouse mortality in the field

Extrapolation From Field to Field

example: from reduced invertebrate community diversity in one stream to another stream.

Analysis of Indirect Effects

example: relating removal of long-leaf pine to reduced populations of red-cockaded woodpecker

Analysis of Higher Organizational Levels

example: relating reduced individual fecundity to reduced population size

Analysis of Spatial and Temporal Scales

example: evaluation of the loss of a specific wetland used by migratory birds in relation to the larger scale habitat requirements of the species

Analysis of Recovery

example: relating short-term mortality to long-term depauperation

In addition to these extrapolations, an evaluation of indirect effects, other levels of organization, other temporal and spatial scales. and recovery potential may be necessary. Whether these analyses are required in a particular risk assessment will depend on the assessment endpoints identified during problem formulation.

Important factors to consider when evaluating indirect effects include interspecies interactions (e.g., competition, disease), trophic-level relationships (e.g., predation), and resource utilization. Effects on higher (or lower) organizational levels depend on the severity of the effect, me number and life stage of organisms affected, the role of those organisms in the community or ecosystem, and ecological compensatory mechanisms.

The implications of adverse effects at spatial scales beyond the immediate area of concern may be evaluated by considering ecological characteristics such as community structure and energy and nutrient dynamics. In addition, information from the characterization of exposure on the stressors spatial distribution may be useful. Extrapolations between different temporal scales (e.g., from short-term impacts to long-term effects) may consider the stressors' distribution through time (intensity. duration, and frequency) relative to ecological dynamics (e.g., seasonal cycles, life cycle patterns).

In some cases, evaluation of long-term impacts will require consideration of ecological recovery. Ecological recovery is difficult to predict and depends on the existence of a nearby source of organisms, life history and dispersal strategics of the ecological components, and the chemical-physical environmental quality following exposure to the stressor (Cairns. 1990; Poff and Ward, 1990; Kelly and Harwell, 1990). In addition, there is some evidence to suggest that the types and frequency of natural disturbances can influence the ability of communities to recover (Schlosser, 1990).

Evaluation of Causal Evidence

Another important aspect of the ecological response analysis is to evaluate the strength of the causal association between the stressor and the measurement and assessment endpoints. This information supports and complements the stressor-response assessment and is of particular importance when the stressor-response relationship is based on field observations. Although proof of causality is not a requirement for risk assessment. an evaluation of causal evidence augments the risk assessment. Many of the concepts applied in human epidemiology can be useful for evaluating causality in observational field studies. For example, Hill (1965) suggested nine evaluation criteria for causal associations. An example of ecological causality analysis was provided by Woodman and Cowling (1987), who evaluated the causal association between air pollutants and injury to forests.

Hill's Criteria for Evaluating Causal Associations (Hill, 1965)

1. Strength: A high magnitude of effect is associated with exposure to the stressor.

2. Consistency: The association is repeatedly observed under different circumstances.

3. Specificity: The effect is diagnostic of a stressor.

4. Temporality: The stressor precedes the effect in time.

5. Presence of a biological gradient: A positive correlation between the stressor and response.

6. A plausible mechanism of action.

7. Coherence: The hypothesis does not conflict with knowledge of natural history and biology.

8. Experimental evidence.

9. Analogy: Similar stressors cause similar responses.

Not all of these criteria must be satisfied. but each incrementally reinforces the argument for causality. Negative evidence does not rule out a causal association but may indicate incomplete knowledge of the relationship (Rothman, 1986).

3.23. Stressor-Response Profile

The results of the characterization of ecological effects are summarized in a stressor-response profile that describes the stressor-response relationship, any extrapolations and additional analyses conducted, and evidence of causality (e.g., field effects data).

Ideally, the stressor-response relationship will relate the magnitude, duration, frequency, and timing of exposure in the study setting to the magnitude of effects. For practical reasons, the results of stressor-response curves are often summarized as one reference point., for instance, a 48-hour LC_{50}- Although useful, such values provide no information about the slope or shape of the stressor-response curve. When the entire curve is used, or when points on the curve are identified, the difference in magnitude of effect at different exposure levels can be reflected in risk characterization.

It is important to clearly describe and quantitatively estimate the assumptions and uncertainties involved in the evaluation. where possible. Examples include natural variability in ecological characteristics and responses and uncertainties in the test system and extrapolations. The description and analysis of uncertainty in characterization of ecological effects are combined with uncertainty analyses for the other ecological risk assessment elements during risk characterization

Additional Issues Related to the Analysis Phase

- Quantifying cumulative impacts and stress-response relationships for multiple stressors.
- Improving the prediction of ecosystem recovery.
- Improving the quantification of indirect effects.
- Describing stressor-response relationships for physical perturbations.
- Distinguishing ecosystem changes due to natural processes from those by man.

4. RISK CHARACTERIZATION

Risk characterization (figure 4) is the final phase of risk assessment During this phase, the likelihood of adverse effects occurring as a result of exposure to a stressor are evaluated. Risk characterization contains two major steps: risk estimation and risk description. The stressor-response profile and the exposure profile from the analysis phase serve as input to risk estimation The uncertainties identified during all phases of the risk assessment also are analyzed and summarized. The estimated risks are discussed by considering the types and magnitude of effects anticipated, the spatial and temporal extent of the effects, and recovery potential. Supporting information in the form of a weight-of-evidence discussion also is presented during this step. The results of the risk assessment including the relevance of the identified risks to the original goals of the risk assessment, then are discussed with the risk manager.

4.1. Risk Estimation

Risk estimation consists of comparing the exposure and stressor-response profiles as well as estimating and summarizing the associated uncertainties.

4.1.1. Integration of Stressor-Response and Exposure Profiles

Three general approaches are discussed to illustrate the integration of the stressor-response and exposure profiles: (1) comparing single effect and exposure values; (2) comparing distributions of effects and exposure; and (3) conducting simulation modeling. Because these are areas of active research, particularly in the assessment of community- and landscape-level perturbations, additional integration approaches are likely to be available in the future. The final choice as to which approach will be selected depends on the original purpose of the assessment as well as time and data constraints.

Comparing Single Effect and Exposure Values

Many risk assessments compare single effect values with predicted or measured levels of the stressor. The effect values from the stressor-response profile may be used as is, or more commonly, uncertainty or safety factors may be used to adjust the value. The ratio or quotient of the exposure value to the effect value provides the risk estimate. If the quotient is one or more, an adverse effect is considered likely to occur. This approach, known as the Quotient Method (Barnthouse et al., 1986). has been used extensively to evaluate the risks of chemical stressors (Nabholz 1991; Urban and Cook. 1986). Although the Quotient Method is commonly used and accepted, it is the least probabilistic of the approaches described here. Also, correct usage of tbe Quotient Method is highly dependent on professional judgment. particularly in instances when the quotient approaches one. Greater insight into the magnitude of the effects expected at various levels of exposure can be obtained by evaluating the full stressor-response curve instead of a single point and by considering the frequency, timing, and duration of the exposure.

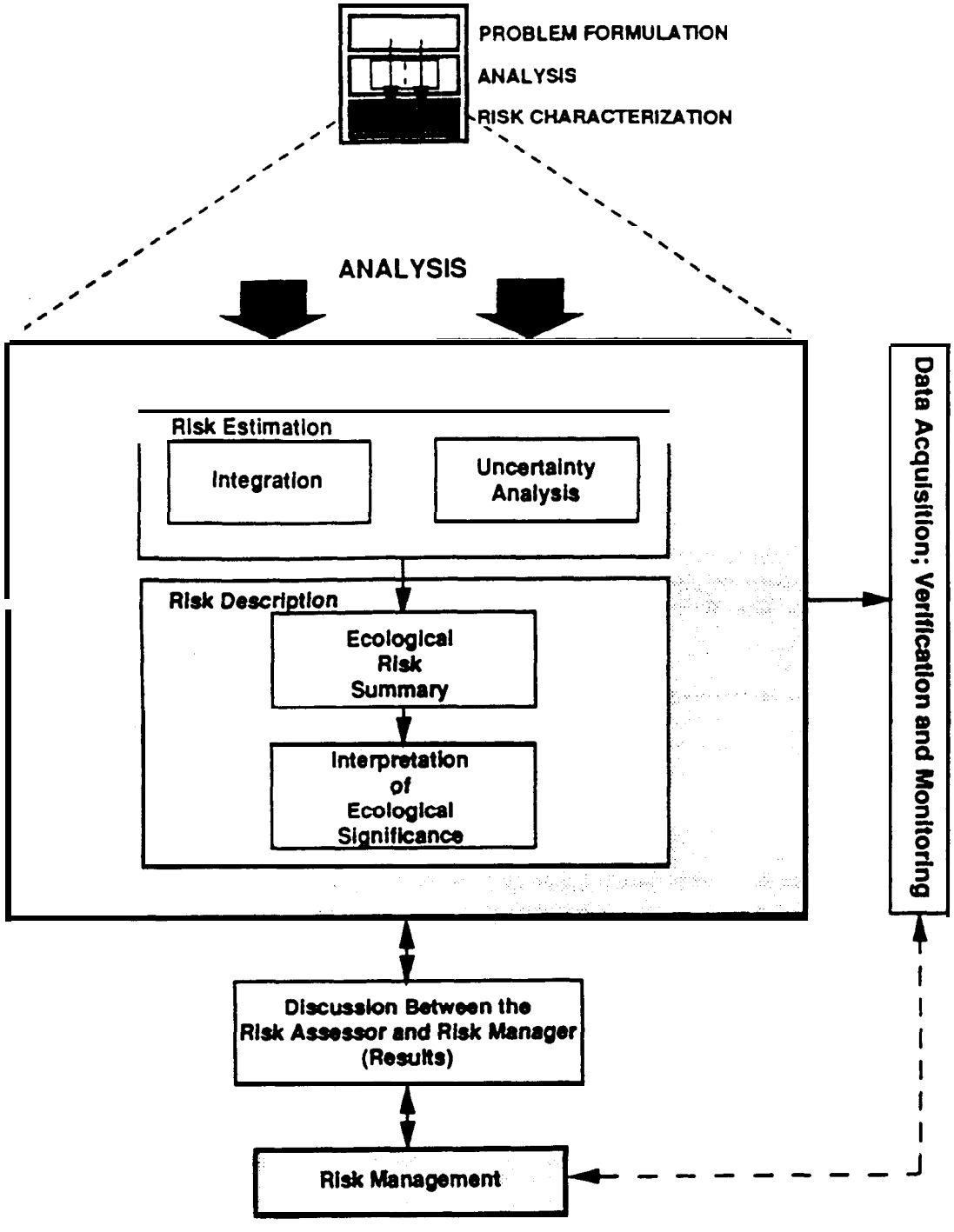

Figure 4. Risk Characterization

Comparing Distributions of Effects and Exposure

This approach uses distributions of effects and exposure (as opposed to single values) and thus makes probabilistic risk estimates easier to develop. Risk is quantified by the degree of overlap between the two distributions; the more overlap, the greater the risk An example of this approach, Analysis of Extrapolation Error, is given in Barnthouse et al. (1986). To construct valid distributions, it is important that sufficient data amenable to statistical treatment are available.

Conducting Simulation Modeling

Simulation models that can integrate both the stressor-response profile and exposure profile are useful for obtaining probabilistic estimates of risk Two categories of simulation models are used for ecological risk assessment: single-species population models are used to predict direct effects on a single population of concern using measurement endpoints at the individual level, while multi-species models include aquatic food web models and terrestrial plant succession models and are useful for evaluating both direct and indirect effects.

When selecting a model, it is important to determine the appropriateness of the model for a particular application. For example. if indirect effects are of concern, a model of community-level interactions will be needed. Direct effects to a particular population of concern may be better addressed with population models. The validation status and use history of a model also are important considerations in model selection. Although simulation models are not commonly used for ecological risk assessment at the present time, this is an area of active research and the use of simulation models is likely to increase.

In addition to providing estimates of risks simulation models also can be useful in discussing the results of the risk characterization to the risk manager. This dialogue is particularly effective when the relationship between risks to certain measurement endpoints and the assessment endpoint axe not readily apparent (e.g., certain indirect effects and large-scale ecosystem-level disturbances).

4.1.2. Uncertainty

The uncertainty analysis identifies, and, to the extent possible, quantifies the uncertainty in problem formulation, analysis, and risk characterization. The uncertainties from each of these phases of the proccess are carried through as part of the total uncertainty in the assessment. The output from the uncertainty analysis is an evaluation of the impact of the uncertainties on the overall assessment and, when feasible, a description of the ways in which uncertainty could be reduced.

A complete discussion of uncertainty is beyond the scope of this report, and the reader is referred to the works of Finkel (1990). Holling (1978). and Suter (1990b). However, a brief discussion of the major sources of uncertainty in ecological risk assessment is appropriate. For illustrative purposes, four major areas of uncertainty are presented below. These are not discrete categories. and overlap does exist among them. Any specific risk assessment may have uncertainties in one or all of these categories.

Conceptual Model Formulation

As noted earlier, the conceptual model is the product of the problem formulation phase, which, in turn. provides the foundation for the analysis phase and the development of the exposure and stressor-response profiles. If incorrect assumptions are made during conceptual model development regarding the potential effects of a stressor. the environments impacted, or the species residing within those systems. then the final risk assessment will be flawed. These types of uncertainties are perhaps the most difficult to identify, quantify. and reduce.

Information and Data

Another important contributor of uncertainty is the incompleteness of the data or information upon which the risk assessment is based. In some instances, the risk assessment may be halted temporarily until additional information is obtained. In other cases, certain basic information such as life history data may be unobtainable with the resources available to the risk assessment In yet other cases, fundamental understanding of some natural processes with an ecosystem may be lacking. In instances where additional information cannot be obtained, the role of professional judgment and judicial use of assumptions are critical for the completion of the assessment.

Stochasticity (Natural Variability)

Natural variability is a basic characteristic of stressors and ecological components as well as the factors that influence their distribution (e.g., weather patterns. nutrient availability). As noted by Suter (1990b), of all the contributions to uncertainty, stochasticity is the only one that can be acknowledged and described but not reduced. Natural variability is amenable to quantitative analyses, including Monte Carlo simulation and statistical uncertainty analysis (O'Neill and Gardner, 19779; O'Neill et al., 1982).

Error

Errors can be introduced through experimental design or the procedures used for measurement and sampling. Such errors can be reduced by adherence to good laboratory practices and adherence to established experimental protocols. Errors also can be introduced during simulation model development. Uncertainty in the development and use of models can be reduced through sensitivity analyses, comparison with similar models, and field validation

In summary, uncertainty analyses provide the risk manager with an insight into the strengths and weaknesses of an assessment. The uncertainty analysis also can serve as a basis for making rational decisions regarding alternative actions as well as for obtaining additional information to reduce uncertainty in the risk estimates.

4.2. Risk Description

Risk description has two primary elements. The first is the ecological risk summary, which summarizes the results of the risk estimation and uncertainty analysis and assesses confidence in the risk estimates through a discussion of the weight of evidence. The second element is interpretation of ecological significance. which describes the magnitude of the identified risks to the assessment endpoint

4.2.1. Ecological Risk Summary

The ecological risk summary summarizes the results Of the risk estimation and discusses the uncertainties associated with problem formulation, analysis, and risk characterization. Next, the confidence in the risk estimates is expressed through a weight-of-evidence discussion The ecological risk summary may conclude with an identification of additional, analyses or data that might reduce the uncertainty in the risk estimates. These three aspects of the ecological risk summary are discussed in the following sections.

Summary of Risk Estimation and Uncertainty

Ideally, the conclusions of the risk estimation are described as some type of quantitative statement (e.g., there is a 20 percent chance of 50 percent mortality). However, in most instances, likelihood is expressed in a qualitative statement (e.g., there is a high likelihood of mortality occurring). The uncertainties identified during the risk assessment are summarized either quantitatively or qualitatively, and the relative contribution of the various uncertainties to the risk estimates are discussed whenever possible.

Weight of Evidence

The weight-of -evidence discussion provides the risk manager with insight about the confidence of the conclusions reached in the risk assessment by comparing the positive and negative aspects of the data, including uncertainties identified throughout the process. The considerations listed below are useful in a weight-of-evidence discussion:

- The sufficiency and quality of the data A risk assessment conducted with studies that completely characterize both the effects and exposure of the stressor has more credibility and support than an assessment mat contains data gaps. It is important to state if the data at hand were sufficient to support the findings of the assessment. In addition, data validity (e.g.. adherence to protocols, having sufficient replications) is an important facet of the weight-of-evidence analysis.

- Corroborative information. Here the assessor incorporates supplementary information that is relevant to the conclusions reached in the assessment. Examples include reported incidences of effects elicited by the stressor (or similar stressor and studies demonstrating agreement between model predictions and observed effects.

- Evidence of causality. The degree of correlation between the presence of a stressor and some adverse effect is an important consideration for many ecological risk assessments. This correlation is particularly true when an assessor is attempting to establish a link between certain observed field effects and the cause of those effects. Further discussions of the evaluation of causal relationships may be found in the section on characterization of ecological effects (section 3.2.2.).

Identification of Additional Analyses

The need for certain analyses may not be identified until after the risk estimation step. For example. the need to analyze the risks to a fish population (an assessment endpoint) due to an indirect effect such as zooplankton mortality (a measurement endpoint) may not be established until after the risk to zooplankton has been characterized. In such cases, another iteration through analysis or even problem formulation may be necessary.

4.2.2. Interpretation of Ecological Significance

The interpretation of ecological significance places risk estimates in the context of the types and extent of anticipated effects. It provides a critical link between the estimation of risks and the communication of assessment results. The interpretation step relies on professional judgment and may emphasize different aspects depending on the assessment Several aspects of ecological significance that may be considered include the nature and magnitude of the effects, the spatial and temporal patterns of the effects, and the potential for recovery once a stressor is removed.

Nature and Magnitude of the Effects

The relative significance of different effects may require further interpretation. especially when changes in several assessment or measurement endpoints are observed or predicted For example, if a risk assessment is concerned with the effects of stressors on several ecosystems in an area (such as a forest, stream, and wetland), it is important to discuss the types of effects associated with each ecosystem and where the greatest impact is likely to occur.

The magnitude of an effect will depend on its ecological context. For example, a reduction in the reproductive rate may have little effect on a population that reproduces rapidly, but it may dramatically reduce the numbers of a population that reproduces slowly. Population-dependent and -independent factors in the ecosystem also may influence the expression of the effect

Finally, it is important to consider the effects in the context of both magnitude and the likelihood of the effect occurring. In some cases, the likelihood of exposure to a stressor may be low, but the effect resulting from the exposure would be devastating. For example. large oil spills may not be common, but they can cause severe and extensive effects in ecologically sensitive areas.

Spatial and Temporal Patterns of the Effects

The spatial and temporal distributions of the effect provide another perspective important to interpreting ecological significance. The extent of the area where the stressor is likely to occur is a primary consideration when evaluating the spatial pattern of effects. Clearly, a stressor distributed over a larger area has a greater potential to affect more organisms than one confined to a small area However, a stressor that adversely affects small areas can have devastating effects if those areas provide critical resources for certain species. In addition, adverse effects to a resource that is small in scale (e.g.. acidic bogs) may have a small spatial effect but may represent a significant degradation of the resource because of its overall scarcity.

The duration of any effect is dependent on the persistence of the stressor as well as how often the stressor is likely to occur in the environment. It is important to remember that even short-term effects can be devastating if such exposure occurs during critical life stages of organisms.

Recovery Potential

A discussion of the recovery potential may be an integral part of risk description, although the need for such an evaluation will depend on the objective of the assessment and the assessment endpoints. An evaluation of the recovery potential may require additional analyses, as discussed in section 3.1., and will depend on the nature, duration, and extent of the stressor.

Depending on the assessment objectives, all of the above factors may be used to place the risks into the broader ecological context This discussion may consider the ramifications of the effects on other ecological components that were not specifically addressed in the assessment. For example, an assessment that focused on the decline of alligator populations may include a discussion of the broader ecological role of the alligator, such as the consauction of wallows that act as water reservoirs during droughts. In this way, the potential effects on the community that depends on the alligator wallows can be brought out in risk characterization

4.3. Discussion Between the Risk Assessor and Risk Manager (Results)

Risk characterization concludes the risk assessment process and provides the basis for discussions between the risk assessor and risk manager that pave the way for regulatory decision-making. The purpose of these discussions is to ensure that the results of the risk assessment are clearly and fully presented and to provide an opportunity for the risk manager to ask for any necessary clarification Proper presentation of the risk assessment is essential to reduce the chance of over-or under-interpretation of the results. To permit the risk manager to evaluate the full range of possibilities contained in the risk assessment it is important that the risk assessor provide the following types of information:

- the goal of the risk assessment;
- the connection between the measurement and assessment endpoints
- the magnitude and extent of the effect, including spatial and temporal considerations and if possible, recovery potential;
- **the assumptions used and the uncertainties encountered during the risk assessment;**
- a summary profile of the degrees of risk as well as a weight-of-evidence analysis; and
- the incremental risk from stressors other than those already under consideration (if possible).

The results of the risk assessment serve as input to the risk managament process,where they are used along with other inputs defined in EPA statutes, such as social and economic concerns, to evaluate risk management options.

In addition, based on the discussions between the risk assessor and risk manager, follow-on activities to the risk assessment may be identified, including monitoring, studies to verify the predictions of the risk assessment, or the collection of additional data to reduce the uncertainties in the risk assessment. While a detailed discussion of the risk management process is beyond the scope of cl-us report consideration of the basic principles of ecological risk assessment described here will contribute to a final product that is both credible and germane to the needs of the risk manager.

Additional Issues Related to the Risk Characterization Phase

- Predicting the time required for an ecological component to recover from a stressor.
- Combining chemical and nonchemical stressors in risk characterization.
- Incorporating critical effect levels into risk characterization.
- Better quantification of uncertainty.
- Developing alternative techniques for expressing uncertainty in risk characterization.

5. KEY TERMS

assessment endpoint -- An explicit expression of the environmental value that is to be protected.

characterization of ecological effects--A portion of the analysis phase of ecological risk assessment that evaluates the ability of a stressor to cause adverse effects under a particular set of circumstances.

characterization of exposure--A portion of the analysis phase of ecological risk assessment that evaluates the interaction of the stressor with one or more ecological components. Exposure can be expressed as co-occurrence, or contact depending on the stressor and ecological component involved.

community--An assemblage of populations of different species within a specified location in space and time.

conceptual model--The conceptual model describes a series of working hypotheses of how the stressor might affect ecological components. The conceptual model also describes the ecosystem potentially at risk, the relationship between measurement and assessment endpoints, and exposure scenarios.

direct effect--An effect where the stressor acts on the ecological component of interest itself, not through effects on other components of the ecosystem (compare with definition for indirect effect).

ecological component-Any part of an ecological system. including individuals, populations, communities. and the ecosystem itself.

ecological risk assessment-The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.

ecosystem-The biotic community and abiotic environment within a specified location in space and time.

exposure--Co-occurrence of or contact between a stressor and an ecological component

exposure profile--The product of characterization of exposure in the analysis phase of ecological risk assessment. The exposure profile summarizes the magnitude and spatial and temporal pattern. of exposure for the scenarios described in the conceptual model.

exposure scenario-A set of assumptions concerning how a exposure may take place, including assumptions about the exposure setting, stressor characteristics. and activities that may lead to exposure.

indirect effect--An effect when the stressor acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest

measurement endpoint--A measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint. Measurement endpoints are often expressed as the statistical or arithmetic summaries of the observations that comprise the measurement

median lethal concentration (L&J--A statistically or graphically estimated concentration that is expected to be lethal to 50 percent of a group of organisms under specified conditions (ASTM, 1990).

no observed effect level (NOEL)--The highest level of a stressor evaluated in a test that does not cause statistically significant differences from the controls.

population--An aggregate of individuals of a species within a specified location in space and time.

recovery--The partial or full return of a population or community to a condition that existed before the introduction of the stressor.

risk characterization--A phase of ecological risk assessment that integrates the results of the exposure and ecological effects analyses to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. The ecological significance of the adverse effects is discussed, including consideration of the types and magnitudes of the effects, their spatial and temporal patterns, and the likelihood of recovery.

stressor--Any physical, chemical, or biological entity that can induce an adverse response.

stressor-response profile--The product of characterization of ecological effects in the analysis phase of ecological risk assessment. The stressor-response profile summarizes the data on the effects of a stressor and the relationship of the data to the assessment endpoint.

trophic levels--A functional classification of taxa within a community that is based on feeding relationships (e.g., aquatic and terrestrial green plants comprise the first trophic level and herbivores comprise the second).

xenobiotic--A chemical or other stressor that does not occur naturally in the environment. Xenobiotics occur as a result of anthropogenic activities such as the application of pesticides and the discharge of industrial chemicals to air, land, or water.

6. REFERENCES

American Society for Testing and Materials. (1990). Standard terminology relating to biological effects and environmental fate. E943-90. In: ASTM; 1990 Annual Book of ASTM Standards, Section 11, Water and Environmental Technology, ASTM, Philadelphia, PA.

ASTM. See American Society for Testing and Materials.

Auer, C.M.; Nabholz, J.V.; Baetcke. K.P. (1990). Mode of action and the assessment of chemical hazards in the presence of limiting data: use of structure-activity relationships (SAR) under TSCA. Section 5. Environmental Health Perspectives (87):183-197.

Barnthouse, L.W.; Suter, G.W., II; Bartell, S.M.; Beauchamp, J.J.; Gardner, R.H.; Linder, E.; O'Neill. R.V.; Rosen, A.E. (1986). User's Manual for Ecological Risk Assessment. Publication No. 2679, ORNL-6251. Environmental Sciences Division. Oak Ridge National Laboratory, Oak Ridge, TN.

Cairns, J., Jr. (1990). Lack of theoretical basis for predicting rate and pathways of recovery. In: Yount, J.D.; Niemi, G.J., eds. Recovery of Lotic Communities and Ecosystems Following Disturbance: Theory and Application Environmental Management 14(5):517-526

Clements, R.G.; Johnson, D.W.; Lipnick, R.L.; Nabholz, J.V.; Newsome, L.D. (1988). Estimating toxicity of industrial chemicals to aquatic organisms using structure activity relationships. EPA-560-6-88-001. U.S. Environmental Protection Agency, Washington, DC. (available from NTIS, Springfield, VA. PB89-117592.)

Finkel, A.M. (1990). Confronting Uncertainty in Risk Management: A Guide for Decision-Makers. Center for Risk Management, Resources for the Future, Washington, DC.

Hill, A.B. (1965). The environment and disease: association or causation? Proceedings of the Royal Society of Medicine. 58:295-300.

Holling, C.S. (1978). Adaptive Environmental Assessment and Management. John Wiley and Sons, New York, NY.

Kelly, J.R.; Harwell, M.A. (1990). Indicators of ecosystem recovery. In: Yount, J.D.; Niemi, G.J., eds. Recovery of Lotic Communities and Ecosystems Following Disturbance: Theory and Application. Environmental Management 14(5):527-546

Kendall, R.J. (1991). Ecological risk assessment for terrestrial wildlife exposed to agrochemicals: a state-of-the-art review and recommendations for the future. Presented at the Ecological Risk Assessment Workshop sponsored by the National Academy of Sciences Committee on Risk Assessment Methodology, 26 Feb - 1 Mar 1991.

McKim, J.M.; Bradbury, S.P.; Niemi, G.J. (1987). Fish acute toxicity syndromes and their use in the QSAR approach to hazard assessment. Environmental Health Perspectives 71:171-186.

Nabholz, J.V. (1991). Environmental hazard and risk assessment under the United States Toxic Substances Control Act. Science of the Total Environment 109/110:649-665.

National Research Council (1983). Risk Assessment in the Federal Government: Managing the Process. National Research Council, National Academy Press, Washington, DC.

National Research Council. (1986). Ecological Knowledge and Environmental Problem-Solving: Concepts and Case Studies. National Research Council, National Academy Press, Washington, DC.

NRC. See National Research Council.

O'Neill, R.V. (1979). Natural variability as a source of error in model predictions. In: Systems Analysis of Ecosystems. G.S. Innis and R.V. O'Neill eds. International Cooperative Publishing House. Burtonsville, Maryland. pp 23-32.

O'Neill, R.V.; Gardner, R.H.; (1979). Sources of uncertainty in ecological models. In: Methodology in Systems Modeling and Simulation. BP. Zeigler. M.S. Elzas, G.J. Klir, and T.I. Orens eds. North Holland Publishing Company. pp 447-463.

Poff, N.L.: Ward, J.V. (1990). Physical habitat template of lotic systems: recovery in the context of historical pattern of spatiotemporal heterogeneity. In: Yount, J.D.; Niemi, G.J., eds. Recovery of Lotic Communities and Ecosystems Following Disturbance: Theory and Application. Environmental Management 14(5):629-646.

Rothman, K.J. (1986). Modem Epidemiology. 1st ed. Little, Brown and Company, Boston. MA.

Schlosser, I.J. (1990). Environmental variation. life history attributes, and community structure in stream fishes: implications for environmental management and assessment. Environmental Management 14(5):621-628.

SETAC. See Society of Environmental Toxicology and Chemistry.

Society of Environmental Toxicology and Chemistry. (1987). Research Priorities in Environmental Risk Assessment. Report of a workshop held in Breckenridge, CO, August 16-21, 1987. Society of Environmental Toxicology and Chemistry, Washington, DC.

Suter II, G.W. (1989). Ecological endpoints. In: U.S. EPA. Ecological Assessments of Hazardous Waste Sites: A field and laboratory reference document. Warren-Hicks, W.; Parkhurst, B.R.; S.S. Baker, Jr. eds. EPA 600/3-89/013. March 1989.

Suter II, G.W. (1990a). Endpoints for regional ecological risk assessments. Environmental Management 14(1):19-23.

Suter II, G.W. (1990b). Uncertainty in environmental risk assessment. In: von Furstenberg, G.M., ed. Acting Under Uncertainty: Multidisciplinary Conceptions. Kluwer Academic Publishers. Boston, MA. pp 203-230.

Thomas, J.W.; Forsman, E.D.; Lint, J.B.; Meslow, E.C.; Noon, B.R.; J. Verner. (1990). A Conservation Strategy for the Spotted Owl. Interagency Scientific Committee to Address the Conservation of the Northern Spotted Owl. 1990-791/20026. U.S. Government Printing Office, Washington, DC.

Urban, D.J.; Cook, N.J. (1986). Standard Evaluation Procedure for Ecological Risk Assessment. EPA/540/09-86/167, Hazard Evaluation Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, DC.

U.S. Department of the Interior. (1987). Injury to fish and wildlife species. Type B Technical information document. CERCLA 301 Project. Washington, DC.

U.S. EPA. See U.S. Environmental Protection Agency.

U.S. Environmental Protection Agency. (1979). Toxic substances control act. Discussion of premanufacture testing policies and technical issues; Request for comment. 44 Federal Register 16240-16292.

US. Environmental Protection Agency. (1990a). Environmental Monitoring and Assessment Program. Ecological Indicators. EPA/600/3-90/060, Office of Research and Development Washington, DC.

U.S. Environmental Protection Agency. (1990b). Reducing Risk: Setting Priorities and Strategies for Environmental Protection. Science Advisory Board SAB-EC-90-021. Washington, DC.

U.S. Environmental Protection Agency. (1991). Summary Report on Issues in Ecological Risk Assessment. EPA/625/3-91/018, Risk Assessment Forum. Washington DC.

U.S. Environmental Protection Agency. (in press-a). Peer Review Workshop Report on a Framework for Ecological Risk Assessment. EPA/63O/R-92/001, Risk Assessment Forum, Washington, DC.

U.S. Environmental Protection Agency. (in press-b). Ecological Risk Assessment Guidelines Strategic Planning Workshop. EPA/630/R-92/002, Risk Assessment Forum, Washington, DC.

Woodman, J.N.; Cowling, E.B. (1987). Airborne chemicals and forest health Environmental Science and Technology 21(2):120-126.

Appendix D
HTRW Technical Project Planning Process

D.1 Introduction

The USACE recognizes the need for cost-effective and efficient %/response actions for HTRW projects. The level of effort required in conjunction with the data collection activities for a HTRW project are based on DQOs which address data quality and quantity requirements of the users. The recently published Engineer Manual, Tech***nical Project Planning - Guidance for HTRW Data Quality Design*** (USACE 1995b) (EM 200-1-2) [referred to ***as the*** HTRW ***Technical Project Planning Guidance in*** this appendix] provides project planning guidance to develop data collection programs and define DQOs for HTRW sites. This appendix summarizes the four phases of the HTRW technical project planning - data quality design process with respect to scoping requirements and data needs for conducting ERAS to support risk management decisions.

The importance of early planning and getting the risk assessor involved in the planning process at each phase of the HTRW response action is emphasized so that data needed to assess potential ecological risks will be cost-effectively collected. In identifying data needs for the ERA, the risk assessor must fully understand the customer goals, regulatory programs driving the HTRW project execution and the associated project decision statements (PDs), the study elements for each relevant project phase, and the types of ERA needed by the study elements. An ECSM should be developed and used to focus data needs to evaluate risks for complete exposure pathways to significant ecological receptors or for the ecosystem to be protected. In addition, it is important to simultaneously consider the data needs for both the ERA and the human health assessment throughout the HTRW planning program. Both assessment processes will have some data needs in common which should be identified so that dup lication of effort is avoided.

This appendix is divided into the following sections:

- Introduction - This section presents the scope and introductory statements.
- Overview of the HTRW Technical Project Planning Process - This section summarizes the four-phases (Phase I through Phase IV) of the data quality design process.
- Roles and Responsibilities - This section describes the roles and responsibilities of the risk assessor in the data quality design process. In addition, how this individual uses the skills and experience of the expert ecologist(s) and/or the advisory panel such as the BTAG to focus the approach and the data needs to support site decisions is described.
- Data Needs for HTRW Executable Project Phases - This section presents a framework for conceptualizing data needs, establishing data requirements, and the basis for requiring such data. Conceptualizing and establishing the rationale for data use and data needs are critical elements of the Phase II data quality design process. This section addresses key executable project phases (i.e., PA/SI and RFA; RI and RFI; FS and CMS; and RD/RA and CMI)
- Summary Conclusions - This section summarizes the role and responsibility of a risk assessor in the four-phased HTRW data quality design process, along with general data needs and study elements to support making site decisions in each executable phase of the HTRW project.

D.2 Overview of the HTRW Technical Project Planning Process

The key to the HTRW technical project planning process for a response action is understanding the customer's needs and the regulatory requirements/basis for making site decisions. Designing the data collection strategy requires professional judgment, scientific decisions, regulatory policy, and the customer's goals, to which no single person including the data implementor, can easily

develop a data acquisition strategy to satisfy all users' needs.

The project planning process at various stages requires the involvement of appropriate project personnel which consist of:

- Decision makers (customer, PM, TM).
- Data users (risk assessors, remedial design engineers, compliance specialists, and responsibility-specialists or legal counselors for identifying potentially responsible parties [PRPs]).
- Data implementors and reviewers (statistician, sampling specialists [e.g., geologists, hydrogeologists, meteorologists, and biologists], analytical specialists [chemists], the health and safety officer, etc.).

The primary products of this data quality design process are the Scope of Work, DQO statements for use in the Sampling and Analysis Plan (SAP), and detailed estimates of costs associated with the selected data collection program. Other uses for the above outputs could be to form the basis for developing specific language of or as excerpts from: the FFA/IAG under CERCLA or the FFCA under RCRA; Department of Defense and State memorandum of understanding (DSMOA); and the Project Management Plan (PMP), etc.

[1] For example, the risk assessor has recommended taking sediment samples in a swale or runoff channel originating from a PCB spill area to evaluate the potential risks to wetland receptors. The statistician has recommended using a grid design with systematic random sampling to determine where sediment samples are to be collected from the swale. However, a decision has to be made on the grid size, which is dependent on the variability of PCB concentrations in previously collected sediment samples and the acceptable error rate or level of confidence for not being able to detect a hot spot. Therefore, designing the sampling program represents a joint effort of the Technical Planning Team members. The use of previously collected sediment data and setting a predetermined confidence level will involve a management decision by the PM/regulator and the USACE customer. Input from the risk assessor and statistician include both professional judgment and scientific decisions (i.e., delineation of the exposure unit [Eu] or study area, concern levels to be detected, sampling depth based on potential exposure pathways for valued receptors to be protected, and the concept of systematic random sampling).

D.2.1 Phase 1 - Develop Project Strategy

Phase I of the technical project planning process involves understanding the customer's objectives and requirements for making site decisions, and putting together a logical approach which addresses the questions to be answered or the decisions needed for specific project phases.

In terms of project execution from site discovery to close-out, key inputs required for decision-making can be more readily defined after site-specific conditions are generally understood, and the action plan/strategy is developed. A strategy may be defined as the approach by which actions and resources are organized, targeted, and used in order to fulfill a mission or meet certain objectives or policies. For example, after having a general understanding of the release, migration, and transport properties of the COECs, the ecological assessment component of the strategy for a typical CERCLA or RCRA site could be: (1) identify if sensitive species or valued resources (receptors) exist onsite or in the site vicinity; (2) if such receptors exist, collect chemical data to identify the boundary of the area of ecological concern; (3) ascertain if receptors are located within the boundary: (4) recommend no further action if the response to item (1) or (3) is negative; (5) compare chemical data with literature or benchmark (screening) values for the receptors or surrogate species if the response to items (1) and (3) is positive: (6) further assess the site at the population or community level to determine the significance of the potential ecological impact if the screening levels or literature values in item (5) have been exceeded, and (7) implement removal, remedial, or corrective action if the ecological risk determined in (5) and/or (6) is judged to be significant

Before development of the site strategy, certain site information should be gathered for review by the technical project team. Such information includes, but is not limited to, regulatory or compliance requirements; previously collected chemical or nonchemical data; history of operations: documented incidents or corroborated reports of ecological concern (e.g., animal mortality/morbidity, anatomical or pathological anomalies in aquatic or terrestrial receptors, etc.); and information obtained from the PA/site reconnaissance. In addition, before development of an overall site strategy in Phase I, the following project management information should be obtained:

- Customer's goals and meaning or concept of site closeout to focus and define site problem(s).
- Customer's budget and schedule constraints.
- Primary and secondary regulatory pro rams under which the HTRW project is executed.[2]
- The stages or project phases under the above regulatory programs (i.e., project phase on the critical path [decision-tree] for actions).
- Stressors (COECs or nonchemical entities), existing or potential exposure pathways, known or suspected ecological effects from the COECs/ nonchemical entities, and endpoints (i.e., value of resources to be protected) relevant to the customer's objectives or concern.
- OUs, SWMUs, CAMUs, temporary units, areas of contamination, etc., and potential exposure units (EUs) or the boundary of ecological concern.
- Reasonably anticipated future land uses of the site (which are needed to conceptualize exposures to ecological receptors under future exposure scenarios).
- Anticipated remedies (including removal actions, interim measures, presumptive remedies, and innovative technologies, if feasible).
- Objectives and scope of all possible executable phases from the current project phase to site closeout.

Based on the above information, the customer and technical planning team members may consult with the relevant expert ecologist(s) or advisory panel (e.g., BTAG) before finalizing (or determining) the overall site strategy ***or*** the strategy for the current project phase.

The following activities will be critical for a successful implementation of the site strategy:

- Identify site Constraints and Dependencies (i.e., Work Breakdown Structure [WBS]; product milestones: level and duration of efforts: availability and timing of funding: technical limitations or requirements; and regulatory deadlines).
- Develop potential options, as appropriate, for achieving site closeout (e.g., removal or accelerated cleanup, phasing [in series or parallel], or no further action/monitoring only).
- Decide on the executable phase and choose or assemble project decision statements (PDs) specific for the phase, focusing on the critical path and needs for data inputs.
- Develop a preliminary ECSM or update an existing ECSM to help meet project objectives and data needs.
- Finalize USACE Acquisition Strategy to perform work, issue a preliminary Scope of Work (an outline for the Statement of Work), and/or develop a Site Summary/I'M Memo, which incorporates all of the above.

The key output for Phase I is preparation of a Scope of Work Outline and/or TM memorandum which identifies the customer's goals and the concept of site closeout,

[2] There are currently unresolved RCRA/CERCLA integration issues which concern administrative, statutory, and jurisdictional overlap. For example, a Federal facility that is listed or proposed on the NPL may have interim status or may be a permitted facility under RCRA. Alternatively, it is possible that releases from a RCRA regulated unit caused the NPL listing. In these cases, the questions that follow would be Which statute should be used as the primary vehicle to require cleanup, if cleanup is needed?" and "Which agencies (EPA and/or State) should oversee the investigation and cleanup?" In certain instances, it is possible that a Natural Resource Damage Assessment (NRDA) may be required by the customer (DoD, DOE, Department of Commerce) or other relevant natural resource trustees, such as the U.S. Department of Interior (USDOI) or a State natural resource management agency. By early planning (which may involve negotiations and documentation of understanding with the agencies), the applicable agreements/scope of work and other issues can be adequately addressed. This process should work well for risk assessment and other technical evaluations/data category requirements in the HTRW project. When a State requires an ecological risk assessment approach or sets cleanup standards substantially different from those of the EPA, the data needs to satisfy/supplement or reduce uncertainties in the State's approaches should also be considered early in this project planning process.

time/budget, site and project strategy, preliminary work acquisition strategy, and definition of PDs for data users to identify data needs (Phase II of the technical project planning process). With this information, the HTRW site's PMP can be developed or modified.

D.2.2 Phase II - Identify Potential Data Needs to Support Decisions

Phase II of the technical project planning process focuses on identifying the data needs and minimum data quality requirements to support site decisions identified in the PDs. Phase II activities to identify data needs include:

- Review of the preliminary ECSM and identification of project study elements (key deliverables or work output) to satisfy PDs for the current executable project phase. For the risk assessor, the following project study elements may be appropriate:

  - Determine if the site should be eliminated based on the lack of ecological concern, specifically, the lack of valued resources to be protected and/or the lack of food sources to support sensitive ecological species.

  - Assess baseline ecological risks to determine the need for remediation.

  - Identify or develop potential risk-based PRGs, wildlife concern levels, or benchmark values.

  - Evaluate the appropriateness of early actions, interim measures, presumptive remedies, or accelerated cleanup/removal actions, especially for hot spot areas, to eliminate or mitigate current exposure to ecological receptors.

  - Evaluate potential early actions or remedies for their potential ecological impacts during response actions or after the remedies have been implemented, including the estimated time for recovery.

  - Support RD/RA criteria (e.g., source control via construction of a slurry wall and diversion of runoff away from a nearby stream containing valued game fish species).

- Conceptualize data needs to support the relevant project study elements. For the risk assessor, the data needs should be used to:

  - Refine the ECSM, if applicable (i.e., identify additional potential ecological receptors or potential exposure pathways; assess pathway completeness and the significance of actual or potentially complete pathways, including potential biomagnification across trophic levels), multiple ECSMs may be needed to address common sources or locations, transport/migration pathways, and target receptors.

  - Identity applicable inference or linkage between measurement and assessment endpoints and/or other sets of endpoints and the strength of such correlations.

- D&ermine data needs by focusing on data need categories and the ECSM critically evaluating their uses or application (based on project background information, requirements of PDs, and project study elements) to this or subsequent project phases.

  [Chapter 4 of the HTRW Technical Project Planning Guidance provides general site investigation data needs checklists and an example ECSM to illustrate the process for data needs determination. A checklist for ERAS, entitled *Super-fund Program Checklist for Ecological Assessment/Sampling* (EPA 1993a), provides basic information and data needs for a qualitative screening evaluation of a COEC at a site. The risk assessor may also consult with a specific EPA Region or State for similar checklists.]

- Document data needs by identifying the data user (risk assessor), the intended use, and data quality appropriate for the use? For the risk assessor, the data needs should be documented by:

[3] As discussed in Section D.4, the risk management decisions associated with the PDs will be supported by the data collected for the ecological risk assessment or analysis. The required quality should be appropriate to the level of acceptable data uncertainties in the risk management decisions. See Chapter 9 for details regarding risk management decision-making and evaluation of uncertainties.

- Segregating data types and grouping them by pathway and ecosystem, i.e., source area, medium, sampling location ***or*** depth, target receptors, etc., based on established site information and the ECSM.[4]

- Specifying an acceptable confidence level in terms of data variability or ranges of data uncertainty, particularly in the testing of hypothesis[5]

- Preparing data needs worksheets for each pathway which document data types and locations, and associated QA/QC requirements (including the percent minimum detectable relative difference [MDRD] and acceptable confidence levels). Examples of data needs worksheets are presented in the HTRW Technical Project Planning Guidance.

D.2.3 Phase III - Identify Data Collection Options

Phase III of the technical project planning process incorporates data needs identified from Phase II, and project constraints or preferences in designing a data acquisition approach. Phase III generally includes the following activities:

- Review of Phases I and II information to ensure that the requested data (documented in the data needs worksheets) submitted by all users are consistent with data use and am needed to fill data gaps for site decision-making.

- Conceptualization of the overall approach to satisfy data requirements, including data for the testing of hypotheses. This activity also considers chemical and physical characteristics of the site contaminants, particularly those of ecological concern (e.g., chemicals with a high bioconcentration factor [BCF]); location of sources: biological receptors: exposure pathways: media or biota to be sampled, and sampling strategies.

- Development of approaches for sampling and analysis activities.[6] This activity identifies and

[4] Relevant site information may include records of prior investigations at or near the site, removal actions, histay of operations, and documentation of the current or future land use (exposure setting) at the site as determined by the local land use planning authority or an independent land use expert, etc. Information may be site-specific or general. Published reports concerning the site geology, hydrology, or ecology may include: the Soil Conservation' Service's (SCS) soil map: the flood insurance rate maps and flood hazard boundary maps from the Federal Emergency Management Agency (FEMA); the USFWS wetland maps: topographic maps from the U.S. Geological Survey (USGS): and commercially available digitized flora/fauna data for the Geographic Information System (GIS). Risk assessors should evaluate these data for their applicability and useability based on the DQQ approach.

[5] The observed variability (total error) in any statistical analysis of a sample population represents bias in sampling (systematic error) and variability among the individuals in the population and/or the measurement (ability of the measurement tool to consistently record the true result vs random error). The data users specify the limits of data uncertainty by informing the data implementor/ statistician of acceptable confidence levels to protect against false positive or Type I error (rejecting the null hypothesis and stating the site is contaminated, when the site is in fact not contaminated) and false negative or Type II error (accepting the null hypothesis that the site is not contaminated, when in fact the null hypothesis is false and the site is contaminated). Based on acceptable uncertainty for protecting the ecological receptors or ecosystems, economics, and other criteria, the data user also defines a region of indifference when errors of either type are considered acceptable. Generally speaking, the Type I error may be as low as 80%, and the Type II error 90%. for the RI or RFI project phase. Lower errors may be suggested for other HTRW project phases for consideration by the customer or the regulatory agencies.

[6] In designing the abiotic sampling approach, purposive (judgmental), conventional statistical, or geostatistical methods may be considered to estimate the number of samples needed and their locations. At this stage, planning for the collection of paired samples for chemical analyses and toxicity tests should be considered. Additionally, the field screening or laboratory methods, sampling/data gathering techniques (e.g., composite vs. grab samples), and appropriate QA/QC checks should be evaluated to ensure that they meet quality assurance objectives for each (executable) stage of the project. These QA/QC checks may also include performing a regression analysis and establishing a correlational coefficient between the field measured data and confirmational laboratory analytical data.

screens for data overlap, defines potential sampling strategies, and recommends the most appropriate sampling and analytical methods (field or laboratory methods and their detection limits) based on data needs of current and future executable phases. Determining overlaps of data needs and combining preliminary options, as appropriate, should optimize data collection efforts. The data implementors (statistician, chemist, geologist, biologist, and others) work with the data users to clarify data needs, and to conceptualize potential sampling approaches.

- Evaluation of cost, schedule, technical feasibility of the sampling/analytical methods, elimination or minimization of potential confounding factors (e.g., effects of natural selection, seasonal fluctuation, etc.), strength of cause-effect relationships, and other constraints or benefits associated with the sampling approaches to arrive at data collection options. The trade-offs among requisite data quality and quantity goals to meet the prescribed confidence levels or error rates, and the above factors arc discussed among the data users, data implementors, the expert ecologist(s)/ advisory panel, and PM or TM. The data implementors determine data quantity based on the required data quality and confidence proposed by the data user. These activities include:

  - Quantify data to be collected. If relevant preliminary site data are available, the number of samples or data quantity needed can be estimated based on professional judgment and/or the need to supplement or confirm existing data. Alternatively, a statistical approach can be used to identify the required number of samples based on the ability to meet the maximum acceptable error rate (level of confidence) at an assumed or demonstrated data variability (variance) and the minimum detectable relative difference (MDRD) for the relevant area of investigation, area of ecological concern, or exposure area.

  - Establish data quality requirements. (For chemical data, QA/QC requirements include detection limits, types and numbers of QA/QC samples [i.e., blanks, duplicates, and control samples], frequency of sampling/analysis, and documentation).[7] The objectives of these requirements are to provide a QA program (precision, accuracy, completeness, representativeness, and comparability) for the chemical data to be collected. For nonchemical types of data, e.g., establishing comparability among reference (background) locations or assessing aquifer properties used in contaminant transport modeling, a separate set of

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[7] Duplicates are usually two samples collected at the same time and location as a measure of homogeneity of the medium and the precision in sampling. Replicates or splits usually originate from one sample that is divided and sent in the same sample delivery cooler/package to the same laboratory as a check of laboratory instrument precision and accuracy (replicate samples may be split for independent analysis by different laboratories for comparability of analytical results). Field blanks are samples of contaminant-tree medium that are either transferred from one sample container to another in the field or exposed to field conditions (at the same duration of sampling and sample preparation) for use as an indication of sample contamination during the entire process of field sampling and sample processing. Trip blanks are needed for samples collected for volatile organic compound (WC) analysis; they are samples of contaminant-free media, which are kept unopened, and which accompany the site VOC samples as a measure of cross-contamination during collection, shipment, and storage. Rinsate blanks are samples of deionized water that are run over the sampling equipment, after decontamination of the equipment for use as a measure of adequacy of decontamination procedures and potential cross-contamination. Laboratory control samples are samples of the control matrix spiked with certified reference materials or analytes that are representative of the target analytes. These samples are used to verify the precision and bias of the analytical process, i.e., the results are compared with control limits established for the analytical method to determine data useability. Other laboratory control procedure samples are the matrix spike and the matrix spike duplicate which are used to document the effect of matrix interference on the analytical method performance, and method blanks, which are used to assess laboratory-induced contamination.

quality assurance requirements will be established and can be done on a case-by-case basis.[8]

- Document data collection options by identifying sample types (media), numbers, locations of the sampling stations, and sampling and analytical methods. A sampling plan may be prepared at this time to communicate data collection options and to provide a rough cost estimate (order of magnitude) for each recommended option. It is preferable that three options be developed for selection by the customer and other site decision-makers. The project team should also recommend the optimum collection program for consideration by the decision-makers.

The key output for Phase III is an array of data collection options which can be presented to the customer and decision-makers for option selection under Phase IV. The data collection options presented must be consistent with the customer's goals and concept of site closeout, time/ budget, site and project strategy (especially, logical arguments and steps to be taken in linking the field measurements to the assessment endpoints), PDs, and the project study element(s). The Phase III technical project planning process output which is an array of data collection options should be able to:

- Incorporate data needs of the data users and define the "right" data types for development of DQOs (for the current executable phase, subsequent phases, and/or the project as a whole).

- Reduce areas of data collection overlap (e.g., those requited for preliminary remedial design, human health risk assessment, ERA, and preassessment screen of potential NRDA actions [if applicable]).

- Meet budgetary, schedule, and administrative (FFA, IAG, regulatory compliance) constraints.

- Meet QA/QC requirements and predefined acceptable uncertainty criteria.

Since the data needs are driven by site decision requirements, e.g., those related to the ERA, the ECSM provides the cornerstone for the data collection table development. Table D-l outlines the linkage between the ECSM and data collection strategy for conducting a baseline ERA.

D.2.4 Phase IV - Select Data Collection Options and Assign DQOs

The Phase IV technical project planning process involves the selection and documentation of the data collection program in support of an ERA or risk analysis. Such documentation will provide a historical knowledge which justifies and guides the data review and data use. Phase IV includes the following activities:

- Preparation of a fact sheet or matrix table summarizing the data collection program options. The fact sheet assigns costs and presents characteristics of each data collection option (e.g., types of sampling and analysis activities, numbers of samples, benefits, uncertainties or limitations, schedules, technical requirements, and other constraints). To support the PM or TM in preparing the fact sheet or the matrix table, the risk assessor identifies the project study element and data needs required to complete the study element. The risk assessor should document which arc the critical samples or field survey activities and those data or parameters which are sensitive and, therefore, require a higher level of QA/QC. In addition, the risk assessor provides rationale for tradeoffs in quality, quantity, and sampling methods, the anticipated benefits: and data uncertainties for the fact sheet/matrix table.

- Design of a data collection program. This activity includes presenting the data collection program options to the customer/decision-maker, refinement of the customer/decision-makers' preferred option; and final selection of an option.

[8] For example, the customer determines that fate and transport information is needed to demonstrate a low environmental concern to the aquatic receptors from the potential migration of groundwater to surface water. After the data implementor has consulted with the hydrogeologist/modeler (data user) assigned to the HTRW project, this data implementor may recommend to the TM and the project team that a simple one-dimensional model, although more conservative, may be a better choice than a three-dimensional model, given the time and budget constraints for a particular project phase.

Table D-1
Linkage Between ECSM and Data Collection Strategy

ECSM (Null Hypothesis)	Linkage (Accepted/Rejected)	Data Needs (Qualitative/Quantitative)
The ECSM indicates a potential for exposure of a valued ecological receptor population via Pathway X; within a defined confidence interval, the risk is acceptable	Current vs. Future scenario: plausible/ not plausible	In support of the null hypothesis, qualitative data and/or quantitative data will be presented in the risk assessment
Receptor types	Likelihood receptor types present: High/Low	Land Use/Field Reconnaissance or Survey to identify indigenous or surrogate species that are sensitive to the COECs and are biologically relevant to the assessment endpoints or resources to be protected
COECs	Site related vs. reference or non-site-related sources	History or records of operations/sampling of media to demonstrate comparability of site characteristics at reference locations
Potential for release/transport	Physical and chemical properties of COEC and source matrices, and the physical/chemical characteristics of the transport medium: amenable/not amenable	Literature values, structure-activity relationship (e.g.EPA's QSAR), bioavailability (acid volatile sulfide/simultaneously extracted metal [SEM/AVS] ratio), binding characteristics (organic carbon contents), measurement data of medium flow or speed and COEC transport characteristics
Exposure point concentration estimate	Considerations for chemical fate and attenuation; uptake and excretion: reasonable/unreasonable	Professional judgment based on physical, chemical and biological properties of COEC in media, boundaries or barrier/ measurement or predicted (modeled) values
Toxicity assessment	Exposure-response relationship including assessment methodology is appropriate/not appropriate	Preponderance or the weight-of-evidence assessment of uncertainties (a discussion of the strength and limitation of the data) for this tier and phase of data collection strategy

- After the data collection program option has been selected by the decision-makers, the project team documents the selected option by finalizing DQOs and scope of work sections and prepares a detailed cost estimate in support of the decision document.

It should be emphasized that in the process of deliberations of data collection and design options, the customer may decide to eliminate, reduce, or modify the quantity of data collected if the customer feels that they are not critical to supporting DQOs and decision-making. For example, if the customer is very familiar with the site history and has the operating records/supporting data, he or she may decide that only compounds X, Y, and Z arc the only COECs. The sampling effort should therefore focus on these parameters for subsequent chemical analysis, and not the full Target Compound List (organics), Target Analyte List (TAL), 40 CFR 261 Appendix VIII or Appendix IX chemicals. If tissue samples arc analyzed for chemical residues, those chemicals with little or no potential for bioaccumulation (e.g., volatile organic compounds) should not be included in the list of analytes. A good understanding of the ECSM, the chemical properties and fate, and the regulatory decision-making process in the HTRW program is a key factor which will affect a productive team effort in this final technical project planning phase.

D.3 Rob and Responsibilities of a Risk Assessor In the Data Quality Design Process

The purpose of the HTRW data quality design process is to implement Total Client Satisfaction (TCS) and Total Quality Leadership (TQL) programs. To do so successfully, each project team member, under the leadership of the PM or TM, participates and works cooperatively with other team members to develop data collection program options for the customer. Such options cannot be truly developed without a thorough understanding of several key elements. This section addresses these key elements and defines the role and responsibilities of the risk assessor regarding site strategy development, identifying PDs, and defining study elements and data needs/quality to support risk management decisions. With a clearly defined role and responsibilities, the risk assessor can be more focused in serving the customer so that quality data collection options can be developed.

D.3.1 Site and Project Strategy Development

Under Phase I of the HTRW technical project planning process, the technical planning team members work with the customer to develop the overall site strategy for the current and subsequent executable phases of the project. Further, the site future uses, probable remedies, and options to achieve site closeout are identified in this phase. Therefore, a thorough review of the site history and background information by the risk assessor will help fulfill his or her role/responsibility in assisting the strategy development. It is also imperative that the risk assessor understands the customer's goal, concept of site closeout, and communicates his/her thoughts and suggestions to other team members with respect to the following areas:

- The risk assessment requirements for the primary and secondary regulatory programs. These requirements may range from a qualitative determination of whether or not there is a valid ecological concern, a screening ecological assessment, a baseline ERA, development of PRGs to protect valued ecological resources, and risk (ecological effects) screening of potential remedial alternatives. It should be noted that some risk assessment requirements may be simple and others complex with respect to data needs. The risk assessor should be open and candid about such risk assessment or risk analysis requirements, potential assessment approaches and their associated costs and time requirements, and their strength and weaknesses as inputs in making site decisions.

- Implications of current and future land use and risks. The risk assessor should explain to the project team members and the customer how current and reasonably anticipated future land uses (according to customer's goal) are factored into assessment of available food sources, habitats, and exposure to site contaminants for sensitive ecological receptors. Furthermore, any direct and indirect effects to be measured should also be explained.

- Expert advice or inputs. The risk assessor may present arguments and rationale to the expert ecologist(s)/advisory panel regarding whether the assessment endpoints (species or the resources to be protected) are appropriate, or the rationale for the lack of significant ecological concerns.

- Site background information review and development of preliminary ECSM(s). The risk assessor should review all site background information, especially the general site geology/ hydrology: potential COECs or the nonchemical stressors; the physical and chemical properties of the stressors; and their release, migration, transport, and fate properties. The objective is to conceptualize and refine the preliminary ECSMs for use in evaluating potential site closeout options and guiding selection of data needs in Phase II of the technical project planning process.

- Short-term and long-term reliability of potential remedies, technologies, or removal actions. Under Phase I, the probable remedies and site closeout options am identified. The types of remedy or technologies employed should be thoroughly evaluated by the risk assessor. The evaluation should focus on the ability and reliability of each alternative to reduce ecotoxicity, exposure, and risk, as well as their impact on existing habitats and potential recovery of such habitats after implementation of the proposed actions or removal of the nonchemical stressor. These technical comments should be based on the ECSMs.

- A "sanity check" or a check of implementability and data useability for potential study elements. It is the responsibility of the risk assessor to identify constraints, benefits, and shortcomings of employing certain assessment techniques or data gathering activities. The objective is to

keep the project team in focus so that ancillary and research projects without benefit or gain in knowledge for the customer's site decision-making are not pursued. Essentially, the risk assessor looks out for the customer's interest and critically assesses if a particular study or data requisition is warranted.

To summarize, the risk assessor plays the role of a key project team member (other key members are responsibility-legal; remedy-design engineer: and compliance specialist) and interacts with the customer, PM, TM, and other team members to develop the overall site strategy and strategy for the executable project phases. The risk assessor contributes to development of the strategies through communications and dialogues of his or her knowledge in ERA requirements for the pertinent regulatory programs, implications of land use or risk, and viability of certain site closeout options and remedies based on the preliminary ECSMs. Where appropriate, the risk assessor consults with the expert ecologist(s) or the advisory panel and forges a consensus based on PDs regarding problem identification and formulation, the assessment approach, data adequacy, cause-effect relationships between stressors, and any observed environmental effects.

D.3.2 PDs and Study Elements

Under Phase II of the HTRW data quality design process, the technical planning team members conceptualize potential data needs based on understanding of the site and project strategies and decisions to be made under the applicable regulatory program. In doing so, it is the responsibility of the risk assessor to understand and articulate the basis for the PDs in terms of the risk assessment inputs in making the site decision. The risk assessor identifies the project study element for the current phase and subsequent phases (if appropriate), and conceptualizes/defines data needs in support of the project study element.

It is also important that the risk assessor and the PM/TM have a common understanding of the project study elements and the objectives/utility of the elements to support site decisions. Where the study element will be a cooperative effort among project team members, the elements have to be communicated and understood by all affected members. For example, a field survey to establish the existence of sensitive environments and valued resources or the collection of co-located media samples for toxicity testing to establish RA objectives can be integrated into the field investigation activities to identify the locations of "hot spots" under an engineering evaluation/cost analysis (FE/CA) for a potential removal action. In another example, quarterly groundwater sampling of monitoring wells could be integrated into the same study element to monitor the community structure or health (diversity and abundance) of indicator species such as benthic macroinvertebrates at the reference locations and downstream locations of a site for a long-term field survey. The risk assessor should communicate his or her thoughts and suggestions with respect to the following areas:

- Study elements to be performed and breakout of the elements. The data needs for the element and its subelements have to be conceptualized and identified. The risk assessor and other team members need to identify the study element or subelement which may be executed by other project team members.

- Provide rationale for data needs in terms of useability in satisfying information requirements for PDs. The risk assessor presents to the PM/TM or the affected project team members' thoughts/ideas and data requirements for executing the study element. The risk assessor may find these communications helpful because other project team members may be able to identify data sources or provide alternative approaches to satisfy data needs.

- Define and document data needs. With an understanding of the PDs and rationale for making site decisions, the risk assessor has the responsibility to define data needs and explain how the data will be used in the study element in support of site decisions. The risk assessor has the responsibility to articulate data needs based on the ECSM, and recommend data quality and confidence levels (applicable for abiotic or certain biotic sampling) for a particular information need on the data needs worksheet.

- Sensitive data or critical samples. Where the information or parameter is sensitive as to its effect on the result to the study element, the risk assessor should identify these parameters to the project team. The strength and weakness of the requested data in making inferences, testing of a hypothesis, and providing the weight-of-evidence presentation with respect to analyzing uncertainty in the ERA should also be discussed.

To summarize, the risk assessor plays the role of a key project team member and interacts with the customer, PM, TM, and other team members (as appropriate) to conceptualize data needs. The risk assessor has the responsibility to justify the data needs based on the ECSM and the requirements of the project study element. The data needs are defined and documented formally, e.g., using data needs worksheets.

D.3.3 Data Need/Quality to Support Risk Management Decisions

Under Phase III and Phase IV of the HTRW technical project planning process, the risk assessor and other project team members identify sampling approaches and data collection options, refine options, and document the selected option. Negotiations and tradeoffs are anticipated during these project planning phases because data needs, quality, and confidence levels may not be completely satisfied due to budget, schedule, and other constraints. The risk assessor's responsibility is to identify and communicate to the data implementors key data needs and their associated desired quality and confidence level needed for the project study element. Among others, it is the responsibility of the risk assessor to stay focused, only requiring those data pertinent to support risk management decisions. The risk assessor should communicate his thoughts and suggestions with respect to the 'following areas:

- Sampling approaches and analytical requirements. Based on site background information and the preliminary ECSM, the risk assessor should have already provided input to the data implementors and TM on the types (medium-specific), desired confidence level, time and location for the samples under Phase II. These requirements should be based on the ECSM and the physical/chemical characteristics of the COECs (if known) and the site matrices. If certain COECs are suspected, the risk assessor should review their respective PRGs or benchmark levels, and ensure that the analytical limits are below such levels. This approach applies to both biotic (e.g., tissue residue analysis) and abiotic samples. In Phase III, the risk assessor communicates and explains data needs and quality assurance requests to the data implementors.

- Refinement of data collection options. Based on consideration of project constraints, and customer's preference/input, the proposed data collection program options may require refinement. This may involve phasing the site investigation or addressing certain "hot spot" areas first or limiting the study ares to the EU or area where the sensitive receptors or valuable resources may be at risk. The risk assessor can contribute substantially to this refinement effort by identifying the major exposure pathways and media of concern.

- Field survey/site reconnaissance. The risk assessor should conduct a thorough site reconnaissance and review all site references and background information before developing the ECSM for use in identifying complete exposure pathways and the exposure point (medium). This site visit and review also serve to verify the feasibility/practicality of exercising certain field data collection options, including locations of the sampling stations and the existence of biota to be sampled. Data collection options should be presented to the decision-makers in a clear and concise manner, e.g., matrix tables supplemented by bulletized discussion of the advantages and disadvantages, including data uncertainty associated with each option.

- Optimization of the data collection program. The risk assessor works with other project team members to prioritize data needs, if necessary, and identify the optimum sampling strategy or cost-effectiveness ideas. As a key member of the project team, the risk assessor should review past site data and anticipate data needs for future project phases to incorporate cost-effective data strategy into the data collection option(s). (In addition to chemical data, incident reports, environmental impact studies, or fish or wildlife consumption advisories published by local college/university, natural resources department, State fish or wildlife conservation districts should be reviewed) All data collection options must be able to satisfy the short-term and long-term goals.

- Assignment of DQOs. Statements concerning data needs and use and their benefits/limitations in support of project decisions should be prepared for presentation to the customer in the form of a fact sheet for a particular option. After the data collection program option is selected, the risk assessment finalizes such statements as DQOs for use in the TM package or the scope of work for work acquisition. An

essential element in a particular DQO is the decision statement (if-then) regarding data outcome and options. The DQOs should comply with the customer's request for information to make informed site decisions. For example, if the assessment endpoint is protection of downstream bivalves or oyster beds during sediment remediation and the measurement endpoint is a combination of COEC concentration in the boundary sediment and turbidity (expressed as total suspended solids), the DQO statement may indicate the maximum frequency of exceedance of these parameters during a specified time period, say 12 hours. If exceedance occurs, then sediment dredging is suspended until normal conditions are reestablished.

Playing the role of a key project team member, the risk assessor supports development of viable data collection program options by identifying key data needs and their required level of confidence and quality. The risk assessor has the responsibility to identify the benefits and limitations of certain data and develop the appropriate DQOs for obtaining such data. The risk assessor also has a responsibility to work with other project team members to optimize the data collection program options consistent with the overall site strategy and the customer's goals.

D.4 Data Needs for HTRW Executable Project Phases

For scoping of data needs to perform a risk assessment or a risk analysis, the risk assessor and the PM/I'M agree on the project study element for that executable phase. The study is focused on providing the exposure and risk information to support risk management decision-making for the PDs.[9] Key PDs are statutory or regulatory requirements which have been identified for each HTRW executable project phase in the HTRW Technical Project Planning Guidance. To assist the risk assessor and those who oversee performance of the risk assessment/risk analysis (e.g., PM, TM, and the customer), this section provides a framework for identifying data needs associated with typical study elements for HTRW executable project phases under CRRCLA and RCRA (i.e., PA/SI and RFA; RI and RFI; FS and CMS; RD/RA and CMI). Typical data needs are also presented for these project phases. It should be noted that data needs should not be

[9] For the purpose of this manual, the project planning approach used to identify data needs pertains to assessing ecological risks posed by the site under the baseline or no-further-action scenario. If removal or remedial actions are warranted, data will be needed to derive remedial action objectives (cleanup goals) and to perform screening or detailed risk-based evaluation of the short-term and long-term impacts from the potential removal or remedial alternatives. In addition, the risk assessors may be requested to coordinate with other technical planning team members to provide inputs and help define data needs for other site evaluations. These requests may be for the planning of certain response actions, e.g., compliance/cleanup verification levels based on uncertainty of the risk-based remediation action objective; assignment of response action responsibility based on the contribution to site risk from multiple releases into the environmental medium, etc. These data scoping activities are not the focus of this section, although the general approach for scoping the data needs may be applicable.

finalized until a review of the existing data has been conducted to determine data gaps.

The framework for conceptualizing and defining risk assessment data needs consists of the following steps, which are in accordance with the HTRW Technical Project Planning Guidance:

- Background information review (Step 1) -- The purpose of this review is allow the risk assessor to become familiar with site features, hazards (potential COECs or nonchemical stressor[sl to be evaluated), available exposure-response or toxicity information, and exposure (potential exposure pathways). The review assists the formulation of the problem, evaluation of potential ecological concerns, and the development of the preliminary ECSM.

- Assemble PDs and identify project study elements specific for each PD (Step 2) - The purpose of this step is to identify the decisions to be made so that the study element or the type of ERA or risk evaluation can be established to support decisions.

- Conceptualize data needs based on the ECSM (Step 3) - This data scoping step requires the risk assessor to identify data needs based on the ECSM and the study element required. Existing chemical, nonchemical, or exposure data can be used to characterize exposure to ecological receptors (both spatially and temporally) with or without the application of fate/transport or other models (e.g., food web models).

  [As appropriate, the risk assessor may also consider data needs in future project phases in order to refine the ECSM or to facilitate risk evaluation of anticipated removal or remedial actions (if such needs can be more cost-effectively satisfied by the data collection program in the current project phase)].

- Define and group data needs (Step 4) -- This scoping activity entails defining the necessary data (i.e., data gaps) based on earlier steps, and groups data needs by medium, location (spatial attribute), or time (temporal attribute). For example, quarterly sampling of groundwater intersecting the surface water (seep samples) to estimate the exposure point concentration of COECs for freshwater species to be protected.

- Document data needs (Step 5) - This step requires the risk assessor to document the data needs by providing the basis or reason for the data, how the data are to be used to help make site decisions, and the proposed data quality and confidence level. The documentation is needed so that a record is established to identify the originator of the data request, the application or use of the data, and the required quality. Since environmental data could be reported in any manner to tit the user's need, the risk assessor may also document and communicate such data compilation needs in this scoping step.

The following sections present the scoping requirements for a risk assessment or risk analysis performed for the HTRW project phases. For each project phase, the section identifies the type of background information usually available, the PDs for the project phase, typical project study element(s) to be performed, and the data needs/ groupings. The discussion of data needs focuses on why such data are needed and how they are to be used. The discussions are not intended to be all-encompassing: data needs depend very much on the project study element, amount of useable data already in existence, and site-specific conditions.

D.4.1 Exposure Pathway Analysis and Risk Screening; PA/SI and RFA

Focusing on risk assessment/analysis data needs, this section discusses the HTRW data scoping for the preliminary site evaluation phase in CERCLA and RCRA. This site evaluation phase is known: under RCRA as a RFA; under the CERCLA removal (emergency response) authority as a Removal Assessment; and as a PA/SI under the CERCLA remedial program. Other HTRW site assessments, although not specifically covered under these statutes, e.g., the Baseline Environmental Survey in a BRAC, are expected to be functionally equivalent. The project execution phase for the PA/SI and the RFA is generally known as a Phase I project execution stage. For a Phase I project execution stage (i.e., PA/SI or RFA), the following technical project planning approach should be considered.

D.4.1.1 Background Information Review

Before the data needs are conceptualized, it is recommended that the risk assessor (and the technical planning team members) carefully review all site background information including: TM Memorandum: RCRA Section

3019 exposure information for land disposal and certain land treatment units (if applicable): file searches (available State and/or EPA enforcement or incident reports, fish and wildlife consumption advisories, Prescore of the HRS, SI Worksheets, HRS scoring package, checklists, notes and photos documenting the site's environmental setting, etc.): USGS or State geological survey bulletins/ references and topographical and National Wetland Inventory Maps; State Fish and Wildlife Department information on fisheries, endangered or threatened species/ habitats; EPA databases (Geographic Exposure Modeling Systems [GEMS], PATHSCAN [surface water information], etc.); aerial photos; and the commercially available GIS digitized data package.

In addition, the data quality used to produce the SI or Expanded SI reports for proposed placement on the NPL (if applicable) should be reviewed, along with a determination of whether additional data are needed to support PDs. The purpose of this review is to obtain a good understanding of the following issues:

- Regulatory concerns or site problems relating to ecological receptors,[10] and the significant exposure pathways (source, migration/transport mechanism, exposure routes, and receptors) to be addressed.

- Status of the project with respect to an identifiable decision path leading to site closeout.

- Customer's or PM's goals and objectives, plan of actions, compliance requirements, and budget/ time constraints for the current phase and subsequent phases of the project life cycle (if known).

0.4.1.2 PDs

The following describes the decision step within the critical path of the HTRW response program relating to the CERCLA and RCRA SA phase:

- PA/SI -- Upon completion of a PA/SI, the critical path is likely to be elimination of the site from further action or, if the site score is above 28.5 on the I-IRS, for listing on the NPL, or require further investigations (under a RI/FS). The no-further-action decision may also include referral by the USEPA to the State for further assessment.

- RFA -- Upon completion of a RFA, the critical path is similar to that for the PA/SI, i.e., determine whether potential SWMUs can be eliminated from further action or should be further investigated in the RFI phase.

The above broadly defined decision steps in the project life cycle indicate that the type of decision to be made for the SA phase under these regulatory programs is similar to one another (i.e., "Should the site be eliminated from further investigation?"). The objectives for an SA at this early project phase concern the identification of past or current releases, locations, boundaries, assessment of the need for removal or interim measures, and documentation of all risk reduction actions. Logically, if there is no documented history of chemical releases or there are containment devices with good structural integrity to intercept the releases, there should be little basis for further action. On the other hand, if there were documented releases, the decision will have to be based on a more complicated analysis to ascertain: (I) the environmental significance of the release (based on limited medium contamination and an exposure pathway analysis); (2) the need for removal actions or interim measures to mitigate risks: and (3) priority of site actions (i.e., hazard ranking of this site relative to other sites) under the HRS or other prioritization schemes, such as EPA's National Corrective Action Prioritization System (NCAPS), guidance on setting priorities for NPL candidate sites (EPA 1992p), or the DoD's site ranking/prioritization system."

[10] In addition to the regulatory actions or concerns, the risk assessor should also review any draft or final reports from universities and the local or State natural resource agencies concerning the site environmental setting and ecological concerns. The regional USFWS should be consulted for the existence of endangered or threatened species, including Category 2 and rare species. The Army's BTAG may be consulted regarding the significance of any expressed ecological concerns.

[11] High priority is assigned by EPA to sites for which SIs have been completed and where (1) people are currently exposed to hazardous substances, pollutants, or contaminants: (2) actual contaminant has been documented, especially at or above a health-based benchmark: (3) a large potentially affected target population is nearby: (4) contamination to a sensitive environment or fishery has been documented: (5) the State has recommended the site be listed on the NPL pursuant to CERCLA 105(a)(8)(B); or (6) the ATSDR has issued a health advisory or is planning to.

On a project management level (not programmatic management level), items (1) and (2) above are the only relevant considerations. Therefore, specific PDs associated with this executable project phase are:

- Determine if the "site," SWMU, AOC, etc., can be eliminated from further action (i.e., investigation and/or remediation).

- Determine if removal action(s)/interim measure(s) are needed to mitigate imminent threat to human health or to the environment.

D.4.1.3 Project Study Elements

The objectives of the study elements (screening ERAs or risk screening) are to address the PD on whether or not the site should be eliminated and whether or not removal actions should be undertaken. Project study elements should provide evidence in support of or in refute of past or potential future release, transport, and human health/environmental impacts. Additional support can be provided by a hazard evaluation which considers the chemical identity, concentration, and/or volume of the past or possible future releases, or the nature, spatial and temporal attributes of the nonchemical stressor, and an exposure pathway analysis which includes the identification of ecological receptors of concern or valued resources.

For the SA project execution phase, preliminary quantitative chemical data are preferred, although not likely to exist, and qualitative information on the site setting (specifically, a habitat evaluation for the potential exposure to sensitive ecological species or valued resources) are needed for all or any one of the following project study elements:

- Perform a qualitative or semiqualitative screening risk evaluation by comparing limited site data (usually from purposive sampling of visually contaminated areas) to benchmark concern levels such as those identified in the USFWS contaminant review series by Eisler (1986-1988); NOAA's ER-L and ER-M values for sediments: Ontario's LELs and SELs; chemical-specific ARARs[12] such as State or Federal AWQC, Great Lakes National Program Office's sediment concentrations for PCBs, mercury, pesticides, and other chemicals: background concentrations: inorganic (mineral) nutrient levels, or other appropriate toxicity-based literature values (e.g., AQUIRE database).

- Conduct a qualitative exposure assessment, based on the ECSM, and identify completeness of potential exposure pathways and their significance or likelihood of release/transport which could result in exposure by the target receptors. The assessment should also consider: the size of the site containing the chemical contaminants in relation to the foraging range of the target species to determine the EU, the physical and chemical characteristics of the contaminants (including the bioconcentration and biomagnification potential): and media matrices.

- Conduct HRS scoring using PreScore/SI Worksheets to determine the contribution of the environmental concerns to a HRS score, and to determine if potential early actions/removal actions or update of information may significantly reduce the need for or the scope of a future CERCLA action.[13]

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[12] Other than Federal and State AWQC, which are a ready, frequently used source of chemical-specific, ecologically based (pseudo-risk-based) ARARs, essentially there are no chemical-specific ARARs for ecological concerns. Additionally, cleanup to an ARAR does not necessarily equate with attainment of protective levels.

[13] The results of this review and HRS scoring exercise should be presented to the Customer/PM. If the risk assessor can justify a lower HRS score or an insignificant risk, based on site-specific information, a request for regulatory relief (delisting, modification of permit conditions, etc.) to the agencies may be considered. This approach may also be useful to eliminate or prioritize SWMUs for a RFI.

- In limited cases where there are available chemical data, a screening risk assessment may be performed by employing mean and maximum observed concentrations, and conservative exposure assessment assumptions and models. This screening risk assessment may include the use of conservative BCFs, BAFs, fractions of soil and vegetation ingested by a herbivore; the equilibrium partitioning (EP) model to predict pore water concentration in wetland sediment (applicable for nonpolar organic compounds): or box models or limited dilution models to predict the exposure point concentration for a mixing zone between groundwater and surface water for aquatic organisms.

The above project study elements may discuss current and future land use and population characteristics, based on the discussion of potential exposure pathways. The study or evaluation may employ the weight-of-evidence approach to present potential risk qualitatively and indicate uncertainties of the evaluation. The exposure pathway analysis and recommendations should focus on the potentially complete pathways. The PA prescore may also be used to justify whether or not a RI/FS, RFI/CMS, or removal actions/interim measures are likely to be needed.

D.4.1.4 Conceptualizing and Defining Data Needs

Data needs for the risk assessment should be based on the preliminary ECSM(s) which should be established in this phase of the HTBW project planning process, and should generally be limited to responding to the above-defined PDs. The data needed may be nonchemical in nature, e.g., USGS 7½- minute maps, U.S. Chamber of Commerce Census reports, County Soil Maps, aerial photos, surveys, interviews with local conservationists/naturalists, or other sources of information that can be used to establish the existence of potential exposure pathways and receptors. The data needed may also be chemical in nature, e.g., sediment and surface water quality data of potentially impacted wetlands. In other words, the site strategy and PDs developed under Phase I of the HTBW project planning process will be the focus of this data-scoping activity. The output of this data-scoping (Phase II) activity are the Data Needs Worksheets for this SA (or Phase I) project execution phase or subsequent phases of project execution.

D.4.1.5 Establish Preliminary ECSM(s)

To establish the preliminary ECSM the risk assessor should focus on obtaining information needed to relate risk associated with the site and assess potential early/ immediate response actions. Ihe ECSM, described in greater detail in Chapter 3, presents all potential exposure pathways (sources, release mechanisms, transport media, exposure points, exposure routes, and receptors [including the relationships among receptor populations in a community and across trophic levels]) and identifies those pathways which are complete (significant or insignificant) and incomplete. The information should be able to assist the risk assessor in developing a preliminary ECSM or multiple ECSMs if there are multiple SWMUs, AOCs, OUs, or CAMUs/TUs or if there are multiple ecological receptors for these groups of sites or SWMUs. The CAMUs and TUs are most pertinent to the risk assessor for addressing remediation risk (Phase III project execution phase) from nonchemical entities since they encompass the boundary where remedial activities will be conducted. The risk assessor and project team members use the ECSM to focus the data collection effort on those significant pathways that may pose potential risks or food-chain effects and to address PD requirements.

Existing data should be reviewed for their quality and use in defining new data acquisition requirements for a preliminary or screening risk assessment/risk analysis and for a baseline risk assessment. Any uncertainty in the preliminary ECSM due to data gaps should also be identified in the ECSM. Information needed to develop an ECSM includes:

- COECs (information concerning the source characteristics, ecotoxicity, BCF, BAF, potential laboratory or field sample contamination, background and concentrations).

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

- Potential receptors (endangered, threatened, sensitive, and rare species) and their home ranges, and resources of commercial or recreational value to be protected in the target media.

- Major exposure routes or pathways of concern (e.g., ingestion of chemically contaminated fish by raptors).
- Known release or likelihood of a release of a site chemical from a source, and the manner in which the release could occur.
- Level of contamination when compared to available ARARs, benchmark values, or PRGs.
- Data useability factors, based on quality assurance characteristics, parameters analyzed, validation results, and the way the data were compiled, that may severely restrict their use in the risk assessment (e.g., total organic halogen and soil gas data, combination of deep soil and surface soil data sets, low recovery of internal standards, etc.).
- Removal actions or interim corrective measures taken since site listing or report publication, which may have substantially mitigated exposure and risk.
- Areas or units which have COECs and exposure pathways in common and which pose a common threat to human health and the environment.
- Potential secondary sources of contaminants, and their release/transport mechanisms.

D.4.1.6 Define Data Types and Preferred Data Quality Requirements

Generally, the data needs for a Phase I project execution phase (or SA phase) are qualitative in nature and do not require intrusive field investigations, although field surveys (e.g., habitat evaluations) could be highly beneficial to identify the basis for ecological concerns. Where chemical data are desirable to confirm the presence or absence of releases, a Phase II HTRW technical project planning activity should be employed to define the data type according to complete or potentially complete exposure pathways. The pathways may include soil and groundwater ingestion, ingestion of food chain products, and direct contact or co-occurrence of the receptors with the contaminated media in space and time. The corresponding chemical data to assess such exposure pathways include soil, groundwater, food chain products, and airborne contaminant concentrations. The ECSM should be used to organize the corresponding relationships. As a data user, the risk assessor defines the exposure AOC for a pathway, the data quality needed, and preferred sampling strategy or methods. Examples of data types, according to medium, for use in assessing potential exposure pathways are:

- Surface soil (ingestion/dermal contact and inhalation of airborne particles).
- Surface water (ingestion/dermal contact).
- Groundwater (generally limited to the mixing zone only).
- Contaminated food (ingestion - the food web investigated can be simple involving one trophic level, or complex, involving different trophic levels).

The risk assessor then prepares Data Needs Worksheets for each pathway which document the data types, quality requirements, or needs. For example, the QA/QC requirements could be set as medium or low (QA3 or QA2).[14]

[14] EPA has identified three or more levels of QA/QC objectives based on the intended data use (EPA 1992d,e): (a) QA1 is a screening objective to afford a quick, nonrigorous. and least expensive (time/money) preliminary assessment of site contamination. It produces data for which there are neither definitive identification of the chemicals nor definitive quantitation of their concentration levels, although a calibration or performance check of method is required along with verification of the detection level. Applicable activities are: sample's physical/chemical properties, extent of contamination relative to concentration differences, delineation of plume in groundwater (head space or soil gas analyses), placement of monitoring well, waste compatibility, preliminary health and safety check, nonanalyte specific categorization, and preliminary identification/quantitation of chemicals (e.g., pH, ignitability, chlorine presence, etc.); (b) QA2 is a verification objective which requires a minimum of 10% verification of chemical identity (by an analyte-specific method) of the field or laboratory results, and a minimum of 10% verification of quantitation (accuracy of measured concentrations). It is intended to give the data users a level of confidence for a selected portion of preliminary data. Applicable activities are: sample's physical and chemical properties, extent and degree of contamination, and verification of plume in groundwater, health and safety check, chemical identification, and cleanup. (c) QA3 is similar to QA2 except that 100% of sample results are confirmed for identity, e.g., the use of GC/MS analytical method. That level is most appropriate for critical samples used to support site decisions. Applicable activities: comparison with action levels, treatment/disposal, site removal/remediation, health risk assessment, source identification/delineation, and cleanup verification.

The level of confidence (maximum error rate) required of the sample results should not be set so high, or the detection limits so low, as to be unrealistic and unachievable, considering the potential variability of the sample results in a given matrix and the available analytical techniques. However, it should be noted that chemicals which bioaccumulate cannot be effectively eliminated based on low concentrations or concentrations below nondetection. In this instance, analysis of tissue residues may be appropriate in future project phase(s), i.e., in the RI/FS or RFI/CMS project phase. For nonchemical types of data, the quality assurance requirements are established and done on a case-by-case basis. The risk assessor may utilize a weight-of-evidence approach to assess the data needs and their uncertainties in the SA project phase. The approach generally consists of qualitative data, such as from a site reconnaissance, to identify if there is stressed vegetation or dominance of tolerant species commonly found in contaminated sites. Subsequent collection and analyses of abiotic (media) may be performed in some cases to aid making informed site decisions at this stage of the HTRW response process. For example, soil discoloration and vegetation stress at the downgradient location (of a hazardous waste storage area) were observed where runoff is likely to take place. A small number of selective surface soil samples will be sufficient to make the decision on whether release from the source has occurred and to ascertain if the release is still localized.

D.4.1.7 An Outline or Summary of the Approaches In the Risk Assessment/Risk Evaluation, Uncertainty Discussion and Recommendations

The approaches or contents of an anticipated risk assessment/risk evaluation summary should be explained or made known to the decision-makers in the project planning stage in unambiguous terms. This is to avoid potential misuse of the risk assessment results, and can be used as a means to make sure that the selected data collection option will meet the users needs.

Due to limitations in data quality and quantity, the risk assessment/risk evaluation performed in a PA/SI, RFA, or in other site assessments is generally qualitative in nature, e.g., a discussion on the potential exposure pathways and preliminary ECSM. In the rare instance when a quantitative risk assessment is performed (e.g., the Toxicity Quotient Method), the results should be considered preliminary and screening in nature since the nature and extent of the contamination is not clearly defined at this time. In both cases, the uncertainty is considered high and should be identified as such by the risk assessor in a qualitative discussion. A quantitative assessment of uncertainty, using Monte Carlo analysis or other quantitative methods to propagate error, is not appropriate because this type of risk assessment or analysis is not meant to be used as a predictive tool. The recommendations derived from the assessment are general, i.e., the recommendations are expressed as “likelihood,” “probable,” and “deterministic.”

The preferred level of confidence for nonchemical data could be ranked medium to low. These levels of confidence are justifiable within an SA stage when different data inferring the presence or lack of environmental risk are collected, and a weight-of-evidence discussion of uncertainty is used to explain the evaluation findings and the recommendation(s). For example, the topography, visual observations, history of spills, runoff pattern, and the analytical results of purposive sampling would be sufficient, as a whole, to support the argument whether contamination of a medium is likely or unlikely.

If chemical data are available, the level of confidence will depend on the experience and expertise of the laboratory to deliver quality data, associated QA/QC control, sampling method, sample handling/preservation method, and last, but not least, variability of the chemical concentrations in the medium that was sampled. It is recommended that the risk assessor and chemist/data reviewer coordinate their efforts to design a sample collection program which is most likely to produce sample results with an acceptable level of confidence. The following factors should be considered in this planning activity in order to reduce uncertainties:

- Use of EPA-approved methods or ASTM protocols and the associated QA/QC for conducting chemical analyses.

- Laboratory QA/QC Program - A reputable laboratory with established internal and external audit procedures should be used. For analyses performed on a given instrument using a given analytical method, the laboratory should be able to provide a reasonable estimate of the range of possible values, given a detectable or estimated value in the data summary report. The laboratory should also conduct a preliminary QA/QC check before the laboratory results are finalized.

- Level of Quality Assurance - Depending on data use, the level of quality assurance for a PA/SI and RFA can be QA1 (field screening to assist

identifying sampling locations), QA2 (presence or absence of contaminants with some confirmational analyses), or QA3 (confirmational analyses of chemical identification and quantification, e.g., gas chromatography/mass spectrometry [GC/MSl method).

- Field and Laboratory QA/QC Samples - If soil or sediment samples are collected and are to be used in a future phase(s) of work, considerations should be given to collecting sufficient volumes for laboratory QA/QC analytical samples (i.e., duplicate, matrix spike, and matrix spike duplicate samples) and for field duplicates; water samples require field duplicates. In addition, samples for the analyses of 'volatile and semivolatile organic chemicals should be checked for surrogate recovery. Laboratory blanks should also be analyzed to check for the presence of potential laboratory contaminants.

- Data Variability - Detection of hot spots is generally not the objective of the sampling program under a PA/SI or RFA. The number of samples required to represent the level of contamination with a predetermined level of confidence will depend on the uniformity or homogeneity of the contamination. This information can only be obtained via previous sampling events.

D.4.2 Baseline Ecological Risk Assessment; RI and RFI

This section focuses on HTRW data scoping (data needs and DQOs) for a detailed site investigation phase under CERCLA or RCRA. The detailed site investigation phase under RCRA is known as a RFI/CMS and under CERCLA as a RI/FS. Other HTRW site investigations are expected to be functionally equivalent, for example, for BRAC; for permitting of an onsite hazardous waste incinerator (RCRA Subtitle C, Subpart 0); for miscellaneous units (RCRA Subtitle C, Subpart X): or for pertinent land disposal units (RCRA Subtitle C, Subparts J, K, and L). The site investigation execution phase for CERCLA and RCRA is generally known as a Phase II execution project phase.

D.4.2.1 Background Information Review

By a Phase II execution project stage, the risk assessor and the project team should have some understanding of the site background and descriptions of site characteristics from a review of the preliminary (PA/SI or RFA) data contained in the Federal Facility Docket or pertinent project files. At certain sites, removal actions, risk screening/exposure pathway analysis, or HRS scoring may have been performed. This information will be useful in scoping the data needs for a baseline ERA. Before the site strategy for the Phase II execution project phase is developed or revised, it is recommended that the project team carefully review the TM memorandum (or its updates), all site background information, file searches, and other relevant information concerning site ecological resources, habitats, and the receptors of concern.

The data collection approach and quality requirement should address concerns expressed in the NPL or the RFA report/permit requirements. The site strategy plan should be revisited and the need for additional data to support PDs examined.

The background information review should focus on the following issues:

- Regulatory concerns or site problems (or newly identified concerns) relating to: receptors, COECs (e.g., ecotoxicity, BAF, BCF), stressors of concern, and exposure pathways of concern.

- Project status with respect to the decision path leading to site closeout.

- Customer's or PM's goals and objectives, plan of actions, compliance requirements, and budget/ time constraints for the detailed site investigation and later project phases.

D.4.2.2 PDs

Broadly defined decision steps relating to detailed site investigations in CERCLA and RCRA within the critical path of the HTRW response program are:

- RI -- Upon completion of the RI or the RI/FS (if the FS is conducted simultaneously with the RI) and signing of the Super-fund Records of Decision (ROD), the critical decision step will be either the elimination of all or certain OUs/ AOCs from the next phase of the project, (i.e., no RD/RA needed based on the baseline ERA and compliance with ARARs) or a RD/RA is needed (for portions of the site or for the entire site) which proposes selected remedies to mitigate risks and comply with ARARs. The decision path also includes considerations for removal actions/interim actions and public

notice/participation on the proposed remedies or no action alternative.

- RFI -- Upon completion of the RFI, the critical decision step is likely to be either that (1) further study is required (i.e., corrective measure study) to define baseline risk and to propose remedial alternatives or (2) no further remedial action is required (i.e., compliance is achieved with respect to permit conditions or RCRA enforcement actions) based on comparison with proposed action levels, ARARs, or benchmark values. If the baseline risk assessment indicates unacceptable risks, corrective measures (selected remedial alternatives) will need to be implemented. The decision path also includes considerations for removal actions/interim corrective measures.

There are many objectives for a RFI and RI. For example, a Phase II project executable stage identifies COECs, investigates the amount of release and the nature/extent of media contamination, evaluates the fate and transport properties of CORCs and affected media, assesses baseline risks, determines the opportunities for removal actions or interim corrective measures/early actions, assesses and recommends remedial alternatives to mitigate risks, and documents investigation and response actions. Generally, if there is no appreciable evidence of release or if the baseline ecological risk is acceptable (determined either through a baseline risk assessment or a comparison with ecologically concern levels or benchmark levels), there should be little basis for a FS, CMS, RD/RA, or a CMI. If contamination is found at the site (onsite, offsite, or at multiple locations) and ecological receptors could co-occur with this contamination spatially or temporally (e.g., during the early life cycle in the species natural history), a site-specific baseline risk assessment will be needed to ascertain if:

- Further investigation (e.g., to address hot spots) is warranted with or without removal actions.
- Immediate or emergency response actions to mitigate short-term risks are needed.
- Remedial alternatives/corrective measures should be implemented to mitigate site risks.

Therefore, specific project decisions (PDs) associated with a Phase II executable project phase are:

- Determine if the "site," SWMU, AOC, and, more appropriately, the EU, pose significant risk to the environment to warrant remediation or corrective measure.
- Determine if removal actions/interim corrective measures are needed to mitigate imminent threat to the environment.

D.4.2.3 Project Study Elements

The project study elements for a Phase II project execution stage are concerned with defining the site nature and extent of contamination (including establishment of background or reference chemical concentrations to meet PD requirements): establishing an understanding of the fate and transport mechanisms of chemicals based on the findings of a site characterization element; and conducting a baseline ERA (based on the site characterization, fate/transport findings, site features, hazard [ecotoxicity or stress] and exposure information). For a Phase II project execution phase, data may be needed for all or any one of the following project study elements (including the baseline ERA) to respond to PDs of whether or not there is a need to undertake removal actions or remedial action/corrective measures. If a FS or CMS is to be performed after the RI or RFI, the project study elements must also support a decision of whether to go forward with the FS or CMS based on significant adverse impact (or risk) to the ecological receptors of concern or to valued resources. Potential study elements for a Phase II project execution phase are identified as follows:

- Evaluate the basis or need for emergency response or nonemergency (nontime critical) removal actions based on frequency, duration, and intensity of hazard, and the magnitude of response.
- Evaluate if potential removal options are protective.
- Identify and assess if SWMUs and OUs should be combined into CAMUs or AOCs for future remediation (if the ecological species or resources are spatially co-located with the units or areas requiring remedial action or corrective measure, the impact of these actions should be assessed as one single exposure unit [e.g., where the impacts of excavation/disposal or treatment permanently alter or destroy the landscape, available food sources, and habitats of ecological species of concern whose home ranges are within the remediated area]).

- Determine whether remedial actions are needed or no action is required for the entire site or portions of the site based on an assessment of the spatial and temporal distributions between the ecological receptors and the COECs. the baseline ERA in the impact area, and the fate and transport properties of COECs in the transport media.

- Provide justification or a basis to allow expeditious development of a FOST for a BRAC site which is also on the NPL, so that uncontaminated areas of a DoD facility can be transferred, sold, or segregated from the contaminated area of the site for the planned land use or continuation/modification of current operations, i.e., data of sufficient quality and quantity are needed to delineate contaminated areas which pose unacceptable risk.

D.4.2.4 Conceptualizing and Defining Data Needs

This project execution phase (Phase II) is comprised of four data tiers. Successive tiers are progressively more expensive and time consuming, starting with an assessment of individual effects or abiotic levels in Tier I to the study of population and community structure (diversity, richness and abundance) and function (recycling of energy and nutrients, and biomass/standing crop production) in higher tiers. Physical and biological models and extensive field monitoring and model validation may be required for the higher tiers. This multiple-option system of structured data needs is designed to allow the risk assessor and the project team members to economize data needs and to evaluate ecological risk cost-effectively. If data from the lower tiers ate deemed to be inadequate by the customers and regulators for decision-making, a higher tier may be pursued, if such studies or tests provide sufficient cause-effect relationships, associations, or inferences between the measurement endpoints (field or laboratory measurements/observations) and the assessment endpoints (species or resources to be protected). Generally, most HTRW projects with ecological concerns need only employ Tier I or Tier II data-gathering activities to satisfy site decision needs.

It should be noted that data needs at this stage of the HTRW project planning should focus primarily on the question: "What is the nature and extent of contamination and does the contamination co-occur with the spatial/ temporal distribution of ecological receptors?" If the answer is positive, the risk assessor's responsibility as the project team member should be to assist the customer and PM to decide the locations and media requiring removal or remediation based on the risk screening performed in the PA/SI or RFA, or the baseline ERA to be performed. Guided by the ECSM (established in the Phase I and refined if necessary in the Phase II project execution phases), data may be needed for all or any one of the following risk assessment/evaluation tasks to respond to the Phase II project execution phase PDs:

- Determination of current and future land use (including conversion of land to park and wildlife refuge) and the societal value of the resources to be protected.

- Fate and transport modeling of COECs in groundwater, air, and/or sediment (where applicable, [data needs may include pH, hardness, total suspended solids, precipitation rates, infiltration rates, aquifer thickness, hydraulic conductivity, total organic carbon, grain size, acid volatile sulfide concentration, bulk density, porosity, and processed meteorological data]).

- Collection of abiotic (exposure media) data including the nature and extent of contamination and biotic data to support the assessment of potential receptors and populations.

The site strategy and PDs developed under Phase I of the HTRW project planning process (Develop Project Strategy) for a RFI and RI will be the focus of this data scoping activity. Data needs may be nonchemical in nature, e.g., availability of food sources for indigenous species, land use planning/zoning maps published by the local government, regional geologic or hydrologic reports pub lished by the State or the USGS, Census or other survey reports or fact sheets, NOAA reports, or any other information that can be used to establish site characteristics, the existence of potential exposure pathways, receptors, or likelihood of exposure. Although some of this information may have been gathered in the PA/SI or RFA project execution stage, this information should be made as complete and as accurate as possible in order to prepare a defensible baseline ERA. Additionally, data needs may be chemical in nature, i.e., constituent concentrations in the exposure media (air, groundwater, soils, sediments, or surface water).

The output of this data scoping activity will be Data Needs Worksheets for this project execution phase (and subsequent project execution phases, if appropriate).

D.4.2.5 Define Data Types and Preferred Data Quality Requirements

This Phase II HTRW data-scoping activity eventually defines the data type according to potential exposure pathways. The ECSM is used to organize data needs and their relationships to PDs. Examples of data types, according to medium, for use in assessing potential ecological exposure pathways are: soil and surface-water ingestion, ingestion of food chain products/prey species, inhalation of airborne contaminants, and direct contact with the contaminated media. In each of these data types, monitoring data or data for modeling the exposure point contaminant concentration in the media are needed.

The risk assessor prepares Data Needs Worksheets for each pathway, documenting data types, quality requirements, or needs. Chemical data to be collected should be identified with QA/QC requirements. Customer's appropriate requirements for data quality, e.g., USACHPPM's data validation guidelines, should be followed In addition, the level of confidence (maximum error rate) required of the sample results should be set, after considering the potential variability of the sample results in a given matrix and potential laboratory/sampling handling errors. For nonchemical types of data, the QA requirements will be established and data can be obtained on a case-by-case basis. At a minimum, the source of nonchemical data and an assessment of their uncertainties, particularly reliability and representativeness, for use in demonstrating, correlating, or inferring ecological risk at the site should be documented." *See Rapid Bioassessment Protocols for Use in Streams and Rivers: Benthic Macroinvertebrates and Fish* (EPA 1989j) *and Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference* (EPA 1989c).

The level of confidence in the chemical data is dependent on the experience and expertise of the laboratory to deliver quality data QA/QC control, sampling method, sampling handling/preservation methods, and variability of the chemical concentrations in the medium sampled. Coordination between the risk assessor and chemist/data reviewer is recommended in order to design a sample collection program which is most likely to produce sample results with an acceptable level of confidence, considering such factors as laboratory QA/QC, level of QA required for the data, QA/QC samples, and data variability. Sensitive parameters should be identified in this scoping phase so that the site-specific data may be collected in a manner as to minimize the degree of uncertainty.

Typically, for the data types or parameters in a Phase II project execution stage, the data quality with respect to their identity should be good (i.e., QA3 or above), and the error rates should be relatively low (i.e., Type I error = 0.2 and Type II error = 0.1 or lower). An evaluation of data quality should examine the following five broad categories:

- Data Collection Objectives
- Documentation
- Analytical Methods/Quantitation Limits
- Data Quality Indicators
- Data Review/Validation

D.4.2.5.1 Data Collection Objectives. Data collection objectives should be examined as part of a data evaluation to determine whether the type and scope of analyses are appropriate for ERA purposes, and whether supportive information (such as QA/QC protocols) is available. Optimally, all data available for an ERA will have been collected with consideration of specific minimum requirements. These data should be evaluated in terms of the attainment of the objectives and the degree to which the minimum requirements were attained during sampling and analysis.

D.4.2.5.2 Documentation. The collection and analysis of site media should be adequately documented to demonstrate that the samples were collected, handled, and analyzed according to the DQOs and minimum requirements specified for ERA data, Documentation on adherence to these minimum requirements should be available for review by the risk assessor. Six types of documentation commonly developed for a site investigation are:

- Work Plan with DQOs. This plan scopes the extent of the site investigations and assessments and should identify the objectives for data collection and use.

[15] One of the key steps in establishing data quality and useability is the identification of reference area(s) which reflect background or local conditions unrelated to the site. Careful assessment and site visits and an early agreement with the regulatory agency are critical in order to address this issue effectively. The objective is to remove as many confounding factors as possible from the risk evaluation and to allow the ERA to go forward.

- SAP/Quality Assurance Project Plan (QAPP). This plan should specify the types and location of samples, the methods of sample collection, storage, and sample custody (i.e., tracking, shipping, and receipt), analytical procedures, and the level and type of QA/QC applied to the sample collection and analyses.

- Standard Operating Procedures (SOP). Provides consistency in the data collection, handling, and analytical procedures.

- Field Records. Field records document information on direct reading instruments, field conditions, some QA/QC protocols, and variations from SOPs or SAPs/QAPPs. Ecological observations made during abiotic media sample collection are an important component of the field records for the ERA.

- Chain-of-Custody Forms. Documents how the sample was handled (e.g., filtering, preservation, refrigeration) and the analyses requested, provides sample tracking, and documents receipt.

- Data Validation Report. These reports summarize the results of the data validation process and identify variations from protocol and qualifications to the data

Depending on the nature of the site and the preliminary Biota Checklist, a separate biological assessment document presenting more detailed ecological observations at the site may be required. Such assessments are typically required where threatened or endangered species are determined to be potentially present on the site.

After the data become available, the risk assessor should look for any deviations from designated protocols and evaluate their impact upon the data useability. Lack of documentation does not signify that the data are not useable, but it does limit the evaluation of data quality. Protocol deviations cause the uncertainty associated with use of the data to increase.

D.4.2.5.3 **Analytical** Methods **and Quantitation** Limits. The analytical methods applied to ERA data collection should be specified as part of the minimum requirements prior to the data collection. Three broad types of analyses are available (each having a different potential use in an ERA):

- Field screening data, such as those collected with direct-reading or field instruments (e.g., photoionization detectors, combustible gas indicators or field chemistry tests). Because of the uncertainty associated with these methods (due to lack of stringent QA/QC protocols) the data are best used only in a supportive role or used in conjunction with verified results from more reliable methods.

- Field laboratory analyses, such as those obtained from a mobile onsite laboratory.

- Fixed laboratory analyses.

Both the field and fixed laboratory analyses provide data appropriate for inclusion in an ERA if appropriate QA/QC procedures have been followed and the data are of good quality, as determined by the data validation process. In addition, several different laboratory analytical protocols are available, varying in the instrumentation, the level of QA/QC, sensitivity, quantitation limits and other factors. Appendix III of EPA's ***Guidance for Data Useability in Risk Assessment (Part A)*** (EPA 1992d) presents a summary of common analytical methods and identifies the instrumentation and detection/quantitation for different analytes. This resource should be consulted.

Two analytical protocols that are commonly applied to environmental samples are the EPA's Contract Laboratory Program (CLP) protocol and the SW-846 protocol. The analytical methods, quantitation limits, degree of QA/QC, and documentation differ between these two protocols. EPA's *Regulations on Test Procedures for the Analysis* of *Pollutants in Water* (40 CFR 136) should also be consulted.

Required quantitation limits should be low enough to enable detection of chemicals at concentrations of potential ecological concern. Quantitation limits are generally specified by the analytical method, however, deviations from planned quantitation limits can occur as a result of matrix interferences, high chemical concentrations, laboratory variations, and other factors. Therefore, the quantitation limits achieved in the analysis should be examined to evaluate whether deviations from the minimum requirements have occurred and whether those deviations have impacted the useability of the data.

The risk assessor needs to understand the type of quantitation limit associated with the analytical method and what is reported with the data. An understanding of the terminology is also needed. The term "'detection limit" is a general term that refers broadly to the concentration at which a chemical can be detected by a given analytical method. Although often used interchangeably, "detection** and "quantitation" are not synonymous. A detection limit is the lowest level of chemical in a sample that can be distinguished from the normal "noise" of an analytical instrument or method. A quantitation limit is the lowest level of a compound that can be accurately and reproducibly quantified. Compounds can be detected in a sample at concentrations too low to accurately quantify. Several different types of detection or quantitation limits are available. Each provides slightly different information on the sensitivity of the analysis and the meaning of analyzed data. These include the following:

- Instrument Detection Limit (IDL). The IDL is generally the lowest concentration of a chemical that can be detected by an instrument. This limit does not consider the analytical method, sample matrix, handling, or preparation factors.

- Method Detection Limit (MDL). The MDL represents the minimum concentration of a compound that can be detected by a specific analytical method and is generally higher than the IDL. This limit considers sample matrix, handling, and preparation factors. This estimate of a detection limit may be biased low, since it assumes 100% recovery of a compound by the analytical method.

- Sample Quantitation Limit (SQL). The SQL is a sample-specific limit that considers sample matrix, handling, and preparation factors. In addition, sample-specific adjustments (such as dilution) are considered.

- Contract-Required Quantitation/Detection Limits (CRQL and CRDL). The EPA's CLP specifies a CRQL for organic analyses and a CRDL for inorganic analyses. These limits are related to the SQL that has been shown to be routinely within the defined linear ranges of the required calibration procedures.

In general, SQLs are the most appropriate for use in an ERA, since they account for most of the variability in the sample preparation and analysis. For an ERA, the quantitation limits achieved in a data set should be sensitive enough to detect chemical concentrations associated with acceptable ecological risk and hazard levels. The appropriate quantitation limits can be determined a priori by performing a screening evaluation or using reference concentrations and unit risk levels.

D.4.2.5.4 Data Quality Indicators. Five data quality indicators need to be considered when reviewing chemical analytical results. These are:

- Completeness.
- Comparability.
- Representativeness.
- Precision.
- Accuracy.

The assigned data validator should examine these factors as part the formal data validation procedures. However, it is important for the risk assessor to understand the terms and their meaning in order to understand the data validation reports.

D.4.2.5.5 Data Review/Validation. Review and validation of chemical data can be performed at different levels and depths, depending on the desired use of the data. Prior to inclusion in an ERA, site data should undergo a validation process. Data validation should be performed by a chemist or other qualified individual. The risk assessor need only to know that the data have been reviewed or validated according to acceptable protocols, and all data have been appropriately qualified. Summary reports from the data validatom will inform the risk assessor of any variations or deviations from accepted protocols. The data review process should include an examination of the following factors:

- Evaluation of data completeness.
- Verification of chain-of-custody forms for correctness.
- Verification of instrument calibration.
- Measurement of laboratory precision using duplicates.
- Measurement of laboratory accuracy using spikes.

- Assessment of adherence to method specifications and quality control limits.
- Examination of holding times.
- Examination of blanks for contamination.
- Evaluation of the method performance in the sample matrix.

Different analytical protocols have different data validation requirements and may use different qualifiers or criteria for evaluating data. For example, USAEC uses different letter qualifiers to denote validation results than does the CLP. The risk assessor needs to be clear about who the audience is (e.g., NPL or State-led) and what are the appropriate validation requirements for the protocols used to ensure appropriate interpretation of the data.

At some point, the risk assessor may need to consider the precision and accuracy of the data validation protocol relative to the (anticipated) toxicity benchmark levels. For instance, when site media concentrations are orders of magnitude greater than benchmarks, a lesser degree of precision and accuracy is required. This would allow for use of a less stringent analytical protocol (i.e., Level 2 or 3 CLP, instead of Level 4).

D.4.2.6 An Outline or Summary of Approaches in the Risk Assessment/Risk Evaluation, Uncertainty Discussion and Recommendations

The approaches and contents of the anticipated baseline ERA should be explained or discussed in the project planning stage in unambiguous terms. The output of the discussion should be an outline or summary to be presented to the PM, customer, and other decision-makers, e.g., in the form of a technical memorandum which may be appended to the Work Plan to the agencies for approval. Since the ERA is conducted in a tiered approach, a decision diagram should be presented for discussion. The purpose of this documentation is to avoid potential misuse of the data or the risk assessment results, and can be used as a means to make sure that the selected data collection option meets the users' and decision-makers' needs. At this project planning phase, the customers, PM, data users, and decision-makers are provided the opportunity for comments on the approaches to analyze/assess risks and characterize/minimize uncertainties.

The EPA is site-specific, providing discussion and references to the potential exposure pathways presented in the ECSM. The exposure and risk characterization models should be highlighted in the outline/summary. In general, EPA-published models or peer-reviewed or validated models should be used to minimize uncertainty.

In explaining the data acquisition options, it is recommended that the risk assessor point out potential setbacks, problems, or difficulties that may be encountered in a "real world" situation. Although data are planned to meet DQOs, it is not unusual to receive data of various quality (confirmed by data validation) and quantity (data collection or analysis completeness check) due to unforeseeable circumstances or events in the field. For example, there may not be sufficient biological samples or species to be collected within the budgeted time period, and the targeted species may also be absent (despite early site reconnaissance which indicates their presence). Therefore, it is imperative that the risk assessor explain to the decision-makers early in the project planning stage approaches to conduct the baseline ERA and other risk evaluations. In particular, the risk assessor should explain the minimum data quality considered to be acceptable, how nondetects are treated, and how medium-specific data are evaluated or compiled to derive/model the exposure point concentration in the risk assessment.[16] The discussion should be based on the ECSM, focusing primarily on all potentially complete and significant pathways, and the weight-of-evidence approach to address uncertainties.

Uncertainties associated with the baseline ERA performed in a particular tier in this project phase should be explained and characterized to the extent possible. At a minimum, a discussion of the confounding factors and ways to eliminate these factors by a weight-of-evidence discussion is highly recommended. In recent years, the use of sensitivity analysis and Monte Carlo simulation has gained acceptance in characterizing uncertainties and propagation of risks. If Monte Carlo simulations are planned, the data (and their sources) used in the simulations should be defined in this phase of the HTRW project planning process. However, their use must be supervised by experienced ecotoxicologists and statisticians. The propagation of exposure and the exposure-response data could be demonstrated for a site with

[16] For example, if the FU data are skewed, it will be necessary to address site risk by separating the hot spot areas. The risk assessor may indicate this option in the Work Plan to further characterize hot spot areas without delaying the assessment of risks for the non-hot-spot areas.

exposure scenarios and ecotoxicity data involving multiple trophic levels.

The outline or summary should specify quality/quantity requirements, provide justifications for their use, and explain how they can be obtained. If semiquantitative risk assessment analysis is performed for the site, e.g., descriptive comparison of ecological attributes between the site and reference areas, the results should be presented with scientific logic and rationale: a weight-of-evidence approach is likely to increase the level of confidence of the conclusions or recommendations for the ERA performed in that specific tier.

D.4.3 Risk-Based Analysis of Remedial Alternatives; FS and CMS

The data-scoping requirements for the FS or CMS project execution phase focus on data to support a screening evaluation of all the potential remedial alternatives for their effectiveness to reduce the baseline site risk. Following the screening evaluation, a more detailed comparative evaluation of viable remedial alternatives (recommended options) for their risk-reduction capabilities is also conducted. The latter assesses any short-term risks to the environment, its recovery, and long-term residual risks. It should be noted that "no further action" is a remedial alternative to be evaluated. Many sites are required to have RI and FS or RFI and CMS conducted simultaneously. Therefore the preparatory steps for conceptualizing data needs for a RI/RFI or FS/CMS are comparable and will not be reiterated in this section.

D.4.3.1 Background Information Review

By this Phase III project execution phase, the risk assessor and the project team should have a good understanding of the nature and extent of contamination. In addition, they will also have a good understanding of the site strategy and customer's goals and concept of closeout. In reviewing the background information, the risk assessor should note the area of contamination requiring remediation or corrective action, and the location of these areas relative to sensitive environments and ecosystems to be protected. Existing ecological resource maps or GIS database for the region should be reviewed with respect to the proposed remediation areas, CAMUs, or OUs. Special considerations should be given to:

- Previous or newly identified regulatory concerns relating to residual risks (i.e., risk remaining upon completion of selected remedies and/or proposed removal actions), and the potential for recovery of altered or destroyed habitats.

- Options with respect to the decision path leading to site closeout and compliance if the selected alternative is not effective or fully implemented.

- Customer's goals and objectives, plan of actions, budget/time constraints for RD/RA, removal actions, and the 5-year review, if applicable.

D.4.3.2 PDs

The decision step within the critical path of the HTRW response program relating to detailed site investigations in CERCLA and RCRA are the same as those presented in Section D.4.2.2. The specific PDs are:

- Develop site-specific PRGs or alternative concentration limits (ACLs) for groundwater potentially impacting aquatic receptors, and set realistic and protective performance criteria (the remedial action objectives [RAOs]) based on the PRGs and other factors for the selected remedial alternative or measure.

- Screen remedial alternatives for protectiveness and their ability to meet RAOs while minimizing additional ecological risk or impacts from the implementation of the remedies.

- Determine if removal action(s)/interim corrective measures are needed to mitigate imminent threat to sensitive environments.

D.4.3.3 Project Study Elements

The essence of the project study elements in this project execution phase concerns developing site-specific PRGs, determination of RAOs, and screening remedial alternatives. In addition, considerations have to be given to the fate and transport mechanisms of any potential release or discharge of the media being remediated or stored, or of treatment effluents or byproducts, and the establishment of ECSMs for the potential remedial alternatives needing further evaluation. In addition to evaluating the remedial alternatives for "protectiveness" of the environment, the risk-based evaluation must consider the permanence of the risk and toxicity reduction, interruption of the exposure pathway(s) shown to pose the principal threat in the baseline ERA, and the post-remediation (residual) baseline risk. For example, dredging of toxic

sediment may produce limited or more permanent ecological harm, depending on the precautionary measures taken to minimize resuspension of toxic sediments. Therefore, the potential study elements are summarized and identified as follows:

- Develop PRGs or ACLs for consideration as target cleanup levels or RAOs to protect ecological species.

- Assess if RAOs are protective, given the acceptable risk range and uncertainties in deriving the PRGs or ACLs, background concentrations, and the analytical detection limits.

- Evaluate if risk reductions afforded by the proposed remedial alternatives are permanent and reliable, i.e., to assess if the selected remedies are protective after the implementation period (given the operational and maintenance requirements, treatability study data, and future site exposure conditions). For example, use of biomonitoring or sentinel systems to detect subtle changes or residual risks.

- Evaluate qualitatively or semiquantitatively if the selected remedial options which generate effluents, emissions, or residues (e.g., soil/sediment washing, low temperature thermal desorption, groundwater aeration system, and discharge of effluent to surface water body) during implementation pose short-term risks to terrestrial or aquatic ecological receptors onsite and offsite. If there are potential ecological risks, describe the magnitude and frequency/duration of the risks.

D.4.3.4 Conceptualizing and Defining Data Needs

Data needed for performance of the above project study elements should be based on the ECSM for the remedial alternative and the postremediation ECSM. Data relating to the design and operations, byproducts, and residues produced during and after remediation will be needed. These data types (chemical identity, emission rates, and concentrations) are needed to characterize the potential impact of the process waste stream, emissions, and residues. Due to schedule constraints, it should be noted that the quantitative assessment of short-term risk during remediation and recommendations for control measures may be conducted in the RD/RA or CMI stage.

D.4.3.5 Establish ECSMs

Two ECSMs are to be developed for each remedial alternative: (1) an ECSM during remediation or implementation of the corrective measure and (2) an ECSM for the site after remediation. The former is used to guide data needs to assess short-term risks, and the latter, to guide data needs for the degree of risk reduction or the post-remediation baseline risk. The exposure pathways of concern are primarily air (fugitive dusts from stabilization/earth work or volatile organic chemicals [VOCs] from an air stripper) and groundwater (e.g., discharge of treated effluent to the surface water bodies and the effectiveness of capture well systems to prevent offsite contaminant migration). It should be noted that neither of these evaluations require an assessment of the net environmental benefit if offsite treatment/disposal is an alternative to be evaluated. Therefore, the risk evaluations under a FS and CMS are limited only to impacts to ecological receptors onsite or near the facility. The ECSM determines the following information needs for this project execution phase:

- COECs.

- Potential target media

- Potential receptors in the target media.

- Major exposure routes, pathways, or mechanisms of stress and effects[17].

- Migration and transport potential of site chemicals from the source.

- Exposure areas or EUs.

- Potential secondary sources of contaminants, and their release/transport mechanism (if any).

[17] For example, deposition of fugitive dust or wetland sediments emanated from soil/sediment remediation adjacent to a stream could potentially cause physical as well as chemical changes in the streambed environment for benthic macroinvertebrates).

D.4.3.6 Define Data Needs

It should be noted that data needs at this stage of the HTRW project planning should focus primarily on the questions: "What is the cleanup goal or remediation action objective?; What is the degree of risk reduction offered by the remedial alternative or corrective measure?: Could removal or remedial action at the hot spots be sufficient to substantially mitigate site risk?; and What could be the potential short-term and long-term residual risks (and potential for recovery) associated with implementation of an alternative?"

Guided by the ECSMs, data may be needed for all or any one of the following risk assessment/evaluation tasks to respond to the PDs on whether or not a remedial alternative should be selected:

- Data to support fate and transport modeling calculations.
- Data to conduct qualitative and/or quantitative evaluation of uncertainties in the risk assessment (mean, maximum, minimum, or the entire distribution of values for key parameters identified by a sensitivity analysis).
- Data or information (from State natural resource agencies or local universities) on potentially exposed ecological receptors and populations nearby the site that could be impacted by the remedial action.
- Data to assess risk or hazard (rate, concentration, chemical identity, and toxicity) of emissions or treatment products/residues which may be released and exposed to ecological receptors.
- Representative and quality assured site media data or data on the treatment byproducts and residues.

All the above data may require pre-defined quality and quantity requirements. The risk assessor should coordinate with the PM/I'M and other data users (e.g., modeler, compliance/responsibility specialist, etc.) to acquire site-specific data to evaluate exposure, potential risk or adequacy/feasibility of a response action to protect the environment.

D.4.3.7 Define Data Types and Preferred Data Quality Requirements

This data-scoping activity eventually defines the data type according to potential exposure pathways (i.e., ingestion of and dermal contact with excavated soil/sediment, inhalation of airborne contaminants, etc.). The ECSMs are used to organize the data needs and their relationships to site decisions. Data Needs Worksheets for each pathway will be prepared to document data types, quality requirements, or needs. Chemical data to be collected should be identified with QA/QC requirements. In addition, the level of confidence (maximum error rate) required of the sample results should be set, after considering the potential variability of sample results in a given matrix and potential laboratory/sampling handling errors.

For nonchemical types of data, the QA requirements will be established and can be done on a case-by-case basis. At a minimum, the source of nonchemical data and an assessment of their reliability and representativeness for use at the site should be documented. Emission or discharge data may be modeled (e.g., sediment transport modeling) or estimated from performance test results of a full-size model or a pilot-scale model. Lessons learned or case studies using the same selected remedy or corrective measure should be reviewed for data comparability and applicability. The remedy-design engineer should be consulted to determine the appropriateness of certain treatability data before these data are requested for the risk assessment. The data quality may be lower, if it can be demonstrated that the technology or treatment method is judged to be effective from the engineering evaluation. It should be noted that in certain cases, creation of new habitats may be a viable option, and should be discussed with the expert ecologist(s) and/or the advisory panel (BTAG).

D.4.3.8 An Outline or Summary of Approaches In the Risk Assessment/Risk Evaluation

Like the baseline ERA (Phase II project execution phase), the approaches and contents of the risk-based evaluation of remedial alternatives should be explained or discussed in the project planning stage. The output of the discussion should be an outline or summary (e.g., in the form of a technical memorandum) to be presented to the PM,

customer, and other decision-makers. The purpose of the transmittal is to avoid potential misuse of data or the risk assessment results, and can be used as a means to make sure that the selected data collection option meets the users' and decision-makers' needs. At this data-scoping phase, it is imperative that other data users and the data implementors have the opportunity to review and comment on the data needs to avoid data overlaps or to identify alternative data sources. Where there is a convergence of risk reduction requirements for protecting human health and ecological species, the assessment approach and data needs for evaluating remedial alternatives to provide protection to both receptors should be presented. Where there is a divergent issue of risk reduction measures concerning the protection of human health and potential impact to the environment from the anticipated remedial alternative(s), the assessment procedures of such remedial options should also be clearly explained in terms of assessment uncertainties and choice of actions for the level of protectiveness for both receptors. Both issues should be concisely articulated in the summary or outline.

The ERA in this project execution phase provides a discussion of the potential exposure pathways presented in the ECSM. The exposure and risk characterization models should be highlighted in the outline/summary. In general, EPA-published assessment methods/models or validated models should be used. Risks to ecological receptors of concern or stress to sensitive environments (which may not necessarily be those selected for the RI or RFI phase) may be presented qualitatively or semiquantitatively . The uncertainty assessment for risk analysis under a FS or CMS may be characterized qualitatively. For evaluation of potential alternatives which may produce substantial off-gassing or effluent discharge, quantitative analysis of uncertainty may be accomplished by a sensitivity analysis or a Monte Carlo simulation. In either case, the ranges of values for sensitive parameters have to be known.

D.4.4 Short-Term Risks Associated with Construction; RD/RA, CMI, Removal Action, or Interim Corrective Measure

This section focuses on HTRW data scoping for the evaluation of risks posed by construction of CERCLA and RCRA removal or remedial actions (corrective measures) to endangered/sensitive ecological receptors or valued resources. This risk evaluation provides a more detailed evaluation of the selected remedial alternative (if such an evaluation has not already been performed in the FS or CMS), focusing on recommending options for designing measures to mitigate potential risks from the removal or remedial actions. To meet the risk assessment or evaluation data needs, the risk assessor should coordinate with the PM, TM, and other data users to identify the selected remedies which require risk evaluation in this project phase.

If a screening or comparative risk analysis has already been performed in the RFI/CMS or RI/FS project execution phase, performance of risk assessment tasks in this project phase is generally limited in scope unless there is a need for a more detailed risk assessment because the construction is likely to result in release of site COECs. If this is the case, information from previously performed risk analyses should be reviewed and additional data needs identified. The data needs for an ERA evaluating removal actions or remedial alternatives should generally follow the assessment framework described previously in this appendix, and should focus on identifying and addressing the sources of risks and uncertainty in the mitigating measures. When considering the data needs and their quality/quantity, consideration should be given for completing the evaluation in a timely manner. Striking a balance between the desire for site-specific/ treatability data and assumed data (data from other sites) for use in the evaluation is the key step in this project planning stage. Specifically, the evaluation addresses:

- Short-term impact of the remedial alternatives on site environment (ecological receptors).
- Magnitude, frequency, and duration of the exposure to the stressor (chemical and nonchemical entities).
- Potential chance and time required for a recovery, if applicable.

As with other sections, the scoping/planning of risk assessment in RD/RA presented in this section does not cover radioactive and biological substances.

Other areas for project planning that may require coordination between the risk assessor and other project team members (e.g., the project biologist or ecologist) am:

- Risk of accidental spills and releases from construction of the remedial alternative (i.e., physical hazards, explosions, spills, etc.) resulting in substantial harm to the sensitive environments.

- Risk communications (public perception and understanding of species or resources at risk from implementation of the alternatives).

- Other risk management considerations or criteria, e.g., cost, schedule, O&M/engineering and operational flexibilities, etc.

None of the above are the focus of this section, which addresses short-term risks to terrestrial ecological species from emanation of site chemicals during construction activities.

D.4.4.1 Background Information Review

By this project execution phase, the project team should have a thorough understanding of the site background and characteristics and the approximate boundary of contamination requiring removal or remedial action. With the latter, it may also be possible that removal actions or interim corrective measures have been taken at the site. In addition, a baseline ERA and a risk-based evaluation or justifications for selecting certain remedial alternatives or corrective measures should have been performed according to requirements for evaluation of remedial alternatives under CERCLA Section 121, NCP Section 300.430(e), or Subpart S of the proposed RCRA Corrective Action Rule. This information will be useful in conducting risk analyses to assess the impact to ecological receptors or valued resources qualitatively or quantitatively from the selected remedial alternatives or new/additional removal actions. Before conceptualizing data needs to assess the short-term risks, a site strategy is developed or revised, and it is recommended that the project team carefully review all site background information, and RI/FS reports, and any pertinent field tests or studies.

D.4.4.2 PDs

A good understanding of the agencies' regulatory processes and how the site strategy fits in the regulatory processes, i.e., the program objectives for a RD/RA or CMI, and removal action or interim corrective measure will be helpful to develop PDs. The decision steps for this project execution phase are:

- RD/RA -- Data obtained from the previous project will be used to design a full-scale remedial action plan or report (with specifications for the technology or process employed, and QA to be achieved) which is then issued to the remediation contractors for bid, implementation, and documentation. Upon completion of a RD/RA, the critical path will be either site closeout (site delisted from the NPL) or periodic monitoring with or without a 5-year review to assess residual risk and compliance with ARARs prior to site delisting. The decision path also includes considerations for removal actions prior to or during RA implementation.

- CMI -- The critical decision path is similar to the above CERCLA path. Upon completion of the remedial design phase, the selected corrective measures are implemented. After CMI, the critical path is likely to be either: (1) RCRA compliance status achieved or (2) periodic monitoring to verify compliance. For SWMUs associated with an active hazardous waste management facility, the RCRA corrective action compliance status may be reviewed at the time of the next Part B permit renewal.

- Removal Action or Interim Corrective Measure -- The action or corrective measures are designed to stabilize the site, i.e., control of contaminant migration or interruption of an exposure pathway which poses the principal threat at the site. Although in some cases, the removal action or interim corrective measure is the final site remedy, most sites will require further characterization and determination of remedial action(s). Therefore, the removal action or interim corrective measure should be complementary or consistent with the probable site remedy. Removal action or interim corrective measure can be implemented at any time between site discovery and site closeout.

Through qualitative or quantitative risk assessment or analyses, a determination will be made on whether or not additional controls are needed to address risks during remediation or to address the residual risks. If the current or earlier assessment conducted in the FS or CMS indicates potential risks, the project decisions will focus on determining: (1) whether the selected remedy can be effectively implemented, under the current design and operation plans, without posing an unacceptable short-term risk or residual risk; (2) the need for extraordinary measures (i.e., removal actions specifically targeted at hot spot areas) to reduce the threat of ecological risks or expedite/enhance site remediation; and (3) long-term control measures (operational or engineering) to mitigate site residual risks and to ensure compliance with ARARs, to-be-considered requirements, and permit conditions. Therefore, specific PDs associated with this executable

project phase may include all or any combination of the following:

- Determine whether the selected remedial or removal actions are likely to comply with Federal and State ARARs or with to-be-considered environmental criteria required by the agencies regarding short-term risks.

- Determine if additional control measures are to be designed and implemented for the selected remedies or measures to minimize short-term risks.[18]

- Determine if the selected removal actions/interim corrective measures are consistent with the final site remedy (if such a remedy is reasonably expected).

D.4.4.3 Project Study Elements

The following are potential project study elements associated with assessing short-term risks from construction of removal actions, interim corrective measures, remedial actions, or RCRA corrective measures.

- Evaluate the need for removal actions/interim measures to mitigate the environmental impacts, thereby facilitating implementation of the remedial action or corrective measure. The evaluation should be based on the ECSM developed in the FS or CMS phase when the remedial alternatives were screened and evaluated.

- Establish the fate and transport mechanisms of site media proposed for removal actions or interim corrective measures, e.g., sediment transport modeling.

- Conduct a detailed risk analysis of short-term risks posed by implementation of the removal action/interim corrective measure, and demonstrate that environmental injuries are not likely to occur (only applicable to sites with potential NRDA actions).

- Conduct a baseline risk assessment of the site after implementation of the removal action or interim corrective measure is completed to demonstrate that no further action or remediation is needed because of acceptable ecological risks. (Note: this assessment activity is performed in Phase I or II of the project execution stages).

D.4.4.4 Conceptualizing and Defining Data Needs

Data needed for detailed risk evaluation of the selected remedial alternatives or removal actions should be based on the ECSM, and focus on the potential impact of the remedy or corrective measure to identified receptors. A good understanding of the contaminant fate and transport mechanisms associated with the site action(s) is the key to the assessment. The data needed may be nonchemical in nature, e.g., engineering design parameter to reduce, remove, or change the physical/chemical nature of the emission, effluent discharge, or residues. The sources of these data may be the remediation vendors/contractor, EPA's literature (e.g., feasibility studies under the Superfund Innovative Technology Evaluation [SITE] program), or design information from other sites (lessons learned) using the same/similar technology and wastes. The data needed may also be chemical in nature, e.g., constituent concentrations in the emissions or discharge, or the chemical identify, toxicity information, quantity, rate of release, and fate and transport characteristics of treatment byproducts, derivatives, or residues. The potential changes in bioavailability or solubility due to chemical transformation of the turnover/resuspension media from anoxic to an oxygen-rich environment associated with removal or excavation action should also be assessed. Information concerning the areal extent of potential habitat destruction or alteration is also needed.

The site strategy and PDs developed under Phase I of the HTRW project planning process for this project planning phase, and revised under the Phase II process, will be used to focus data-scoping activities. The outputs of the

[18] It should be rare for the PM of a HTRW site to re-propose another remedial alternative if one has already been selected and entered into the ROD or permit modification. It is plausible that a selected remedy (indicated in a ROD signed a number of years ago) is no longer appropriate based on the new data. Notice of any new remedies will have to be published for public comment, and will require detailed explanations for the change. All of these activities will require additional time and effort.

Phase III technical project planning process are the Data Needs Worksheets for this project phase and, where appropriate, the documentation requirements for site delisting, compliance, or NRDA data collection requirements (40 CFR Part 11, Subtitle A).

D.4.4.5 Establish or Refine ECSM(s)

As additional chemical fate/transport and contaminated media release data are obtained or estimated, the ECSM established in the RFI/CMS or RI/FS project execution phase could be revised, as necessary, to provide a more detailed evaluation of a selected remedy or removal action. The ECSM developed in the previous project phase presents all potential exposure pathways and identifies those pathways which are complete (significant or insignificant) and incomplete under the baseline or no remedial action conditions. This ECSM should be appropriately modified to help the project team focus the data collection effort on evaluating significant pathways as potential emission or discharge sources during remediation.

If substantial waste constituents remain onsite, the residual risks can be assessed based on the baseline ECSM, as long as the waste sources/matrices, spatial relationship with respect to receptors, or the fate/transport properties are substantially unchanged. The ECSM will help address PDs. If multiple remediation actions are to be implemented simultaneously, multiple ECSMs should be developed for the OUs, SWMUs, AOCs, or CAMUs/TUs. The information requirements for development or revision of the ECSM(s) are the same as those described in preceding ECSM sections.

D.4.4.6 Define Data Needs

It should be noted that data needs at this stage of the HTRW project planning should primarily focus on the PD: "What is the short-term risk to the appropriate ecological receptors (individuals and community) or sensitive environments onsite and/or offsite?" For example, if the remedial action requires storage and dewatering of contaminated sediment, a confined disposal area will be required. If the disposal area is constructed onsite, the environmental risks from such a construction activity will need to be evaluated as the construction activity is part of the remedial action. (Note: Ocean disposal of dredged sediment is a permitted activity under Section 103 of the Marine Protection, Research, and Sanctuaries Act of 1972. Guidance for tiered testing of dredged sediment has been published jointly by the USACE and EPA (1991g). Therefore, data scoping discussed in this section does not apply to this particular situation.)

If potential environmental risks may occur, the risk assessor's responsibility as a project team member should be to identify for the customer and PM significant exposure pathways and risks. In this project planning phase, a close coordination between the risk assessor, chemists, modeler, design engineer, and legal-responsibility counselor will be needed to define data quality and quantity needs. The risk assessor may be required to coordinate with other data users (e.g., compliance specialist) to acquire additional site data to document QA compliance, and adequacy of response action to meet the RAOs and ARARs.

Guided by the ECSM, data may be needed for all or any one of the following risk assessment/evaluation tasks to respond to the PD on whether or not there is a need to impose control measure: augment or modify the selected remedy; or conduct removal actions:

- Confirm current and future land use and the environmental setting/characteristics. (If areas adjacent to the site to be remediated will be developed into industrial/commercial use, it is likely that the focus of the societal value of resources to be protected or the ecological receptors of concern will also change. This will need confirmation.)

- Identify mode of operations for single or multiple remedial actions and proximity of these actions to potential ecological receptors and their home ranges.

- Perform a risk assessment/analysis quantitatively or qualitatively, based on the revised ECSM, and present findings with a discussion on uncertainties; some of the data requirements for this may be:

  - Data to support fate and transport modeling/ calculation, e.g., grain size of soil or sediment handled, organic carbon content, oxygen level, river or stream contours, scouring depths, leaching characteristics, processed meteorological data, etc.

  - Data to assess the amount of discharge or residues, e.g, amount of soil resuspension for a specific soil/sediment handling method,

estimation of fugitive, volatilization, or stack gas&articulate emissions, effluent discharge rates, etc. (i.e., representative monitoring or field data to assess risks and demonstrate compliance with protective criteria/standards are needed).

- Data to support qualitative assessment of potential exposure to ecological receptor populations and communities (e.g., method of residue disposal or environmental media into which effluents/emissions are discharged, material handling and movements, associated support services that may impact sensitive environments [construction of access roads through wetlands or woodlands]).

- Data to assess risk or hazard (toxicity information of waste residues, byproducts, derivatives, and degradation products [for bioventing or bioremediation]). [19]

- To compare ARARs and to-be-considered short-term (acute) concern levels (e.g., LC_{50}, LD_{50}, and EC_{50}) with representative site sample or field monitoring data which meet predefined QA/QC criteria

D.4.4.7 Define Data Types and Preferred Data Quality Requirements

This HTRW Phase II data-scoping activity eventually defines the data types according to potential exposure pathways. The ECSM is used to organize the data needs and their relationships to site decisions. Examples of data types according to medium for use in assessing potential exposure pathways for ecological receptors are: incidental ingestion/dermal contact with the treatment residues or effluent and to a lesser significant degree, inhalation of airborne particles or volatilized organic chemicals. In each of these data types, sample or continuous monitoring data and data for modeling the exposure point concentration for the site contaminants or their treatment derivatives/residues in the media may be needed.

To evaluate the selected remedial alternatives under this project phase for their short-term impact during remediation and residual risk after remediation, data relating to the design, operation, and maintenance of the remediation system are needed to calculate the discharge or release rates of the site constituents and the process waste streams. Data required on the process waste streams include chemical characterization of all remediation or treatment byproducts, derivatives, or residues during and after remediation, which may impact onsite and offsite endangered/sensitive ecological receptors. It should be noted that the screening or comparative assessment of remedies may have been conducted in the RI/FS or the CMS stage. The data used in these screening or comparisons should be reviewed to see if they meet the data user's requirements for quality?'

Given the project constraints, the following considerations may be appropriate:

- A qualitative evaluation, based on data from the site or from comparable sites, to provide a screening evaluation of the selected remedy.

- A data collection program that is sufficient to make a defensible evaluation. For example, if air modeling/deposition has already been performed in the RI/FS and RFI/CMS stage, data collected such as the dispersion factor and deposition rates for certain constituents should be used in the detailed analysis of the selected remedy in this project phase.

- Although site-specific data are often preferted, such data may not be needed if the technologies or remedial actions pose risks to humans via the same exposure pathways or routes. In this case, a simple qualitative or quantitative comparison

[19] Bioremediation of groundwater should consider potential toxic degradation products, e.g. transformation of trichloroethylene (TCE) to vinyl chloride. The assessment of discharge of this treated or partially treated groundwater to surface water will require fate/transport data, e.g., half-lives of degradation products and their ecotoxicities.

[20] A focused effort (qualitative or quantitative) should be made in the evaluation of remedies. Offsite remedies or actions should not require evaluation, in most cases. Innovative technologies which produce treatment residues, emissions, or discharge should receive a detailed evaluation (e.g., quantitative evaluation), especially if the technologies have not undergone such an evaluation, using exposure conditions comparable to those at the HTRW site. The risk assessor and project team should leverage existing information or data for the type of remediation technologies considered to provide information for risk management decisions relating to the selected remedy. biomonitoring, and the need for 5-year review.

between the rates of discharge of emissions, based on the design criteria between the site being evaluated and a similar design which does not pose site risk, may be sufficient, unless the constituents and chemicals released are subject to very different degradation rates subsequent to release.

- Some data are more important or critical than others because of potential variability or the extreme conservatism inherent in one type of data versus another. For example, it will not be appropriate to assume the worst case meteorological conditions to express high concern or reject an onsite treatment technology under detailed analysis.

- Generally, the inhalation exposure pathway is a pathway of concern during an RA involving excavation or in situ treatment/removal (air stripping). However, unlike humans, any disturbances are likely to discourage wildlife in the remediation area. Data needs for assessing risks from inhalation are generally of lower priority than those for other pathways. However, the deposition of particulates or spills onto waterways and streams, impacting sensitive or endangered aquatic receptors, should not be ignored.

- Generally, surface-water ingestion and dermal contact are pathways of concern during remediation to aquatic species or wetland species. Leaching of postremediation groundwater would be a concern to assess for these species.

Suggested relevant EPA's guidance for review are:

- *Superfund Remedial Design and Remedial Action Guidance* (OSWER Directive 9355.0-4A) (EPA 1986d)

- *Superfund Selection of Remedy* (EPA 1987b)

- *National Oil and Hazardous Substances Pollution Contingency Plan* (55 FR 8660, March 8, 1990)

- *Guidance on Remedial Actions for Contaminated Groundwater at Superfund Sites* (EPA 19881)

- *AirlSuperfund National Technical Guidance Series (Volumes I through IV)* (EPA 1989h,i; 1992i; 1993d; 1995g)

- *Estimation* of *Air Impacts* for the *Excavation* of *Contaminated Soil* (EPA-450/1-92-004) (EPA 19920).

Some considerations for the quality assurance levels are as follows:

- For fate/transport modeling of air (and surface water, if appropriate) to assess short-term risks, EPA-approved model(s) and user's guidelines should be consulted with regard to data input quality. Most models are based on the conservation of mass, modified by chemical reactions, e.g. redox reaction or sorptive chemical equilibria with the transport medium, or decay. Therefore, the risk assessor and modeler should exercise care in applying models to make sure that the risk assessment results are realistic.

- For detailed evaluation of the potential health impacts associated with a specific remedy, site-specific modeling using representative site data (i.e., data from that particular region with similar meteorologic, topographic, or hydrologic characteristics) should be used.

- For chemical identification and quantification of concentrations, analytical data should be able to meet QA3 (Level 3) or higher quality. In other words, these data should be of a defined level of confidence, and reviewed for precision, accuracy, representativeness, comparability and completeness.

The risk assessor then prepares Data Needs Worksheets for each pathway, documenting data types, quality requirements, or needs. Chemical data to be collected should be identified with QA/QC requirements identified in the RI/FS and RFI/CMS SAP. If appropriate, the level of confidence required of the sample results may be set, after considering the potential variability of the treatability sample results for a given matrix and potential laboratory/ sampling handling errors. For nonchemical types of data, the quality assurance requirements will be established and can be done on a case-by-case basis. At a minimum, the source of nonchemical data and an assessment of their

reliability and representativeness for use at the site and implementation of the selected remedy should be documented. (It should be noted that large RD/RA or CMI projects are likely to require a demonstration pilot-scale study in the RD/RA project phase. The anticipated data needs for this project execution stage should be introduced in the QAPP or the demonstration plan for the RD/RA project phase, so that the study will provide the data needed for assessing short-term risks for the full remediation system[s]).

D.4.4.8 An Outline or Summary of Approaches In the Risk Assessment/Risk Evaluation. Uncertainty Discussion and Recommendations

The approaches and contents of the anticipated risk assessment/evaluation of selected remedial alternatives should be explained or discussed in the project planning stage in unambiguous terms. The output of the discussion should be an outline or summary to be presented to the design engineer, TM, PM, customer, and other decision-makers for discussion and coordination. The purpose of the transmittal is to provide ecological risk evaluation of the remedies specifically with respect to potentially complete exposure pathways and design needs in order to mitigate impact from identified pathways. The outline/ summary is also used as a means to ensure that the selected data collection option meets the users' and decision-makers' needs. At this project planning phase, the customers, PM, data users, and decision-makers are provided the opportunity for comments on the approaches to analyze/assess short-term and residual risks from the remedial action and to collect data, where needed, to reduce uncertainties.

The risk assessment evaluation should be site-specific, with discussion and references to the potential exposure pathways presented in the ECSM pertinent to the release of site constituents or process waste streams by the remedial action. The exposure and risk characterization models should be highlighted in the outline/summary. All exposure and risk models used should be clearly indicated and should be EPA-published models or peer-reviewed/ validated models. Generally, simple modeling and risk characterization methods like those applied in Phase I or under Tier I of Phase II of the HTRW technical project planning process would suffice. The outline/summary should indicate the appropriateness of all models and of combining risks across certain or all pathways. Since data of various qualities may be used (e.g., literature values, site treatability data, data from other site remediation, etc.), the outline should also explain the minimum data quality considered to be acceptable, how nondetects are treated, and how medium-specific data ate evaluated or compiled to derive/model the exposure point concentration in the risk assessment/evaluation.

Uncertainties associated with the risk assessment/analysis performed in this project phase should be characterized qualitatively. Quantitative assessment of uncertainties with the use of Monte Carlo simulations is generally not recommended unless the operational and design variables are highly uncertain and potential risks are to be evaluated based on set ranges of such variables. Nonetheless, the approach used in assessing uncertainties should be carefully thought out in this project planning phase. To minimize uncertainty associated with performance and chemical data needed to assess short-term risks, it is recommended that the risk assessor coordinate with the chemist/data reviewer and design engineer to plan the data collection program most likely to produce the required sample results with an acceptable level of confidence. Use of appropriate sampling methods, laboratory QA/QC, level of QA required for the data, and number of QA/QC samples will help to reduce chemical data uncertainty. To minimize uncertainty associated with the discharge/ emission rates, considerations should be given to obtaining realistic throughput and emission data based on engineer design or modifications of the selected technology, degree of destruction, treatment or ***removal,*** dust/ particulate generation rates, equipment type and soil type, where appropriate.

D.5 Summary Conclusions

Risk assessment or risk analysis is an important component of inputs into risk management or site decisions. Therefore, it is the goal that the assessment is performed with data of the highest quality and statistical confidence. Due to budget, schedule, and other project constraints, however, it is invariably not possible to obtain data of the highest quality at all times. This appendix presents an overview of the four-phased HTRW data quality design process, and a framework for conceptualizing and defining data needs and quality for scoping a risk assessment/risk analysis task for critical phases of the HTRW response action. The HTRW data quality design process emphasizes early planning and communications among data users (e.g., the risk assessor) and the data implementors (e.g., chemist and statistician) to develop cost-effective data collection program options for selection by the customer. The data collection program should be presented with a candid discussion of data limitations and benefits, the reasons why the data are needed, and how the collected data are to be used in site decision-making. This process is designed to increase the

customer's satisfaction because the selected data collection option is the result of team work with process improvement in the conceptualization, development, and refinement of the data collection program.

In scoping risk assessment data needs under Phase II of this data quality design process, the risk assessment follows a five-step procedure recommended by the process. The five-step procedure entails:

- Review Background Information.
- Assemble Project Decision Statements and Identify Study Elements.
- Conceptualize Data Needs.
- Define Data Needs and Group Data.
- Document Data Needs.

Section D.4 is devoted to establishing data needs under this five-step procedural framework for critical phase(s) of the HTRW response action. The HTRW response phases discussed include the PA/SI and RFA - project execution stage: the RI and RFI/FS and CMS - project execution stage: and the RD/RA and CMI - project execution stage. The data needs for assessing short-term risks associated with removal actions or interim corrective measures are also addressed under a RD/RA and a CMI section since both assessments deal with short-term risks from construction. The above discussion on scoping data needs was not intended to be all-encompassing. Rather, it was intended to prompt the conceptualizing and defining of data needs for typical project study elements performed to provide inputs to PDs,

Due to site-specific conditions and requirements, the readers are encouraged to establish data needs based on the fivestep procedures and communicate such data needs early to the data implementors. The data users (risk assessor) should anticipate tradeoffs among data needs, data quality and quantity (which may impact confidence level) due to cost, budget, and other project constraints. The expected data uncertainty and limitations from the tradeoff should be documented in Phases III and IV of the data quality design process along with the associated DQG statements for the selected data collection option.

Appendix E
Monte Carlo Analysis

Variability and uncertainty of the input parameters in a risk assessment represent sources of uncertainty of the assessment. The types of input uncertainty facing the risk assessor include:

1. Natural variability, which is intrinsic in the parameter and cannot be reduced by increased frequency and/or precision in measurement: and

2. Uncertainty of estimation, which can be reduced by increased knowledge about the parameter.

Uncertainty due to natural variability or lack of reliable input data is often so large that the model results are valid only as an indication of the order of magnitude of the output parameter. Sensitivity analysis may be used to identify the input assumptions that have the greatest effects on the model predictions. If those assumptions are highly uncertain, it may be worth investing effort to reduce uncertainty about those assumptions.

Another way to address and quantify uncertainty in modeling is by performing a probabilistic uncertainty analysis. A common method of probabilistic analysis is the Monte Carlo simulation method. In Monte Carlo analysis, the variability and uncertainty of each input parameter is represented by a frequency distribution. The user needs to provide the distribution type (e.g., normal, lognormal, uniform, etc.), along with the mean, standard deviation, and minimum and maximum values of each input parameter, as required by the specific distribution instead of a point estimate as in deterministic analysis. Based on the frequency distribution of the input parameters, the Monte Carlo program selects a randomly generated input data set and calculates the corresponding output. Then, a new input data set is generated at random, and the corresponding new output is calculated. This process is repeated until the statistical distribution of the model output reaches a stable state. In general, for relatively simple physical models and "well behaved" frequency distributions, convergence can be reached in a few thousands of runs. The result of the Monte Carlo analysis is the statistical distribution of the output parameters, with its mean (the arithmetic average), median (the 50th percentile), mode (the most probable value), standard deviation, etc., characterizing the uncertainty of the model predictions. For example, a valid conclusion to draw from the output might be "There is an 8% chance that the exposure dose would exceed the target dose under the conditions evaluated." Probabilistic exposure models can also be used to evaluate food web models as demonstrated in a recent article by MacIntosh, Suter, and Hoffman (1994).

To reduce mistakes and prevent abuses in the use of Monte Carlo techniques in ERAs, good practice principles should be followed. Burmaster and Anderson (1994) proposed 14 principles of good practice to assist people in performing and reviewing probabilistic risk assessments, especially in the context of the Federal and state statutes concerning chemicals in the environments. The authors propose that by following these principles, Monte Carlo risk assessments for hazardous waste sites will be easier to understand, will explicitly distinguish assumptions from data, and will consider effects that could otherwise lead to misinterpretation of the results.

A simplified example of a Monte Carlo simulation using the commercial software, Crystal (BallCB)[1] is presented below. To perform uncertainty analysis with CB, one needs to follow these steps:

1. Develop the model (the risk equation) on an Excel[2] spreadsheet.

2. Identify probability distributions for the input parameters, called Assumptions.

3. Identify the output parameter(s) that need to be analyzed, called Forecast(s).

4. Run the Monte Carlo simulation in Crystal Ball.

5. Stop the simulation when the frequency distribution displayed on-screen for the Forecast is stabilized.

6. Look at the statistics of the Forecast contained in the report generated automatically by Crystal Ball.

7. Modify model and/or input assumptions and rerun until satisfactory results are reached.

The following is an example of an application of Crystal Ball. The calculations simulate a Monte Carlo analysis of deer exposure in a hypothetical contaminated forage browsing scenario.

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[1] Registered trademark of Decisioneering, Inc.

[2] Registered trademark of Microsoft, Inc.

STEP 1. Develop the mode1 on an Excel spreadsheet.

An Excel spreadsheet was prepared of actual data on forage concentrations over a 12-square-mile core area and a larger 30-square-mile area of potential influence. Forage concentrations were available for each l/4 square mile of the entire site area These chemical concentrations can be displayed as they would appear on a map (Figure E-l), with each cell representing a l/4 square mile of the site.

STEP 2. Identify probability distribution for the input parameters, called Assumptions.

In this case, data on actual forage concentrations are known. An average of all forage concentrations over the 12-square-mile core area or 30-square-mile area of influence would overestimate exposure and risk. Use of single point, hotspot forage concentration would also overestimate risk for a large, mobile foraging deer.

The weekly average forage concentrations a deer may be exposed to provide more valuable information. The minimum weekly foraging area for the deer is 1 square mile. Crystal Ball can generate a distribution of probable l-square-mile forage concentrations by averaging concentrations from randomly selected sets of four contiguous l/4-square-mile areas. It is conservatively assumed that the deer is exposed to at least l/4 square mile of its l-square-mile onsite foraging area within the 12-square-mile core area

STEP 3. Identify the output parameter(s) that need to be analyzed, called Forecast(s):

In the present example, the weekly forage intake was identified as the output parameter.

STEP 4. Run the Monte Carlo simulation in Crystal Ball;

STEP 5. Stop the simulation when the frequency distribution displayed on-screen for the Forecast stabilizes:

After about 1,000 trials the statistical distribution of the model output reached an adequately stable state. The mean, median, mode, standard deviation, variance, skewness, kurtosis, coefficient of variability, range minimum, range maximum, range width, mean standard error, and the frequency chart are summarized in the first part of Table E-1.

Different percentile values for the forecast daily intake are summarized in the second part of Table E-l. In this example, the forage concentrations can be compared with dietary concentrations that are known to be safe.

STEP 6. Look at the statistics for the Forecast contained in the report generated automatically by CB.

STEP 7. Modify mode1 and/or input assumption and rerun until satisfactory results are reached.

Application of the Crystal Ball method to realistic data sets shows that under some circumstances, when hot spot concentrations exceed trigger levels, it can be shown that actual exposures are not likely to exceed trigger levels, and if exceedances occur, they are unlikely to have significant impacts on the exposed population. If risk is excessive, remedial alternatives can be evaluated to see of they achieve acceptable risk levels. For example, a remedial option may be to fence off the “hottest” l/4-square-mile sections. In this model, these hot spots may be blocked off (see Figure E-l) and the exposure levels recalculated.

Note that even quantitative uncertainty analyses have remaining, unquantified uncertainty. In this case, such uncertainties include:

- The validity of assumptions regarding safe forage concentrations.
- The likelihood that deer will forage randomly over the whole site.
- The variability in the measured concentrations due to analysis error, sampling error, or seasonal variations, etc.

Risk assessors should identify these remaining uncertainties to avoid giving the false impression that a quantitative uncertainty analysis fully accounts for all uncertainties. It is unlikely that any model can do that.

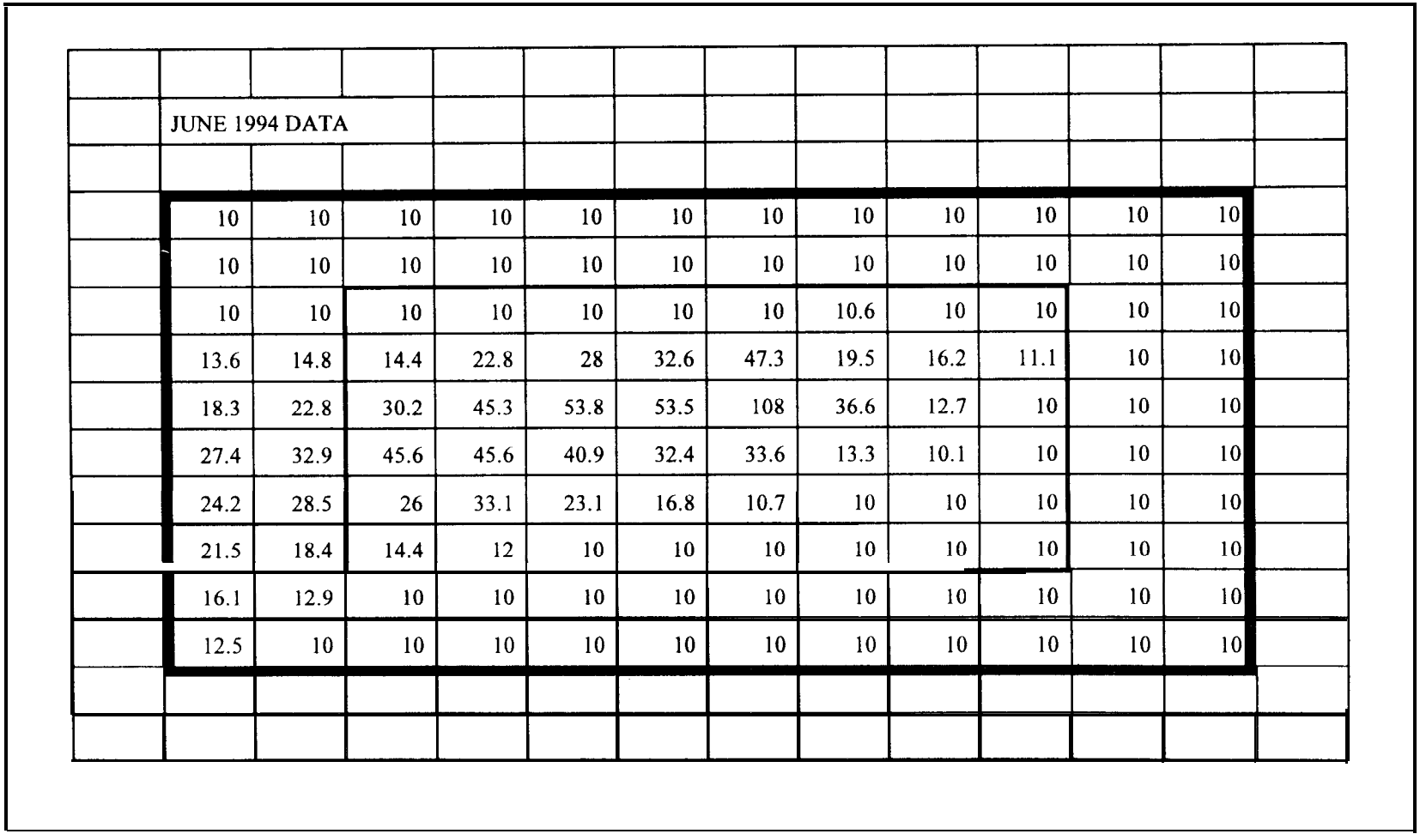


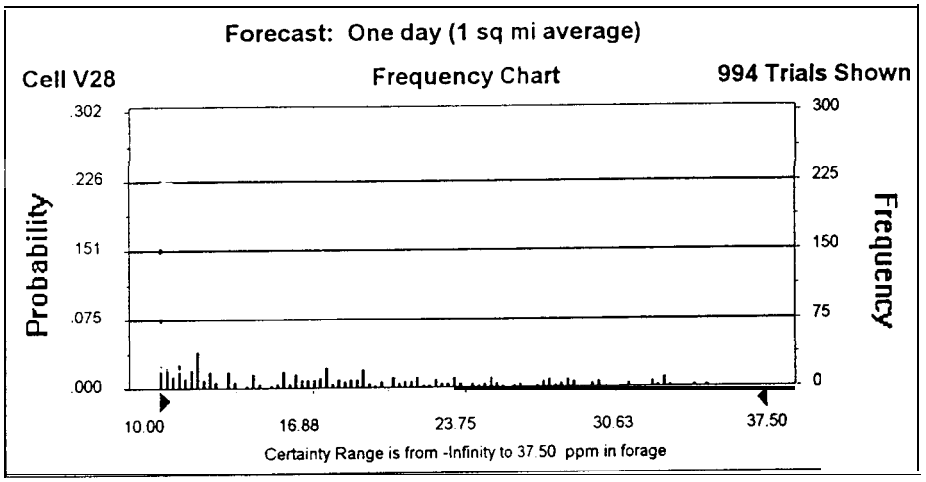
Figure E-1. Chemical concentrations, ppm in forage, 12-square-mile core area and 30-square-mile area of influence are outlined. Each cell represents the average forage concentration over a 1/4-square-mile forage area.

Table E-1
Model output

Forecast: One day (1 sq mi average)

Summary:
Certainty Level is 98.95%
Certainty Range is from -Infinity to 37.50 ppm in forage
Display Range is from 10.00 to 37.50 ppm in forage
Entire Range is from 10.00 to 39.93 ppm in forage
After 1,000 Trials, the Std. Error of the Mean is 0.23

Statistics:	Value
Trials	1000
Mean	16.59
Median (approx.)	13.39
Mode (approx.)	10.15
Standard Deviation	7.38
Variance	54.53
Skewness	0.99
Kurtosis	2.93
Coeff. of Variability	0.45
Range Minimum	10.00
Range Maximum	39.93
Range Width	29.93
Mean Std. Error	0.23



Percentiles:

Percentile	ppm in forage (approx.)
0.0%	10.00
2.5%	10.01
5.0%	10.02
50.0%	13.39
95.0%	32.42
97.5%	33.25
100.0%	39.93

End of Forecast

Appendix F
Ecotoxicity Profiles for Munitions Compounds

The document *Organic Explosives and Related Compounds: Environmental and Health Considerations* (Technical Report 8901, U.S. Army Medical Bioengineering Research and Development Lab, 1989) presents extensive discussion on the synthesis and production and use of organic explosives and related compounds. This document also discusses properties, behavior, and environmental fate of organic explosives and related compounds, and includes toxicity profiles of some compounds. Tables 1, 6, and 7, in Appendix F1, are from this document. This document is referenced by several more recent documents which provide toxicity information about specific compounds.

A more thorough toxicity assessment of several compounds is presented in a U.S. Army Environmental Health Agency (USAEHA) document. Sections presenting toxicity profiles for 2,4,6-TNT (Section 3.1.1) and DNT (Section 3.1.2) in ecological receptors are reproduced in this appendix as Appendixes F2 and F3.

The USAEPA prepares ecotoxicity profiles for organic explosives as well. Copies of these profiles for 2,4,6-Trinitrotoluene, Nitrobenzene, 1,2-Dinitrobenzene, p-Dinitrobenzene, 1,3,5-Trinitrobenzene, 2,6-Dinitrotoluene, 1,3-Dinitrobenzene, and Benzenamine are included in Appendix F4.

Other Sources

Another source of information on several compounds, including general toxicity characteristics, for the metals As, Cd, Cr, Pb, and Hg; the explosives, 1,3-Dinitrobenzene, 2,4-Dinitrotoluene (2,4-DNT), 2,6-Dinitrotoluene (2,6-DNT), HMX, RDX, Tetryl, 1,3,5-Trinitrobenzene, 2,3,6-Trinitrotoluene (2,4,6-TNT); and the pesticides DDD, DDE, and DDT are presented in a USAEHA Joliet document.

Other sources of toxicity information regarding TNT are:

- Palazzo, A.J., and D.C. Leggett, 1986. Effect and disposition of TNT in a terrestrial plant and validation on analytical methods. USCOE, CRREL Report 86-15.

- Caltado, D.A., S.D. Harvey, R.J. Fellows, R.M. Bean, and B.D. McVeety, 1989. Environmental Fate and Behavior of TNT. An Evaluation of the Environmental Fate and Behavior of Munitions Material (TNT, RDX) in Soil and Plan Systems, Pacific Northwest Laboratory, Project Order No. 88PP8853.

Another source of toxicity information regarding RDX is:

. Cataldo, D.A., S.D. Harvey, and R.J. Fellows, 1989. Environmental Fate and Behavior or RDX. An Evaluation of Environmental Fate and Behavior of Munitions Material (TNT, RDX) in Soil and Plant Systems, Pacific Northwest Laboratory, Project Order No. 88PP8853.

Appendix F1
Tables

Source: Burrows, E. P., D.H. Rosenblatt, W.R. Mitchell, and D.L. Parmer, 1989. Organic Explosives and Related Compounds: Environmental and Health Considerations. Technical Report 8901, U.S. Army Medical Bioengineering Research and Development Lab.

* Figure 1 and the references cited are not included in this excerpt.

INTRODUCTION

Explosives and propellants have important military applications; the former are also widely used in mining and construction. Their manufacture represents a sizable segment of the chemical industry [I]. In the course of production, handling, loading of military or civilian devices, and ultimate dispersal or disposal, explosives and propellants *are* released to the environment. There they are disseminated by natural processes and partially converted to secondary products. This report deals only with the more important organic explosives and propellants, and the focus is primarily on physicochemical properties and behavior, environmental fate, toxicity to human beings and wildlife, and environmental criteria; a comprehensive review that emphasizes manufacturing processes, formulations and uses is available [2]. While reasonable attempts have been made to assemble all pertinent material, some sources will doubtless have been missed. In addition to such omissions, there are extensive gaps in our knowledge, especially of environmental fate and chronic toxicity. Table 1 is a summary of the compounds to be covered and the abbreviated names for them that will be used throughout the report.

Table 1. Listing of Explosives, Propellants, and Derived Substances

Compound[a]	Abbreviation
Trinitrotoluene[b]	TNT
Dinitrotoluene[c]	DNT
1,3,5-Trinitrobenzene	TNB
1,3-Dinitrobenzene	DNB
Hexahydro-1,3,5-trinitro-1,3,5-triazine	RDX
Octahydro-1,3,5,7-tetranitro-1,3,5,7-tetrazocine	HMX
1-Acetylhexahydro-3,5-dinitro-1,3,5-triazine	TAX
1-Acetyloctahydro-3,5,7-trinitro-1,3,5,7-tetrazocine	SEX
N,2,4,6-Tetranitro-N-methylaniline	Tetryl
Ammonium picrate/Picric acid	AP/PA
Pentaerythritol tetranitrate	PETN
Nitroglycerin (glyceryl trinitrate)	NG
Nitroguanidine	NQ
Ethylene glycol dinitrate	EGDN
Diethylene glycol dinitrate	DEGDN
Propylene glycol dinitrate	PGDN

a. Structures are presented in Figure 1.
b. Where TNT is used, the 2,4,6-isomer (formerly known as u-TNT) is denoted; other isomers are specifically designated, e.g. 2.3.4-TNT.
c. Where DNT is used, the 2,4-isomer is denoted, possibly with minor amounts of other. isomers -- especially the 2,6-isomer; other isomers are specifically designated, e.g. 2,3-DNT.

Table 6. Acute Toxicities of Munitions Compounds to Rodents

Compound	Rat mg/kg[a] (route)	Mouse mg/kg[a] (route)	Reference
TNT	800-1300 (oral)	600-1000 (oral)	214
DNT	200-800 (oral)	1200-2000 (oral)	215
NG	500-900 (oral)	500-1200 (oral)	216
	100-110 (ip)	100-200 (ip)	216
	25-32 (iv)	10-18 (iv)	216
	500-600 (sc)	30-500 (sc)	216
RDX	40-300 (oral)	60-500 (oral)	201
		19 (iv)	201
HMX	6250 (oral)	2300 (oral)	217
		634 (sc)[b]	207
NQ	>5000 (oral)	5000 (oral)	195,208,209
TNB	450 (oral)	572 (oral)	63
		32 (iv)	63
DNB	83 (oral)	200 (ip)[c]	63
DEGDN	700-1000 (oral)[d]	1300-1400 (oral)[d]	218
	777 (oral)		63
EGDN	616 (oral)		63
PGDN	250 (oral)		63
	479 (ip)	1047 (ip)	63
	463 (sc)	1208 (sc)	63
PA		100 (oral)[e]	63
Tetryl		5000 (sc)[f]	63

a. LD50 unless noted otherwise.
b. In rabbit.
c. LDLo.
d. LD100.
e. LDLo in guinea pig.
f. LDLo in dog.

Table 7. NOEL for Selected Munitions Compounds Estimated from Chronic and Subchronic Toxicity Data

Compound	Duration of Test	NOEL (mg/kg/day)	Species	Reference
TNT	13 wk	1.0[a]	rat	219
	13 wk	1.4-1.45[b]	rat	220
	13 wk	1.45-1.6[b,c]	mouse	220
	13 wk	0.2	dog	220
	26 wk	0.5[d]	dog	221
	2 yr	0.4	rat	222
DNT	1 yr	13.5	mouse	223,224
	1-2 yr	0.6	rat	223,225
	2 yr	0.2	dog	223
NG	13 wk	25.5	rat	226
	1 yr	1.0	dog	227
	2 yr	3-4[b]	rat	227
	2 yr	10-11[b]	mouse	227
RDX	13 wk	15	rat	202
	13 wk	80	mouse	202
	13 wk	1.0	monkey	202
	2 yr	0.3	rat	228
	2 yr	1.5	mouse	229
HMX	13 wk	50-115	rat	207
PA	2 yr	25[e]	rat	230
NQ	13 wk	316	rat	210
DNB	16 wk	0.75	rat	231,232
PETN	1 yr	2	rat	196

a. 5% reduction in weight gain.
b. Males and females were given slightly different doses.
c. Enlarged spleens and hearts.
d. Mild liver lesions observed in 7 of 12.
e. Calculated from concentration in feed (500 ppm), assuming standard animal weight (200 g) and feed consumption (10 g/day)[63].

Appendix F2
TNT

Source: in Chapter 3.0 - Toxicity Assessment, Section 3.1 - Nitroaromatics, U.S. Army Environmental Health Agency (USAEHA) document.

3.0 TOXICITY ASSESSMENT

3.1 NITROAROMATICS

3.1.1 TNT

2,4,6-TNT is a munitions compound currently used for commercial and military purposes. TNT is only slightly soluble in water; the reported solubility is 150 mg/L at 25°C (USABRDL, 1989). Coupled with an estimated soil sorption coefficient (K_{oc}) value of 525, which indicates soil sorption will be negligible, TNT is expected to be mobile in the soil/groundwater system with little retardation in subsurface and sandy soils. With an estimated vapor pressure of approximately 5.5 x 10^{-6} millimeters of mercury (mmHg) at 25°C, TNT is not volatile, and movement through air-filled pores in near-surface soils is presumed to be an insignificant migration pathway. The major pathway for movement into the environment is by surface water runoff and the discharge of waste streams.

Neither oxidation nor nonmicrobial hydrolysis has been identified as an important degradation pathway for TNT [U.S. Army Biomedical Research and Development Laboratory (USABRDL), 1989]. Photolysis of TNT in aquatic environments has proven to be a primary degradation pathway. Subject to seasonal and latitudinal differences, the summer half-life period is reported to be 14 hours, and the winter half-life varies from 22 days at a latitude of 2O°N to 84 days at 50°N (USABRDL, 1987). Microbial hydrolysis occurs, but at a rate significantly slower than photolysis: 19 to 25 days with a lag time of up to 20 days [Hazardous Substances Data Bank (HSDB), 1990]. TNT undergoes biotransformation but not biodegradation because, in the end product, all of the nitro groups are reduced to amino groups (USABRDL, 1987). Similar reductive

transformations by thermophilic microorganisms under composting conditions have been reported (USABRDL, 1990).

3.1.1.1 Health Effects Assessment

EPA [Integrated Risk Information System (RIS) 1990] has derived a chronic oral reference dose (RfD) of 0.0005 mg/kg/day. No interim inhalation or subchronic oral RfDs are available (HEAST, 1990). The chronic oral RfD was derived from a 26-week study in which dogs were dosed via gelatin capsule at 0, 0.5, 2, 8, or 32 milligrams per kilogram per day (mg/kg/day) (IRIS, 1990). Increased liver weight in conjunction with hepatic swelling and hepatocytomegaly was observed in male dogs receiving 8 or 32 mg/kg/day; these effects were only observed in the female rats receiving the 32 mg/kg/day. Although hepatic swelling and hepatocytomegaly were observed at all dose levels, they were described as trace to mild in the lowest dose group (IRIS, 1990). Hemosiderosis of the liver was observed in **a** majority of animals receiving doses of 2 and 8 mg/kg/day, and microscopic evidence of cirrhosis was observed at the 8 and 32 mg/kg/day level (IRIS, 1990). Based on this study, a value of 0.5 mg/kg/day was identified as the lowest-observed-adverse-effect level (LOAEL) based on potential liver toxicity.

EPA has classified TNT as a group C (possible human) carcinogen (IRIS, 1990), which indicates that insufficient data are available regarding TNT's carcinogenicity in humans. Limited evidence of TNT's carcinogenic effects in experimental animals is available. In a 2-year rat feeding study, hepatocellular (male rats) and renal and urinary bladder hyperplasia (female rats) were observed in addition to bladder carcinoma and transitional cell papilloma in animals exposed to a daily dose of 10 mg/kg/day or greater (IRIS, 1990). No

significant change in neoplasms were reported in mice dosed at levels as high as 70 mg/kg/day (IRIS, 1990).

Human toxicity data consist primarily of data from munitions worker studies. Pathological manifestations have been reported as dermatitis, gastritis, and acute yellow atrophy of the liver, as well as petechial hemorrhages; aplastic anemia in older workers and toxic hepatitis in younger workers; nephritis; severe irritation and erythema of the skin; and headache, fatigue, and drowsiness associated with cyanosis. In severe cases, anuria, delirium, convulsions, and coma may occur (HSDB, 1990). Ocular damage may also be manifested, as evidenced by cataracts in a large number of occupationally exposed workers (HSDB, 1990).

In an acute study, dogs were dosed at 0, 0.2, 2.0, or 20 mg/kg/day for 13 weeks; rats received diets containing 0.002-, 0.01-, 0.05- or 0.25-percent TNT; and mice received diets with 0.00l-, 0.005-, 0.025-, or 0.125-percent TNT over the same period (HSDB, 1990). The highest dose caused anemia in all species and increased organ weights (the latter were temporary in dogs and mice). Alterations were seen in most clinical chemistry parameters, and reduced testes size was seen in rats at the highest dose regardless of length of exposure. All effects were reversible except for the testicular atrophy. When injected intraperitoneally into male rats at 100 mg/kg, TNT caused damage in the cerebral, hepatic, and renal biomembranes, and in cell organelles.

In a chronic feeding study in which rats were subjected to a 24-month dosing regimen of 0.4, 2, 10, or 50 mg/kg/day, a no-observed-adverse-effect level (NOAEL) of 0.4 mg/kg/day was established based on an absence of effects to

the spleen, kidney, bone marrow, and the bladder at that dose (IRIS, 1990). In a subchronic feeding study using dogs, rats, and mice, dogs were the most sensitive with effects reported at 2 mg/kg/day, although no effects were reported at 0.2 mg/kg/day. In the rats, toxic effects were reported at 7 mg/kg/day (male) and 7.4 mg/kg/day (female);. in mice, no toxicity was reported until reaching a dose of 35.7 mg/kg/day (male) and 37.8 mg/kg/day (female) (IRIS, 1990).

TNT was mutagenic to three Salmonella typhimurium strains, with or without metabolic activation. However, rats treated for 28 days, with TNT up to 1.8 mgfkg/day evidenced no in vivo genetic damage (IRIS, 1990). No teratogenic or other reproductive effects have been reported, but testicular atrophy was reported in male rats following doses of 25, 125, and 300 mg/kg/day for 13 weeks. The importance of the latter effect is questioned as it was not duplicated in any other species and is a common response of rats to any toxic insult [IRIS, 1990; Oak Ridge National Laboratory (ORNL), 1987]. A NOAEL of S mg/kg/day is indicated by the absence of testicular degeneration and effects on the spleen at this dose level (IRIS, 1990).

3.1.1.2 Ecotoxicity

Aquatic Organisms

Several algal species, but no vascular plant species, were tested to evaluate short-term effects; Table 3.1-1 presents a summary of the results. Following 24 hours of exposure to 8 mg/L of TNT, loo-percent mortality **was** reported in the algae Microcystis aeruginosa (Fitzgerald et. al., 1952). Following exposure of Selenastrum capricomutum to TNT for 7 days, 2.5 mg/L was found to significantly reduce growth, and 10 mg/L was lethal (Won et. al., 1976).

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Table 3.1-1. Acute Toxicity of 2,4,6-TNT to Aquatic Organisms

Scientific Name (Common Name)	Effect	S/F	Duration (hours)	Concentration (mg/L)	Reference
INVERTEBRATES					
Lumbriculus variegatus (oligochaete)	LC50	S	48	5.2	Liu et al., 1983a (LLNL, 1987)
	LC50	F	96	>29.0 (M)	Liu et al., 1983a (LLNL, 1987)
Daphnia magna waterflea)	LC50	S	48	11.7 (M)	Liu et al., 1983a (LLNL, 1987)
	LC50	F	96	1.2 (M)	Liu et al., 1983a (USABRDL, 1989)
	LC50	S	48	11.9	Liu et al., 1983b (LLNL, 1987)
	LC50	F	48	6.6	Liu et al., 1976 (LLNL, 1987)
	LC50	S	48	0.8*	Liu et al., 1983c (LLNL, 1987)
Hyalella azetca (Scud)	LC50	S	48	6.5	Liu et al., 1976 (LLNL, 1987)
	LC50	F	96	6.5	Liu et al., 1976 (LLNL, 1987)
Tanytarsus dissimilis (Midge)	LC50	S	48	27.0	Liu et al., 1983a (LLNL, 1987)
VERTEBRATES					
Oncorhyncus mykiss (was Salmo gairdneri)	LC50	S	96	0.8	Liu et al., 1983a (USABRDL, 1989)
(Rainbow trout)	LC50	S*	96	1.4	Liu et al., 1983a (USABRDL, 1989)
	LC50	F	96	2.0 (M)	Liu et al., 1983a (USABRDL, 1989)
Pimephales promelas (Fathead minnow)	LC50	S	96	2.9	Liu et al., 1983a (USABRDL, 1989)
	LC50	F	96	3.7(M)	Liu et al., 1983a (USABRDL, 1989)
	LC50	S	96	2.0	Liu et al., 1976 (USABRDL, 1989)
	LC50	F	96	2.9	Liu et al., 1983a (LLNL, 1987)
	LC50	F	96	2.58	Smock et al., 1976 (LLNL, 1987)
	LC50	S	96	2.9	Liu et al., 1983a (LLNL, 1987)
	EC50	F	96	0.46	Smock et al., 1976 (LLNL, 1987)

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Table 3.1-1. Acute Toxicity of 2,4,6-TNT to Aquatic Organisms (Continued, Page 2 of 2)

Scientific Name (Common Name)	Effect	S/F	Duration (hours)	Concentration (mg/L)	Reference
VERTEBRATES (Cont'd.)					
Pimephales promelas (Fathead minnow)	LC5O	S	96	3.0	Liu et al., 1983b (LLNL, 1987)
	LC5O	S	96	0.1*	Liu et al., 1983c (LLNL, 1987)
Lepomis macrochirus (Bluegill)	LC5O	S	96	2.6	Liu et al., 1983a (USABRDL, 1989)
	LC5O	S+	96	3.4	Liu et al., 1983a (USABRDL, 1989)
	LC5O	F	96	2.5 (M)	Liu et al., 1983a (USABRDL, 1989)
Ictarus punctatus (Channel catfish)	LC5O	S	96	2.4	Liu et al., 1983a (USABRDL, 1989)
	LC5O	F	96	3.3 (M)	Liu et al., 1983a (USABRDL, 1989)
	LC5O	F+	96	2.4	Liu et al., 1983a (USABRDL, 1989)

Note: EC50 = median effective concentration (Moribund response based on three behavioral responses: shock, loss of motor control, and loss of equilibrium).
LC5O = lethal concentration (lethal for SO percent of exposed group).
M = measured concentration; all others are assumed to be nominal concentrations.
S/F = static or flow-through test.

References in parentheses are secondary sources.

*Test was completed using 2,3,6-TNT.
+Static test containers were aerated during testing.

Source: ESE.

Bringmann and Kuehn (1980) found that cell multiplication was inhibited when Scenedesmus quadricauda, incubated at 27°C was exposed to TNT for 24 hours. Based on the decreased growth, the toxicity threshold was determined to be 1.6 mg/L.

Several aquatic invertebrate species have been tested to determine the acute toxicity of TNT. The results of individual tests, which were performed either as static or flow-through, are presented in Table 3.1-1 with corresponding references. The static 48-hour LC5O values reported for Daphnia manna, representing freshwater invertebrates, are 11.7 and 11.9 mg/L, and a measured 48-hour value of 6.6 mg/L was reported for one flow-through test. A measured value of 1.2 mg/L was reported for a 96-hour flow-through test. In addition to testing the 2,4,6-isomer, the 2,3,6-isomer was tested in a static 48-hour test with a resultant LC5O value of 0.8 mg/L reported. Other species tested include the asellid Hyalella azetca (scud), the chironomid Tanytarsus dissimilis (midge), and the oligochaete Lumbriculus variegatus (worm). Static 48-hour LC5O values reported for these species were 6.5 mg/L, 27.0 mg/L, and 5.2 mg/L, respectively; a measured 48-hour flow-through LC5O value of 29.0 mg/L was reported for L. variegatus.

The acute toxicity of 2,4,6-TNT to several species of vertebrate organisms has been studied (see Table 3.1-1). An evaluation of the effect of water hardness and temperature on the toxicity of TNT to Lepomis macrochirus (bluegill sunfish) found that water hardness was not a factor but that toxicity was lower at 10°C than at 25°C (see Table 3.1-1) (Pedersen, 1971). A study by Liu et. al., (1976) using Pimephales promelas (fathead minnow) found that the 96-hour LC5O increases as the pH increases, and toxicity decreases as TNT is

photodegraded [Lawrence Livermore National Laboratory (LLNL) 1987]. LC5O values for two species in addition to the bluegill and the fathead minnow have been determined. The species are Oncorhyncus mykiss (former taxonomic designation was Salmo gairdneri) or rainbow trout, and Ictarus punctatus or channel catfish. Table 3.1-2 includes a summary of the acute tests and the corresponding references. In response to static 96-hour tests, the rainbow trout, with reported LC5O values ranging from 0.8 mg/L to 1.4 mg/L, appears to be the most sensitive of the four species tested. Static 96-hour LC5O values for TNT ranged from 2.0 to 2.9 mg/L for the fathead minnow, 2.6 to 3.4 mg/L for the bluegill, and a single value of 2.4 mg/L is listed for the channel catfish. in addition to the static tests, results of 96-hour flow-through tests, many of which are measured values, are available for the same four species. As with the static test results, the rainbow trout is the most sensitive, with a measured value of 2.0 mg/L reported. For the fathead minnow, a measured value of 3.7 mg/L is reported, and nominal concentrations of 2.58 and 2.9 are reported. A measured value of 2.5 mg/L is reported for the bluegill, and the nominal and measured values reported for the channel catfish are 2.4 and 3.3 mg/L, respectively. As part of their studies, Liu et. al., (1983a) determined an LC5O value of 0.1 mg/L in the fathead minnow for 2,3,6-trinitrotoluene (2,3,6-TNT), indicating that this isomer is approximately 10 times more toxic than the 2,4,6-isomer.

Several algal species were studied in terms of longer exposure to TNT. Following a 17-day exposure, growth inhibition was reported in Selenastrum capricomutum at a concentration of 5 mg/L (Smock et al., 1976), and a value of 4.1 mg/L was reported by Liu et al., (1983a) to inhibit growth after a 14-day exposure period. Growth inhibition was reported by Liu et al., (1983a)

Table 3.1-2. Chronic Toxicity of 2,4,6-TNT to Aquatic Organisms

Scientific Name (Common Name)	Effect	S/F	Duration (hours or days)	Concentration (mg/L)	Reference
ALGAE					
Selenastrum capricomutum	Growth inhibition	--	14 days	4.1	Liu et al., 1983a (ORNL, 1987)
	Growth inhibition	--	17 days	5	Smock et al., 1976 (LLNL, 1987)
	Growth inhibition	--	7 days	2.5	Won et al., 1976 (ORNL, 1987)
	Death	--	2 days	10	Won et al., 1976 (ORNL, 1987)
Microcystis aeruginosa	Growth inhibition	--	17 days	15	Smock et al., 1976 (LLNL, 1987)
	Growth inhibition	--	14 days	4.1	Liu et al., 1983a (ORNL, 1987)
	Death (100%)	--	24 hr	8	Fitzgerald et al., 1952 (ORNL, 1987)
Anabaena flos-aqua	Growth inhibition	--	14 days	8.2	Liu et al., 1983a (ORNL, 1987)
Naviculla pelliculosa	Growth inhibition	--	14 days	18	Liu et al., 1983a (ORNL, 1987)
Scenedesmus quadricauda	Toxicity threshold	--	16 hr	1.6	Bringmann and Kuehn, 1980 (ORNL, 1987)
PLANTS					
Lemna perpusilla (Duckweed)	Growth inhibition	--	11 days	1.0*	Schott and Worthley, 1974 (USABRDL, 1989)
	Death	--	11 days	5.0*	Schott and Worthley, 1974 (USABRDL, 1989)
	NEC	--	11 days	≤0.5 (M)	Schott and Worthley, 1974 (USABRDL, 1989)

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Table 3.1-2. Chronic Toxicity of 2,4,6-TNT to Aquatic Organisms (Continued, Page 2 of 2)

Scientific Name (Common Name)	Effect	S/F	Duration (hours or days)	Concentration (mg/L)	Reference
INVERTEBRATES					
Daphnia magna (Waterflea)	Incipient LC50	F	192 hr	0.2 (M)	Liu et al., 1983a (USABRDL, 1989)
	Incipient LC50	F	336 hr	0.19 (M)	Liu et al., 1983a (USABRDL, 1989)
	Reproductive	F		1.03	Bailey et al., 1985 (USABRDL, 1989)
VERTEBRATES					
Oncorhyncus mykiss (Rainbow trout)	Incipient LC50	F	240 hr	1.9 (M)	Liu et al., 1983a (USABRDL, 1989)
	ELS, fiy survival	--		0.24	Bailey et al., 1985 (USABRDL, 1989)
Pimephales promelas (Fathead minnow)	Incipient LC50	F	14 day	1.4 to 1.9	Liu et al., 1983a (USABRDL, 1989)
	Incipient LC50	F	192 hr	1.5 **(M)**	Liu et al., 1983a (USABRDL, 1989)
	ELS, repro-ductive	F	90 day	0.04	Bailey et al., 1985 (USABRDL, 1989)
Lepomis macrochirus (Bluegill)	Incipient LC50	F	14 day	1.4 to 1.9	Liu et al., 1983a (LLNL, 1987)
	Incipient LC50	F	312 hr	1.4 (M)	Liu et al., 1983a (USABRDL, 1989)
lctarus punctatus (Channel catfish)	LC50	F	288 hr	1.6 (M)	Liu et al., 1983a (USABRDL, 1989)

Note: ELS = early life stage.
M = measured.
NEC = no-effect concentration.
ORNL = Oak Ridge National Laboratory.
S/F = static or flow-through test conditions.
.. = test conditions not specified.

References in parentheses are secondary sources.

*Test completed with 2,3,6-TNT.

Source: ESE.

in M. aeruginoisa at a concentration of 4.1 mg/L following a 14-day exposure. Smock et al., (1976) reported growth inhibition at 15 mg/L following a 17-day exposure. Growth inhibition was also reported in Anabaena flos-aquae following 14 days of exposure to 8.2 mg/L and in Navicula pelliculosa after a 14-day exposure to 18 mg/L (Liu et al., 1983a). Following an 11-day exposure of duckweed, or Lemna perpusilla, to TNT in a hydroponic solution, growth inhibition was reported at a concentration of 1.0 mg/L, and death was reported at 5.0 mg/L (Schott and Worthley, 1974).

In the testing of invertebrates, a parameter known as the incipient LC5O is reported; this term signifies the concentration at which 50 percent of the exposed population would expire following an indefinite exposure. The measured incipient flow-through values reported for D. magna are 0.2 mg/L following a 192-hour exposure and 0.19 mg/L following a 336-hour exposure (Liu et al., 1983a). A value of 1.03 mg/L was reported by Bailey et al. (1985) as the flow-through concentration at which reproductive effects were observed in D. magna. Chronic toxicity test data are presented in Table 3.1-2.

The bioconcentration potential of TNT in several aquatic species was evaluated by Liu et al., (1983a). Following a 96-hour exposure, a bioconcentration factor (BCF) of 453 was reported for the algae, S. capricomutum, and a whole body BCF of 209 was reported for D. magma. In vertebrates, Liu et al., (1983a) reported a 96-hour BCF of 338 in the viscera of the bluegill, but the muscle BCF was measured at 9.5. Because these values were determined from data collected during the uptake process prior to reaching a steady state, the authors estimated a steady state whole body BCF value of 20.5. In its evaluation of munitions, USABRDL (1989) estimated a BCF value of 8.95 for fish, and

Layton et al., (1987) estimated a BCF value of 7 for fish. In 1983, Xu and Chen investigated the bioconcentration of TNT in a microcosm consisting of Tilapia mossambica (fish), Belbamya purificata, Pista stratiotes (water lettuce), and Anlirrhinum majus. The resulting calculated dry weight BCF values were reported as 210; 171; 1,165 to 1,415; and 1,623 to 2,030, respectively (LLNL, 1987). BCF data are presented in Table 3.1-3.

Terrestrial Organism

Few toxicity tests with terrestrial plants have been reported. One study by Palazzo and Leggett (1986) reported on the effects of TNT on yellow nutsedge grown in a hydroponic solution. At a concentration of 5 mg/L TNT, root weight was reduced by 95 percent. Visible symptoms of root injury included discoloration and growth restriction.

No studies concerning TNT toxicity to wildlife were found in the literature; however, toxicological studies using laboratory animals may serve as models for wildlife species. These studies indicate that, in small doses, TNT is rapidly detoxified and excreted. In acute studies reported by ORNL (1987), lethal dose (lethal for 50 percent of exposed group) (LD5O) values ranged from 794 to 3,190 milligrams per kilogram (mg/kg) for rats and 660 to 1,014 mg/kg for mice; in one study on rabbits, the LD5O value was 940 mg/kg (Table 3.1-4).

In chronic studies, dogs and monkeys exposed to less than 1 mg/kg/day for 90 days showed no toxic effects (ORAL, 1987); however, dogs dosed with 7 mg/kg of TNT twice a week for 9 months showed renal pathological changes. In additional studies reported by ORNL (1987), gastric disorders were reported in dogs exposed to TNT dosages as low as 0.1 mg/kg for 1.5 to 2.5 years.

Table 3.1-3. Bioconcentration Factors* for TNT

Species Name	Tissue	BCF	Reference
Fish (general)		7 (E) 8.95 (E)	LLNL, 1987 (USABRDL, 1989)
Lepomis macrochims (Bluegill)	viscera	338	Liu et al., 1983a (ORNL, 1987)
96 hr uptake	muscle	9.5	Liu et al., 1983a (ORNL, 1987)
(Steady State)	whole body	20.5 (E)	Liu et al., 1983a (ORNL, 1987)
Tilapia mossambica	NS	210	Xu and Chen, 1983 (ORNL, 1987)
Selenastrum capricomutum (96 hr)	NS	453	Liu et al., 1983a (ORNL, 1987)
Belbamya purificata	NS	171	Xu and Chen, 1983 (ORNL, 1987)
Pistia stratiotes (Water lettuce)	NS	1,165 to 1,415	Xu and Chen, 1983 (ORNL, 1987)
Anlirrhinum major	NS	1,623 to 2,030	Xu and Chen, 1983 (ORNL, 1987)
Lumbriculus variegatus (Oligochaete) (96 hr)	whole body	202	Xu and Chen, 1983 (OWL, 1987)

Note: E = estimated.
NS = not specified.

References in parentheses are secondary sources.

*Unitless.

Source: ESE.

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Table 3.1-4. Acute Toxicity* of 2, 4, 6-TNT

Test Species	LD5O Value mg/kg)	Reference
Rat	1,014	Lee et al., 1975
Rat	820	Lee et al., 1975
Rat	3,190	Vasilenko and Kovalenko, 1976
Rat	1,320	Dilley et al, 1978
Rat	794	Dilley et al., 1978
Mouse	1,014	Lee et al., 1975
Mouse	1,009	Lee et al., 1975
Mouse	680	Vasilenko and Kovalenko, 1976
Mouse	830	Newell et al., 1976
Mouse	660	Dilley et al., 1978
Rabbit	940	Vasilenko and Kovalenko, 1976

*Oral dose by gastric intubation with test material suspended in corn or peanut oil; animals were fasted for 16 hours before testing and and observed for 14 days past treatment.

Source: ORNL, 1987.

In studies using rats and mice, rats administered TNT for up to 24 months displayed anemia, hepatotoxicity, and urogenital lesions (ORNL, 1987). Hyperplastic and/or neoplastic lesions of the liver, kidneys, and urinary bladder also were observed at doses of 10 mg/kg/day or greater. The observed carcinoma of the urinary bladder indicates that TNT is a carcinogen to rats under the experimental conditions.

Table 3.1-5 summarizes the results of several chronic studies with 2,4,6-TNT and laboratory mammals. No-observed-effect level (NOEL) values range from 0.4 to 1.45 mg/kg in rats and 0.5 mg/kg in dogs. LOAEL values are reported as 1.45 to 1.6 mg/kg in mice, and lowest-observed-effect level (LOEL) values are reported as 0.5 mg/kg for dogs and rabbits. Only two BCF values were found in the literature. USABRDL (1989) reported an estimated value of 0.0013 for beef (general), and LLNL (1987) reported an estimated value of 0.0026 for beef (general).

3.1.1.3 Criteria and Standards

Current data for calculating water quality criteria are insufficient to meet all EPA guidelines. However, using calculations from previous EPA guidelines, a reasonable estimate of the criterion maximum concentration to protect aquatic life is 557 μg/L; the criterion for continuous concentration is tentatively estimated at 40 μg/L (ORNL, 1987). No ambient water quality criteria (AWQC) currently exist for TNT.

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Table 3.1-5. Chronic Toxicity of 2,4,6-TNT

Species	Effect	Duration	Dose (mg/kg/day)	Reference
Rat	NOEL	13 weeks	1.0	Levine et al., 1984 (USABRDL, 1989)
	NOEL	13 week	1.4 to 1.45	Dilley et al., 1978 (USABRDL, 1989)
	NOEL	2 years	0.4	Furedi et al., 1984 (USABRDL, 1989)
Mouse	LOAEL	13 weeks	1.45 to 1.6	Dilley et al., 1978 (USABRDL, 1989)
Dog	NOEL	13 weeks	0.2	Dilley et al., 1978 (USABRDL, 1989)
	LOEL	26 weeks	0.5	Levine et al., 1983 (USABRDL, 1989)
Rabbit	LOEL	8 months	0.005	Galuzova, 1963 (USABRDL, 1974)

Source: ESE.

Appendix F3
DNT

Source: in Chapter 3.0 - Toxicity Assessment, Section 3.1 - Nitroaromatics, U.S. Army Environmental Health Agency (USAEHA) document.

3.1.2 DNT

DNT exists as any one of six isomen. In the munitions industry, only two isomers are commonly found: 2,4-dinitrotoluene (2,4-DNT) and 2,6-dinitrotoluene (2,6-DNT). These compounds are ingredients of explosives used by commercial and military personnel and are also used as stabilizers in the manufacture of smokeless powder (EPA, 1980).

The estimated soil adsorption coefficient (K_{oc}) values for 2,4-DNT and 2,6-DNT are 251 and 78, respectively (USABRDL, 1989), indicating that there will negligible sorption to soil. Coupled with estimated water solubilities of 280 and 206 mg/L at 25°C (USABRDL, 1989), 2,4-DNT and 2,6-DNT are expected to be mobile in the soil/groundwater system with little retardation in subsurface and sandy soils. With estimated vapor pressures of 0.000217 and 0.000567 mmHg at 25°C for 2,4-DNT and 2,6-DNT, respectively (USABRDL, 1989), these compounds are not volatile. Consequently, movement through the air-filled pores in near-surface soils is presumed to be an insignificant migration pathway.

No evidence exists for other chemical transformation processes, such as hydrolysis or oxidation, under environmental conditions (USABRDL, 1989). The DNTs may be biodegraded or at least biotransformed, as the nitro groups are reduced under aerobic conditions to ammo- and azoxyaromatic compounds (USABRDL, 1989).

3.1.2.1 Health Effects Assessment

No oral or inhalation RfDs have been developed for either 2,4-DNT or 2,6-DNT; EPA indicates that the available data are insufficient for quantitative risk assessment [Health Effects Assessment Summary Tables (HEAST) 1990].

EPA has classified both 2,4-DNT and 2,6-DNT as group B2 (probable human) carcinogens (HEAST, 1990). Bats were exposed to a dietary mixture of the two isomers for a 2-year period, following which liver and mammary tumors were reported (HEAST, 1990). Based on the data generated from this study, an oral cancer slope factor of 0.68 $(mg/kg/day)^{-1}$ was calculated (HEAST, 1990). No inhalation cancer slope factor was developed. The results of a feeding study using rats that were dosed with diethylnitrosamine as a hepatic initiator-promotor indicated that 2,4-DNT and 2,6-DNT are hepatocarcinogens but that the 2,6-DNT isomer is 10 times more potent than the 2,4-DNT isomer (HSDB, 1990).

The primary result of acute exposure is the formation of methemoglobin leading to cyanosis (EPA, 1980). In order of probable occurrence, the following symptoms are reported in humans exposed to the DNTs (HSDB, 1990). First, signs of cyanosis as evidenced by a darkening of the tongue, lips, mucous membranes, and skin with no signs of cardiac or pulmonary insufficiency. This is followed by headache and nausea that can include vomition, then by CNS effects including ataxia, weakness, disorientation, confusion, lethargy, and finally coma; convulsions may occur but are not common. In a similar timeframe postexposure, cardiac effects may be observed that include heart blocks, arrhythmias, and shock. When death does occur, which is not common, it is usually due to cardiovascular collapse (HSDB, 1990). A study of workers

exposed to DNT or toluene diamine found no significant increase in cancer but did find an increase in mortality due to ischemic heart disease.

Male rats orally administered technical grade DNT for a S-day period evidenced markedly elevated microsomal cytochrome P-450-dependent enzyme activities; no other effects were reported (HSDB, 1990). Rats exposed to 34 (males) or 38 mg/kg/day (females) for 13 weeks evidenced depressed weight gain, Doses of 93 and 108 mg/kg/day, respectively, were toxic, with evidence of splenic hemosiderosis and decreased spermatogenesis (HSDB, 1990). In a 2-year rat feeding study, levels of 0.57 (males) and 0.71 mg/kg/day (females) evinced no apparent toxic effect. The next higher dose of 3.9 (males) and 5.1 mg/kg/day (females) was toxic, evidencing depressed spermatogenesis (males) and numerous carcinomas (both sexes) (HSDB, 1990). The mouse is observed to be much more tolerant following exposure to any of the DNT compounds alone or in combination (HSDB, 1990). The compounds 2,4-DNT; 2,6-DNT, and 34-DNT are substantially more toxic than the other isomers (HSDB, 1990).

Technical-grade 2,4-DNT (76.5 percent 2,4-DNT and 18.8 percent 2,6-DNT) was mutagenic with several Salmonella typhimurium strains, particularly in strains that respond to frame-shift mutagens (HSDB, 1990). A separate mutagenic study using S strains of Salmonella typhimurium found that the enzyme nitroreductase was necessary to induce mutation (HSDB, 1990). Both 2,4-DNT and 2,6-DNT were identified as genotoxic, with the potency of the 2,6-isomer much greater than that of the 2,4-isomer (HSDB, 1990).

3.1.2.2 Ecotoxicity

Aquatic Organisms

Several studies have been completed to assess the toxicity of several isomers of DNT to freshwater algae, plants, and invertebrate and vertebrate organisms. The results are presented in Table 3.1-6, and many results are also available in the Ambient Water Quality Criteria for Dinitrotoluene document prepared by EPA (1980d). No AWQC are available for the DNT isomers; however, EPA (1980d) states that acute and chronic toxicity occur at concentrations as low as 330 µg/L and 230 µg/L, respectively, and would occur at lower concentrations in species that are more sensitive than those tested.

Most of the isomers have been evaluated in terms of their potential toxicity to freshwater aquatic organisms (Liu et al., 1983a). The studies consist of 48-hour static LD50 studies using Daphnia magna and 96-hour static LD50 studies using Pimephales promelas (fathead minnow). Other studies were completed using the algae Selenastrum capricornutum and Lepomis macrochirus (bluegill). The results presented in Table 3.1-6 indicate that the 2,3-DNT, 2,5-DNT, and 3,4-DNT isomers are about 10 times more toxic than the 2,4-DNT, 2,6-DNT, or 3,5-DNT isomers. EPA (1980d) reports a SO-percent reduction in cell numbers and chlorophyll a after a 96-hour exposure at levels of the 2,3-DNT isomer that are approximately equal to the 2,3-DNT LD5O values reported in the fathead minnow (Liu et at., 1983a). BCF data are presented in Table 3.1-7.

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Table 3.1-6. Toxicity of DNT Isomers to Aquatic Organisms

Scientific Name (Common Name)	Isomer	Effect	S/F	Duration (hours or days)	Concentration (mg/L)	Reference
ALGAE						
Selenastrum capricornutum	2,3-	SO%	Growth Inhibition		1.37	EPA 1980d
(Blue-green algae)	2,3-	SO%	Inhibition of chlorophyll a		1.62	EPA, 1980d
PLANTS						
Lemna perpusilla (Duckweed)	2,4-	NEC	S	11 days	0.1 to 0.5	Schott and Worchley, 1974 (USABRDL, 1989)
INVERTEBRATES						
Daphnia magna	2,4-	LC5O	S	48 hr	47.5	Liu et al., 1983a (LLNL, 1987)
	2,6-	LC5O	S	48 hr	21.8	Liu et al., 1983a (LLNL, 1987)
	3,5-	LC5O	S	48 hr	45.2	Liu et al., 1983a (LLNL, 1987)
	3,4-	LC5O	S	48 hr	3.7	Liu et al., 1983a (LLNL, 1987)
	2,3-	LC5O	S	48 hr	4.7	Liu et al., 1983a (LLNL, 1987)
	2,5-	LC5O	S	48 hr	3.1	Liu et al., 1983a (LLNL, 1987)
	2,4-	EC5O	S	48 hr	35	EPA, 1980d
	2,6-	EC5O	S	48 hr	21.8	Liu, et al., 1983b (LLNL, 1987)
	2,3-	EC5O	S	48 hr	0.66	EPA, 1980d
VERTEBRATES						
Pimephales promelas (Fathead minnow)	2,4-	LC5O	S	96 hr	32.8	Liu, et al., 1983a (LLNL, 1987)
	2,6-	LC5O	S	96 hr	18.5	Liu, et al., 1983a (LLNL, 1987)
	3,5-	LC5O	S	96 hr	22.6	Liu, et al., 1983a (LLNL, 1987)
	3,4-	LC5O	S	96 hr	1.5	Liu, et al., 1983a (LLNL, 1987)
	2,3-	LC5O	S	96 hr	1.8	Liu, et al., 1983a (LLNL, 1987)
	2,5-	LC5O	s	96 hr	1.3	Liu, et al., 1983a (LLNL, 1987)

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Table 3.1-6. Toxicity of DNT Isomers to Aquatic Organisms (Continued, Page 2 of 2)

Scientific Name (Common Name)	Isomer	Effect	S/F	Duration (hours or days)	Concentration (mg/L)	Reference
VERTEBRATES (Cont'd.)						
Pimephales promelas (Fathead minnow)	2,4-	LC50	--	96 hr	31	EPA, 1980d
	ND	LC50	--	chronic	0.28	USABRDL, 1989
	2,3-	Embryo-larval	--	--	0.23	EPA 1980d
Lepomis macrochirus (Bluegill)	2,3-	LC50	S	96 hr	0.33	EPA, 1980d

Note: ND = isomer not provided.
-- = no pertinent information provided.

References in parentheses are secondary sources.

Source: ESE.

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Table 3.1-7. Bioconcentration Factors* for DNT

Species Name	Tissue	BCF	Reference
2,4-DNT			
Fish (general)	muscle	10.6	Hartley, 1981 (LLNL, 1987)
		11.6 (E)	USABRDL, 1989
		3.8 (E)	EPA, 1980d
		15 (E)	LLNL, 1987
		78	Liu et al., 1983a (LLNL, 1987)
	brain	103	Hartley, 1981 (LLNL, 1987)
	whole body	24.8	Hartley, 1981 (LLNL, 1987)
Beef (far/feed)		0.0034 (E)	USABRDL, 1989
		0.0027 (E)	LLNL, 1987
Daphnia magra		13	Liu et al., 1983c (LLNL, 1987)
Algae (unspecified)		5,225	HSDB, 1990
Selenastrum capricornutum		2,507	Liu et al., 1983a (LLNL, 1987)
2,6-DNT			
Fish (general)	muscle	9.82 (E)	USABRDL, 1989
		13 (E)	LLNL, 1987
Carp	muscle	19 (E)	HSDB, 1990
Beef (fat/feed)		0.0031 (E)	USABRDL, 1989; LLNL, 1987

Note: E = estimated.

References in parentheses are secondary sources.

*Unitless.

Source: ESE.

Terrestrial Organisms

Data for the toxicity of DNT to terrestrial wildlife must be inferred from tests conducted with laboratory mammals because tests have not been conducted with wildlife species. In subacute toxicity studies of 2,4-DNT, dogs were fed daily doses of 1, 5, or 25 mg/kg, and rats and mice were fed doses of 0.07, 0.2, or 0.7 percent of feed for 13 weeks. The highest doses were lethal to some animals in all three species, and the lowest doses produced no toxic effects (EPA, 1980d). All species exhibited methemoglobinemia and anemia. The toxicity of DNT isomers to laboratory animals is presented in Table 3.1-8.

The effects of chronic exposure to 2,4-DNT include liver damage, jaundice, and reversible anemia (EPA, 1980d). Bats fed a technical-grade mixture of DNT (2,4-DNT and 2,6-DNT) or 2,6-DNT for 1 year developed liver cancer (HSDB, 1990). BCF data are presented in Table 3.1-7.

3.1.2.3 Criteria and Standards

Insufficient data are available to develop AWQC for 2,4-DNT.

3.1.3 NITROBENZENE

The predominant use for nitrobenzene (NB) is reduction to aniline, which is then used in dyes, rubber, and medicines. NB also is used as a solvent; combustible propellant; almond essence substitute; in perfume; and in metal, floor, and shoe polishes.

NB is moderately adsorbed to soil; upon leaching into the ground or entering water systems, NB is expected to biodegrade within a few months (HSDB, 1990). In the atmosphere, the predominant degradation route is

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Table 3.1-8. Toxicity of DNT Isomers to Terrestrial Laboratory Mammals

Species	Isomer	Effect	Duration	Dose (mg/kg/day)	Reference
Rat	2,4- and 2,6-	LD5O	Oral Acute	200 to 800	Etnier, 1987 (USABRDL, 1989)
	2,4-	LD5O	Oral	268	EPA, 1980d
Mouse	2,4- and 2,6-	LD5O	Oral Acute	1,200 to 2,000	Etnier, 1987 (USABRDL, 1989)
	2,4-	NOEL	Oral	1,625	EPA, 1980
Rat	2,4-	NOEL	1 to 2 years	0.6	Ellis et al., 1979; Lee et al., 1985 (LLNL, 1987)
Mouse	2,4-	NOEL	1 year	13.5	Ellis et al., 1979; Hong et al., 1985 (LLNL, 1987)
Dog	2,4-	NOEL	2 year	0.2	Ellis et al., 1979 (LLNL, 1987)
		NOEL	2 year	10	Ellis et al., 1985 (LLNL, 1987)

Note: References in parentheses are secondary sources.

Source: ESE.

photolysis, and photoreduction has also been reported (EPA, 1979). Hydrolysis is not reported to occur for NB (EPA, 1979; LLNL, 1987). EPA (1979) reports that oxidation probably does not act as an initial aquatic fate process for NB. Volatilization is not expected to be an important migration pathway for NB because of the low vapor pressures, which are reported as 0.15 mmHg at 20°C (LLNL, 1987; EPA, 1979).

3.1.3.1 Health Effects Assessment

EPA has derived an oral chronic and interim oral subchronic RfD for NB of 0.0005 mg/kg/day (IRIS, 1990) and 0.005 mg/kg/day (HEAST, 1990), respectively. Although still listed in the IRIS database, EPA (HEAST, 1990) states that the chronic value for NB is currently being reconsidered.

in terms of exposure through inhalation, EPA (HEAST, 1990) has derived interim chronic (0.002 mg/kg/day) and subchronic (0.02 mg/kg/day) inhalation RfDs for NB. The interim chronic inhalation RfD has been verified and is pending input to the IRIS database as a final value (HEAST, 1990). These values were derived from an inhalation study in which rats and mice were exposed for 90 days to airborne NB (IRIS, 1990). Rats of both sexes evidenced an increase in hemolytic anemia, and female mice had increased vacuolization of the adrenal cells at 25 micrograms per cubic meter (mg/m^3). Liver and kidney damage was reported at the highest exposure of 81 mg/m^3. The NB oral RfD was then derived as a route-to-route extrapolation from the inhalation study (HEAST, 1990).

Data regarding effects of NB to humans are limited to occupational exposure in Which headaches, vertigo, and methemoglobinemia were the primary symptoms

reported (IRIS, 1990). Although methemoglobin is not formed as quickly by NB as by aniline, the resultant cyanosis is generally more persistent (HSDB, 1990). Other symptoms associated with the inhalation of NB are nausea, vomition, and depressed respiration that may lead to stupor; coma; and, in the most severe cases, death from respiratory failure (HSDB, 1990). Repeated exposure may lead to yellow atrophy, hemolytic icterus, and anemia of varying degrees with the presence of heinz bodies in the red blood cells; all of these symptoms are evidence of liver impairment (HSDB, 1990). Ocular effects are also reported, consisting primarily of browning of the fundus and the conjunctiva (HSDB, 1990).

CNS depression, methemoglobinemia, and marked cyanosis were also reported in experimental animals exposed to NB (HSDB, 1990). The bone marrow in rabbits evidenced changes ranging from hyperplasia to hypoplasia and even aplasia following subcutaneous administration of the compound (HSDB, 1990). The liver damage reported in rabbits included fatty infiltration, and kidneys evidenced minute petechiae, larger ecchymises, or even lobular hemorrhage, depending on the degree of exposure (HSDB, 1990).

NB was fetotoxic when administered subcutaneously to pregnant rats during preimplantation and placentation. Delay of embryogenesis, alteration of normal placentation, and fetus abnormalities were observed (HSDB, 1990). However, no treatment-related effects were reported during organogenesis, indicating that there are no developmental, including teratogenic, effects following exposure to atmospheric levels up to 40 ppm for 6 hours/day on days 6 through 15 of gestation (HSDB, 1990).

EPA has classified NB as a group D (not classifiable) carcinogen, which indicates that there is inadequate or no evidence regarding the carcinogenicity of this compound. EPA has not addressed the carcinogenicity of DNB and TNB (IRIS, 1990; HEAST, 1990).

No evidence of mutagenicity was observed following exposure of Salmonella typhimurium strains to NB (HSDB, 1990).

3.1.3.2 Ecotoxicity

Aquatic Organisms

Acute toxicity to freshwater aquatic life occurs at concentrations of NB ranging from as low as 640 µg/L for the leopard frog to as high as 163,000 µg/L for the fathead minnow (see Table 3.1-9). In the alga Selenastrum capricomutum, 96-hour EC50 values of 42,800 and 44,100 µg/L were reported for reduced cell numbers and inhibition of chlorophyll a, respectively (EPA, 1980). Acute EC50 values for the cladoceran Daphnia magna range from 24,000 to 62,000 µg/L, and acute EC50 values for the bluegill range from 43,000 to 135,000 µg/L (EPA, 1980).

In chronic studies, concentrations as high as 32,000 µg/L produced no effects on fathead minnow embryos or larvae; however, no definitive chronic toxicity data are available (EPA, 1980).

Studies by Lu and Metcalf (1975) on green filamentous algae (Oedogonium cardiacium), snails (Physa spp.), Daphnia, mosquito larvae (Culex quinquifasciatus), and mosquitofish (Gambusia affinis) show that NB was neither stored nor biomagnified. NB was reduced to aniline in all organisms,

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Table 3.1-9. Acute Toxicity Values of NB to Aquatic Organisms

Scientific Name **(Common Name)**	Toxicity Value (µg/L)	Reference
Selenastrum capricomutum (Alga)	ECSO: 42,800 to 44,000	EPA, 1980e
Daphnia magna (Water Flea)	LC50: 24,000 to 27:000 EC50: 60,000	Leblanc, 1980 Kuhn et al., 1989*
Leuciscus idus (Golden orfe)	LC50: 50,000	Wellens, 1982
Pimephales promelas (Fathead minnow)	LC50: 117,000 to 163,000 LC50: 119,000	Holcombe et al., 1984 Geiger et al., 1985*
Oryzias latipes (High-eyes)	LC50: 20,000 to 24,000	Tonogai et al., 1982
Lepomis macrochirus (Bluegill)	LC50: 43,000 to 135,000	Buccafusco et al., 1981
Rana pipiens (Leopard frog)	LC50: 640 to >1,270	Black et. al., 1982

*From HSDB, 1990.

Source: Primary citations may not have been reviewed. Citations were derived from Aquatic Information Retrieval (AQUIRE), 1990.

from 16 to 24 days, depending on the presence of other compounds; in distilled water, the estimated half-life was reported to be 23 days, and the observed value was 69 days (LLNL, 1987). No hydrolysis is reported to occur for DNB (EPA, 1979; LLNL, 1987). DNB was oxidized in the laboratory by a 2-step process involving activated sewage sludge in conjunction with a microorganism (LLNL, 1987).

Volatilization is not expected to be an important migration pathway for DNB because of the low vapor pressure, which is reported as 1.31×10^{-4} mmHg at 25°C (LLNL, 1987; EPA, 1979).

3.1.4.1 Health Effects Assessment

EPA has derived an oral chronic and an interim oral subchronic RfD for DNB of 0.0001 mg/kg/day (IRIS, 1990) and 0.001 mg/kg/day (HEAST, 1990), respectively. The DNB oral RfD was derived from a study in which rats were provided drinking water containing either 3, 8, or 20 mg/L DNB; these doses are equivalent to 0.40, 1.1, and 2.7 mg/kg/day (IRIS, 1990). Increased spleen weights were observed at 8 mg/L, and decreased weight gain and hemoglobin concentrations, testicular atrophy, splenic enlargement, and hemosiderin deposits were reported at the high dose of 20 mg/L. Thus, for oral exposure, 0.4 mg/kg/day was set as the NOEL from which the chronic and subchronic RfDs are derived, and 1.1 mg/kg/day was set as the LOAEL. EPA has not derived any inhalation RfD values for DNB.

The principal toxic effects reported for DNB are the same as for NB because the primary responses to exposure are methemoglobinemia and liver dysfunction (HSDB, 1990). Following chronic exposure, symptoms included headache;

burning pain; and paresthesia in feet, ankles, hands, and the forearms. Apathy, shortness of breath, and heart palpitations were also reported. In addition, chronic exposure led to vision impairment, with visual fields slightly contracted; visual acuity, particularly for reds and greens, was reduced by central scotomas (HSDB, 1990). Although partial ocular atrophy occurs, vision does gradually recover (HSDB, 1990).

Symptoms reported for rats exposed to a l-percent suspension of DNB in corn oil included ataxia, dyspnea, rapid heartbeat, cyanosis, coma, and respiratory failure (HSDB, 1990). In a reproductive study, splenic hemosiderosis was reported in weanlings dosed as low as 0.75 mg/kg/day (HSDB, 1990). No additional experimental animal toxicity data were reported in the reviewed databases (IRIS, 1990; HEAST, 1990; HSDB, 1990).

Data indicate that DNB is a potent testicular toxicant in the male rat (HSDB, 1990). Decreased sperm production, decreased caudal epididymal sperm reserves, nonmotile spermatozoa, atypical sperm morphology, decreased weights of the testes and epididymides, seminiferous tubular atrophy, and incomplete spermatogenesis were all observed in male rats dosed at 3 mg/kg/day; sperm production was decreased in males dosed with 1.5 mg/kg/day (HSDB, 1990).

DNB was be mutagenic to Salmonella tyhimurium strains without metabolic activation (HSDB, 1990).

3.1.4.2 Ecotoxicity

Aquatic Organisms

In acute tests with freshwater organisms, bluegill and rainbow trout were the most sensitive vertebrate species to DNB, with 96-hour LC50 values of 1.44 and 1.70 mg/L, respectively (see Table 3.1-11). Van der Schalie (1983) performed a dynamic acute test with rainbow trout that lasted 30 days and produced an LC50 of 0.37 mg/L.

Only one species (rainbow trout) was found in a 68-day chronic test for DNB which produced results greater than the acute test for the same species by the same author (see Table 3.1-12). The greatest sensitivity for early life stage-no-effect concentration (ELS-NEC) was 0.44 mg/L (>0.37 mg/L in the acute test).

Terrestrial Organisms

See Sec. 3.1.4.2 for additional information on this compound as regards plants. No data were found on the effect(s) to terrestrial plants or animals other than those data noted in Sec. 3.1.3.1.

3.1.4.3 Criteria and Standards

See Sec. 3.1.4.2.

3.1.5 TNB

TNB is an explosive and, although it is less sensitive to impact than TNT, it is considered more powerful and brisant. No photolysis of TNB was reported (LLNL, 1987), nor was hydrolysis reported to occur for TNB (EPA, 1979; LLNL, 1987). TNB was oxidized in the laboratory by a 2-step process involving activated sewage sludge in conjunction with a microorganism (LLNL, 1987).

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Table 3.1-11. Acute Toxicity of DNB to Aquatic Organisms

Scientific Name (Common Name)	Effect	S/F	Duration (hours or days)	Concentration hg/L)	Reference
INVERTEBRATES					
Daphnia magna	LC5O	S	48 hr	49.6	Liu et al., 1983 (LLNL, 1987)
	LC5O	S	48 hr	27.4	van der Schalie, 1983 (LLNL, 1987)
VERTEBRATES					
Oncorhvncus mykiss (was Salmo gairdneri) Rainbow trout)	LC5O	S	96 hr	1.70	van der Schalie, 1983 (LLNL, 1987)
	LC5O	F	30 days	0.37	van der Schalie, 1983 (LLNL l987)
Pimephales promelas (Fathead minnow)	LC5O	S	96 hr	7.0	Liu et al., 1983a (LLNL, 1987)
	LC5O	S	96 hr	7	Bailey and Spanggord, 1983 (LLNL, 1987)
	LC5O	S	96 hr	16.8	van der Schalie, 1983 (LLNL, 1987)
Lepomis macrochirus (Bluegill)	LC5O	S	96 hr	1.44	van der Schalie, 1983 (LLNL. 1987)
Ictalurus punctatus (Channel catfish)	LC5O	S	96 hr	8.13	van der Schalie, 1989 (LLNL, 1987)

Note: References in parentheses are secondary sources.

Source: ESE.

Table 3.1-12. Chronic Toxicity of DNB to Aquatic Organisms

Scientitic Name (Common Name)	Effect	S/F	Duration (hours or days)	Concentration (mg/L)	Reference
VERTEBRATES					
Oncorhyncus mykiss (was Salmo gairdneri) (Rainbow trout)	ELS-NEC	S	**68-day**	**0.84**	van der Schalie, 1983
	ELS-NEC	S	**68-day**	**0.97**	van der Schalie, 1983
	ELS-NEC	S	68-day	0.44*	van der Schalie, 1983
	ELS-NEC	S	68-day	0.50*	van der Schalie, 1983
	NEC			0.16*	van der Schalie, 1983

Note: S = static test.

*Because of the 96 hour flow-through, LC50 (see Table 3.1-11) is lower than the ELS-NEC. Using a value of 0.16 m/L as the NEC is recommended.

Source: LLNL, 1987.

Volatilization is not expected to be an important migration pathway for TNB because of the low vapor pressure, which is reported to be 3.03 x 10^{-6} mmHg at 25°C (LLNL, 1987; EPA, 1979).

3.1.5.1 Health Effects Assessment

Data on the toxicity of TNB are insufficient for deriving a RfD. Based on the rat oral LD50 values for DNB and TNB, which are 83 mg/kg-bw and 450 mg/kg-bw respectively, EPA deems it appropriate to use the DNB rat drinking water study to derive the RfD for TNB. Adjusting the 0.4 mg/kg/day for DNB for molecular weight difference, the corresponding equivalent intake was calculated to be 0.51 mg/kg/day (BUS, 1990). Because the RfD is derived by analogy to a structurally similar compound, a greater uncertainty factor was applied. The oral chronic and interim oral subchronic RfD values are 0.00005 mg/kg/day (IRIS, 1990) and 0.0005 mg/kg/day (HFAST, 1990), respectively.

The toxic effects reported for TNB are the same as for NB and DNB, consisting primarily of damage to the CNS and liver (HSDB, 1990). Death from any of these compounds, although uncommon, is usually due to cardiovascular collapse, and not respiratory paralysis (HSDB, 1990).

No data were presented regarding any reproductive effects of TNB (IRIS, 1990; HEAST, 1990; HSDB, 1990). TNB is mutagenic with several of the Salmonella typhimurium strains; however, metabolic activation reduced the magnitude of the responses (HSDB, 1990).

3.1.5.2 Ecotoxicity

Aquatic Organisms

Only one example was found in the literature regarding the acute effects of TNB to aquatic macrophytes (see Table 3.1-13). In tests using the algae Selenastrum capricomutum, van der Schalie (1983) reported a growth inhibition (with respect to controls) at all concentrations tested (ranging from 0.10 to 17.32 mg/L.)

In 48-hour acute tests with the water flea (Daphina magna), Liu et al. (1983a) reported an LC50 of 2.7 mg/L, and van der Schalie (1983) reported an EC50 at 2.98 mg/L (for immobilization). In completion of the 96-hour LC50 tests with fathead minnows, Bailey and Spanggord (1983) and Liu et al. (1983a) reported concentrations of 1.1 mg/L. However, tests by van der Schalie (1983) present conflicting data with results of 0.49 mg/L and 1.03 mg/L for the same species. Channel catfish was the most sensitive species at 0.38 rng/L (van der Schalie, 1983).

A 21-day chronic toxicity study with daphnia indicated that the no-effect range was between 0.47 and 0.75 mg/L, showing that these ‘invertebrates were less sensitive to TNB than the fathead minnow and rainbow trout (see Table 3.1-14).

Terrestrial Organisms

For data on the effects of 1,3,5-TNB to terrestrial organisms, see Sec. 3.1.3.1. No data were found regarding the effects of this compound to wildlife.

Table 3.1-13. Acute Toxicity of TNB to Aquatic Organisms (Continued, Page 2 of 2)

Species	Effect	S/F	Duration (hours)	Concentration (mg/L	Reference
Pimephales Promeles (Fathead minnow)	LC50	S	96		l.l Liu et al., 1983a (LLN, l987)
					O.Svan der Schalie, 1983 (LLNL, 1987)
	LC50	S	96		1.03van der Schalie, 1983 (LLNL, 1987)
	LC50	S	96		l.lBailey and Spanggord, 1983 (LLNL, 1987)
Lepomis macrochirus (Bluegill)	LC50	S	96		0.85van der Schalie, 1983 (LLNL, 1987)
Ictalurus punctatus (Channel catfish)	LC50	S	96		0.38van der Schalie, 1983 (LLNL, 1987)

Note: References in parentheses are secondary sources.

Source: ESE.

Table 3.1-14. Chronic Toxicity of TNB to Aquatic Organisms

Species	Effect	S/F	Duration (hours or days)	Concentration mg/L)	Reference
INVERTEBRATES					
Daphnia magna	NEC	S	21 days	0.47 to 0.75	van der Schalie, 1983
VERTEBRATES					
Oncorhyncus mykiss (Rainbow trout)	LC50	S	18 days	0.43	van der Schalie, 1983
pimenhales promeles (Fathead minnow)	LC50	S	10 days	0.46	van der Schalie, 1983
	ELS-LEC	S		0.12	van der Schalie, 1983
	ELS-NEC	S		0.08	van der Schalie, 1983

Note: ELS-LEC = early life stage-lowest-effect concentration.

Source: LLNL, 1987.

3.1.5.3 Criteria and Standards

No federal AWQC are available for TNB.

3.1.6 ANILINE

Aniline, which is toxic to humans, is a colorless to brown, oily liquid. Aniline and its methylated derivatives are used in the production of dyes, rubber, pesticides, and pharmaceuticals and in the oil and coal industry.

3.1.6.1 Chemical and Physical Properties

Property	Value	References
Chemical formula	$C_6H_5NH_2$	Joseph, 1985
Molecular weight	93.14	Sax and Lewis, 1989
Boiling point	184°C	Joseph, 1985
Melting point	6.2C	Joseph, 1985
Water solubility	3.5	Joseph, 1985
Vapor pressure	0.6 mmHg	Joseph, 1985
Henrys law constant	1.2×10^{-4}	HSDB, 1990
K_{oc}	NA	NA
$Log_{10} K_{ow}$	NA	NA
Kd	NA	NA

Note: NA = not available.

3.1.6.2 Fate and Transport

Aniline and its derivatives are found in industrial wastewater effluents and in soils mainly as a degradation product of herbicides. In water, aniline decomposes by microbial degradation and photooxidation. Adsorption to sediments and humic materials is moderate and occurs predominantly under

acidic conditions; sorption to colloids is high and may accelerate leaching in groundwater (HSDB, 1990). In air, aniline is photodegradable (HSDB, 1990).

3.1.6.3 Health Effects Assessment

EPA has not derived either oral or inhalation RfD values for aniline (IRIS, 1990; HEAST, 1990). Although methemoglobin is the most prominent noncarcinogenic symptom of aniline toxicity in humans, acute toxicity also causes CNS symptoms, including dyspnea; tachycardia; headache; dizziness; and, in severe cases, possible photophobia, weakness of vision, and slow pupillary action (HSDB, 1990). Other symptoms include cardiac effects, such as heart blocks, arrhythmia, and shock; fatalities usually occur because of cardiovascular collapse and respiratory paralysis (HSDB, 1990).

Acute animal toxicity studies have found that, for most species, the oral LD50 ranges from 440 mg/kg-bw to 500 mg/kg-bw; a similar range of values is reported for dermal exposure (Berkowitz et al., 1978). Acute exposure to aniline leads to the formation of methemoglobin (Doull et al., 1986), which is followed by a corresponding depression of the CNS. The exposure of rabbits to doses up to 50 mg/kg-bw resulted in cyanosis and coma, but no methemoglobin was reported (Berkowitz et al., 1978). Rats exposed to a dose of 22 mg/day in drinking water for a lifetime evidenced SO-percent mortality by day 450 and 100 percent mortality by day 750 (IRIS, 1990). Following the exposure of rats, mice, guinea pigs, and dogs to 5 ppm concentrations in air, only rats evidenced an increase in methemoglobinemia (HSDB, 1990).

EPA (IRIS, 1990) has classified aniline as a group 82 (probable human) carcinogen for oral and inhalation exposure. This classification indicates that

data are insufficient regarding the carcinogenicity in humans but that sufficient animal carcinogenicity data exist. The oral cancer slop factor is 0.0057 $(mg/kg/day)^{-1}$; no inhalation value is available. The primary animal data were derived from a study in which rats were exposed to aniline hydrochloride at dietary levels of 200, 600, or 2,000 mg/kg-feed for 2 years (IRIS, 1990). Splenic sarcomas were observed in the high-dose males, and lesions considered to be precursors to the sarcomas were observed in the high-dose males and, to a lesser degree, in the female rats. Following exposure to aniline hydrochloride at dietary levels of either 3,000 or 6,000 mg/kg-feed for 2 years, statistically significant increases in hemangiosarcomas and fibrosarcomas were observed in the high-dose male rats; other sarcomas were also observed to be increased in the high-dose males (IRIS, 1990). Mice provided food containing aniline hydrochloride at either 6,000 or 12,000 mg/kg evidenced no carcinogenic effects (IRIS, 1990). Rats provided drinking water containing up to 0.12-percent aniline either alone or in combination with the co-mutagen norhaman for 80 weeks evidenced no carcinogenic effects (IRK, 1990).

Aniline was generally nonmutagenic to Salmonella typhimurium except in the presence of the co-mutagen norharman (HSDB, 1990). It was mutagenic in a lymphoma gene mutation assay and caused increased sister chromatid exchanges in vivo in mice and chromosomal aberrations (HSDB, 1990). It was identified as a potential developmental toxin in mammals and amphibians (HSDB, 1990).

3.1.6.4 Ecotoxicity

Aquatic Organisms

Baxrerton et al. (1978) conducted algal assays and liquid culture toxicity tests on several species of blue-green algae, other algae, and bacteria. Results showed that blue-green algae are much more sensitive to aniline and p-toluidine, a methylated derivative, than are the other organisms.

In a study by Witherspoon (1980), population density of Chlorella vulgaris fluctuated with corresponding fluctuations in aniline concentrations in a dye-manufacturing plant waste effluent. In a study a Chlorella (Amman and Terry, 1985), aniline concentrations of 183.9 ppm affected growth, respiration, and photosynthesis. Primary production would be affected over time through sublethal exposures and could be eliminated altogether (Amman and Terry, 1985).

In acute LC50 tests, Daphnia were the most sensitive species tested; midge, snails, and goldfish were the most resistant (see Table 3.1-15). In studies on amphibians, acute LC50 values ranged from 440 to 560 mg/L (HSDB, 1990). Information on chronic studies was not found in the available literature.

Aniline does not bioaccumulate in fish, although it is absorbed and metabolized (HSDB, 1990). For three fish species, the log BCFs are 0.78, 1.0, and 5, and for algae, the log BCF is 0.60 (HSDB, 1990). Aniline is a metabolite of NB, and bioaccumulation via this pathway may occur as well (EPA, 1980).

C-AAAPSRIFS.7/BEA-V.21
12/18/90

Table 3.1-15. Acute LC50 Values of Aniline in Selected Aquatic Species

Scientific Name	*Common Name* or Group	LC50 value	Water Hardness *(mg/L* $CaCO_3$	Reference*
Tanytarsus dissimilis	Midge	>219	NA	Holcombe et al., 1987
Apexa hypnorum	Snail	>210	NA	Holcombe et al., 1987
Daphnia pulex, D. cucculata, and D. magna	Water Flea	0.1 to 0.68	NA	Canton, 1978; Bringham and Kuehn, 1977; Holcombe et al., 1987
Ambystoma mexicanum	Mexican axolotl	440	NA	Verscheuren, 1983
Xenopus laevis	Clawed toad	560	NA	Sloof and Baersecman, 1980
Micropterus sp.	Bass	5.2 to 47.3 4.4 to 43.2	so 200	Marking and Kimerle, 1979 Marking and KimerIe, 1979
Lepomis macrochitus	Bluegill	49.0	NA	Holcombe et al., 1987
Carascius auratus	Goldfish	5.5 to 10.2 4.7 to 10.0 187	50 200 NA	Marking and Kimerle, 1979 Marking and Kimerle, 1979 Holcombe et al., 1987
Ictalurus punctatus	Catfish	5.6 5.0 to 7.4	50 200	Marking and Kimerle, 1979 Marking and Kimerle, 1979
Leuciscus idus melanotus	Golden orfe	51 to 92	NA	Juhnke, 1978
Oncorhyncus mykiss	Rainbow trout	8.2 to 40.5	NA	Abram and Sims, 1982; Holcombe et al., 1987
Pimephales promelas	Fathead minnow	77.9 134	NA 47	Holcombe et al., 1987 Brooke et al., 1984
Catostomus commersoni	White sucker	78.4	NA	Holcombe et al., 1987

Note: NA = not available.

*References cited from HSDB, 1990.

Source: ESE.

Terrestrial Organisms

In studies conducted on the effects of aniline on seedling crops, Nozzolillo (1971) reported that germination and pigmentation were affected and abnormal development occurred following a dose of 0.01 to 0.05 M aniline; root tip destruction was a major deformity. Growth was completely inhibited in bush beans and runner beans at concentrations of 0.03 to 0.05 M.

Results of vertebrate studies report an oral LD50 for rats of 250 mg/kg, an inhalation LC_{LO} of 250 ppm per 7 hours, and an LD50 of 1,400 mg/kg (Sax and Lewis, 1989). At dietary levels of 10, 30, or 100 mg/kg, changes in spleen function were noted (HSDB, 1990). The oral LD50 for dogs is 195 mg/kg, and the skin LD_{LO} is 1,540 mg/kg (Sax and Lewis, 1989). In rabbits, oral and skin LD_{LO} values are 1,000 mg/kg and 820 mg/kg, respectively.

No information was found in the available literature for chronic study results or BCF data.

3.1.6.5 Criteria and Standards

The OSHA permissible exposure limit (PEL) for humans reports skin exposure of S ppm [time-weighted average (TWA)]; the ACGIH TLV reports 2 ppm (TWA) (Sax and Lewis, 1989). No AWQC are available for aniline.

3.2 ASBESTOS

Asbestos is a generic term applied to numerous naturally occurring, fibrous mineral silicates. Asbestos minerals are separated into two major groups, serpentine (which includes the mineral chrysotile) and amphibole (which includes the minerals amosite, crocidolite, anthophyllite, tremolite, as well as

actinolite minerals). Chrysotile is the major type of asbestos used in the manufacture of asbestos products such as asbestos cement pipe, flooring products, paper products (e.g., padding), friction materials (e.g., brake linings and clutch facings), rooting products, and coating and patching compounds (EPA, 1980a).

3.2.1 HEALTH EFFECTS ASSESSMENT

Asbestos risks are limited to workplace exposure only.

3.2.2 ECOTOXICITY

3.2.2.1 Aquatic Organisms

Few data exist currently concerning the effects of asbestos on freshwater aquatic organisms. In fish tissue studies analyzed by transmission electron microscopy, however, microscopic inorganic particles of asbestos were found. Tissue samples obtained from organisms in a river with known chrysotile asbestos contamination and brook trout, lake trout, and channel catfish exposed to water contaminated with amphibole fibers contained mineral fibers identical to those in the water. Muscle tissue concentrations were about one-twelfth the average water concentrations by volume, but liver and kidney fiber concentrations were 500 times greater than muscle tissue concentrations (HSDB, 1990).

Mussels (Mytilus edulis) exposed to water containing asbestos mine tailings in concentrations up to 100 mg/L were examined after exposure. Fibers were found in the epithelial tissue of the stomach and intestinal tract and persisted *even* when the mussels were kept in unpolluted water for several weeks.

Appendix F4
Aster Ecotoxicity Profiles

U.S. Environmental Protection Agency
Environmental Research Laboratory-Duluth

Contact: Scientific Outreach Program
218-720-5602 or fax 218-720-5539

Rep 118-96-7 2,4,6-Trinitrotoluene

I. CHEMICAL IDENTIFICATION

Name	2,4,6-Trinitrotoluene
CAS number	118-96-7
SMILES	c(c(cc1N(=O)=O)N(=O)=O)c(c1C)N(=O)=O
Formula	C7 H5 N3 06

II. ENVIRONMENTAL EXPOSURE ASSESSMENT

Parameter	Value	Source	Reference
Molecular Weight (g/mole)	227.1	Calc.	
Melting Point (C)	82.0	ASTER	
Boiling Point (C)	391	Calc.	
Vapor Pressure (mm of Hg)	1.49E-08	talc.	
Ht Vaporization (Cal/mole)	1.84E+04	talc.	
Solubility in Water (mg/L)	7.16E+03	talc.	
Log P	1.46	CLogP	3573
pKa	not available for this chemical		
Adsorption Coef (log Koc)	2.13	talc.	
Henry's Constant (atm-m**3/mole)	6.20E-13	talc.	

Parameter	Value	Source	Reference
Henry's Constant (atm-m**3/mole)	6.20E-13	Calc.	
Log10 (Henry's Constant) (atm-m**3/mole)	-12.2	Calc.	
Hydrolysis Half-life (days)	hydrolysis unlikely		
BOD Half-life:	HALF LIFE 2 TO 16 DAYS	Calc.	

Mackay Level 1 Environmental Partitioning @25 C Fugacity = 8.938E-13 Pa

0.00 % into air
0.23 % into soil
99.56 % into water
0.00 % into suspended solids
0.00 % into aquatic biota
0.21 % into sediment

III. ECOTOXICOLOGICAL HAZARD ASSESSMENT

Aquatic Hazard Identification

ACUTE DATA

Species Common Name Species Latin Name	Ex Ty	Dur (days)	End point	Effect	Conc Type	Conc (ug/L)	Source	Ref No.
FRESHWATER								
20482: scud Hyalella azteca	S	2.00	LC50	MOR		6500	AQUIRE	6502
20481: Water flea Daphnia magna	S	2.00	LC50	MOR		11900	AQUIRE	6502

BIOCONCENTRATION DATA

Species Common Name Species Latin Name	Ex Ty	Dur (days)	End point	Effect	Conc Type	Conc (ug/L)	Source	Ref No.
FRESHWATER								
128007: Fathead minnow Pimephales promelas	F	2.00-304	BCF	RSD	calcu-lated	6	QSAR	7

OTHER DATA

Species Common Name Species Latin Name	Ex Ty	Dur (days)	End point	Effect	Conc Type	Conc (ug/L)	Source	Ref No.
FRESHWATER								
20480: Oligochaete Lumbriculus variegatus	s2	2.00	LC50	MOR		4900	AQUIRE	6502
20483: Midge Tanytarsus dissimilis	S	2.00	LC50	MOR		24800	AQUIRE	6502

Human Health Hazard Identification

There is no information in the QSAR SYSTEM which would suggest that this chemical is a potential carcinogen or mutagen.

IV. ECOLOGICAL RISK CHARACTERIZATION

A. Environmental Exposure Assessment

Henry's Constant = 6.20E-13 atm-m**3/mole
Log10 (Henry's Constant) = -12.2 atm-m**3/mole

Lyman et al. 1982 would conclude that a chemical with these properties is non-volatile. See page 15-15.

Hydrolysis is not likely to be an important transformation mechanism for this chemical.

B. Ecotoxicological Hazard Assessment

Genetic/Mutagenic Assessment

There is no information in the QSAR SYSTEM which would suggest that this chemical is a potential carcinogen or mutagen.

REACTIVE DINITRO GROUP Dinitroaromatic compounds have generally been associated with an intoxication syndrome that is consistent with a chemical reactivity-based mode of action. This reactivity may be the result of two electron metabolic reductions to electrophilic nitroso compounds [178] or one electron reductions to nitro anion free radicals that redox cycle with oxygen, resulting in oxidative stress [3410].

When sufficient data is available from fathead minnow early life stage (ELS) tests (32-d exposures) completed at ERL-Duluth, QSAR models have been developed to predict chronic values for either survival or growth, which ever is the most sensitive endpoint. A chronic value is defined as the geometric mean of the LOEC (lowest observable effect concentration) and the NOEC (no observable effect concentration). These models have been developed for groups of xenobiotics that have been classified based on their acute modes of toxic action. Empirical observations suggest that when a statistically robust ELS QSAR can be established and when 96-h LC50/32-d ELS chronic value ratios are within a factor of 20 it is reasonable to assume that adverse effects are elicited through the same mode of toxic action in both 4-d and 32-d exposures. If during a chronic exposure a different mode of action is involved, or if metabolic activation is significant, the ratios between acute and chronic endpoint values for a group of xenobiotics are generally quite variable and typically exceed two orders of magnitude. In addition, the statistical strength of ELS QSARs in these instances are poor.

A chronic value cannot be calculated for the fathead minnow for chemicals with a reactive mode of action. 96-h LC50/32-d ELS chronic value ratios for reactive toxicants tested at ERL-Duluth using the fathead minnow range from 1 to 19.5 (log P range of 0.21 to 7.54).

C. Other Information

More information on this chemical is available through the US EPA's Office of Health and Environmental Assessment's IRIS (Integrated Risk Information System) data base.

V. CITATION INFORMATION

REFERENCE NUMBER: 7

Veith, G.D. and P. Kosian

1983

Estimating Bioconcentration Potential from Octanol/Water Partition Coefficients

In: D. Mackay et al., (Eds.), Physical Behavior of PCBs in the Great Lakes, Ann Arbor Science Publishers, Ann Arbor, MI:269-282

REFERENCE NUMBER: 178

Deneer, J.W., T.L. Sinnige, W. Seinen, and J.L.M. Hermens

1987

Quantitative Structure-Activity Relationships for the Toxicity and Bioconcentration Factor of Nitrobenzene Derivatives towards the Guppy . . .

Aquat. Toxicol. 10(2-3): 115-129

REFERENCE NUMBER: 3410

Mason, R.P.

1990

Redox Cycling of Radical Anion Metabolites of Toxic Chemicals and Drugs and the Marcus Theory of Electron Transfer

Environ. Health Perspect. 87:237-243

REFERENCE NUMBER: 3573

Leo, A. and D. Weininger

1988

Daylight Software Version 3.53 for VAX-11 under VMS 4.6+, CLOGP version 3.4

Pomona Medicinal Chemistry Project, Pomona College, Claremont, C.A. Distributed by Daylight Chemical

Information Systems, Inc., 3951 Claremont St., Irvine, C.A. 92714

REFERENCE NUMBER: 6502

Bailey, H.C. and D.H.W. Liu

1980

Lumbriculus variegatus, a Benthic Oligochaete, As a Bioassay Organism

In: J.C. Eaton, P.R. Parrish, and A.C. Hendricks (Eds.),

Aquatic Toxicology and Hazard Assessment, 3rd Symposium,

ASTM STP 707, Philadelphia, PA:205-215

OTHER DATA FROM AQUIRE

ASTER processes all Ecotoxicological Hazard Assessment information through a filter which removes data from the final Report which may not be of the highest quality. This appendix contains Other Data that did not meet the filter requirements, but is contained in the AQUIRE database.

ACUTE DATA

Species Common Name Species Latin Name	Ex Ty	Dur (days)	End point	Effect	Conc Type	Conc (ug/L)	Source	Ref No.
FRESHWATER								
31278: Water flea Daphnia magna	S	2.00	EC50	IMM		11900		5087
40133: Water flea Daphnia magna	S	2.00	LC50	MOR		6600		6021
63020: Bluegill Lepomis macrochirus	S	4.00	LC50	MOR		2200		6041
63021: Bluegill Lepomis macrochirus	S	4.00	LC50	MOR		2100		6041
63022: Bluegill Lepomis macrochirus	S	4.00	LC50	MOR		2200		6041
63023: Bluegill Lepomis macrochirus	S	4.00	LC50	MOR		2700		6041
63024: Bluegill Lepomis macrochirus	S	4.00	LC50	MOR		2800		6041

Species Common Name Species Latin Name	Ex Ty	Dur (days)	End point	Effect	Conc Type	Conc (ug/L)	Source	Ref No.
63025: Bluegill Lepomis macrochirus	S	4.00	LC50	MOR		4100		6041
63026: Bluegill Lepomis macrochirus	S	4.00	LC50	MOR		2700		6041
63027: Bluegill Lepomis macrochirus	S	4.00	LC50	MOR		2800		6041
63028: Bluegill Lepomis macrochirus	R	4.00	LC50	MOR		2300		6041
63029: Bluegill Lepomis macrochirus	R	4.00	LC50	MOR		1600		6041
63030: Bluegill Lepomis macrochirus	R	4.00	LC50	MOR		2300		6041
63031: Bluegill Lepomis macrochirus	R	4.00	LC50	MOR		2300		6041
20477: Bluegill Lepomis macrochirus	S	4.00	LC50	MOR		3000		6502
33459: Fathead minnow Pimephales promelas	F	4.00	LC50	MOR		2580		926
122680: Fathead minnow Pimephales promelas	F	4.00	LC50	MOR		1600		926
122680: Fathead minnow Pimephales promelas	S	4.00	LC50	MOR		2400		5087
40132: Fathead minnow Pimephales promelas	S	4.00	LC50	MOR		2400		6021
40135: Fathead minnow Pimephales promelas	S	4.00	LC50	MOR		1200		6021
40137: Fathead minnow Pimephales promelas	S	4.00	LC50	MOR		2000		6021
20484: Fathead minnow Pimephales promelas	S	4.00	LC50	MOR		3100		6502
71225: Fathead minnow Piiephales promelas	S	4.00	LC50	MOR		3000		10141

Species Common Name Species Latin Name	Ex Ty	Dur (days)	End point	Effect	Conc Type	Conc (ug/L)	Source	Ref No.
20479: Channel catfish Ictalurus punctatus	S	4.00	LC50	MOR		2400		6502
20478: Rainbow trout, donaldson trout Oncorhynchus mykiss	S	4.00	LC50	MOR		1200		6502

PLANT DATA

Species Common Name Species Latin Name	Ex Ty	Dur (days)	End point	Effect	Conc Type	Conc (ug/L)	Source	Ref No.
FRESHWATER								
36218: Green algae Selenastrum capricomutum	S	7.00		PGR		2500		2476
36218: Green algae Selenastrum capricomutum	S	7.00		PGR		1000		2476
46514: Duckweed Lemna perpusilla	S	11.0		PGR		1000		8706
46515: Duckweed Lemna perpusilla	S	11.0		PGR		500		8706
46516: Duckweed Lemna perpusilla	S	11.0		PGR		100		8706
46517: Duckweed Lemna perpusilla	S	11.0		PGR		1000		8706
MEDIA NOT REPORTED								
37241: Green algae Scenedesmus quadricauda	S	NR		MOR		1600		2463
20988: Green algae Scenedesmus qluadricauda	S	NR		PGR		1600		7453

Species Common Name Species Latin Name	Ex Ty	Dur (days)	End point	Effect	Conc Type	Conc (ug/L)	Source	Ref No.
24994: **Green algae** **Scenedesmus quadricauda**	**S**	**7.00**		**PGR**		**1600**		**5303**
57370: Green algae Scenedesmus quadricauda	S	8.00		PGR		1600		15134
33461: Green algae Scenedesmus quadricauda	S	13.0		PGR		7000		926
16758: Cryptomonad Chilomonas paramecium	NR	2.00		PGR		5400		5719
24995: Flagellate euglenoid Entosiphon sulcatum	S	3.00		PGR		1600		5303
37240: Blue-green algae Anacystis aeruginosa	S	NR		MOR		320		2463
57371: Blue-green algae Anacystis aeruginosa	S	8.00		PGR		320		15134
33463: Blue-green algae Anacystis aeruginosa	S	17.0		PGR		50000		926
28080: Blue-green algae Anacystis aeruginosa	S	1.00	LETH	MOR		8000		8065

OTHER DATA

Species Common Name Species Latin Name	Ex Ty	Dur (days)	End point	Effect	Conc Type	Conc (ug/L)	Source	Ref No.
FRESHWATER								
87879: Water flea Daphnia magna	S	1.00	EC0			9mg/L		707
114398: Water flea Daphnia magna	S	1.00	EC100			23mg/L		707

Species Common Name Species Latin Name	Ex Ty	Dur (days)	End point	Effect	Conc Type	Conc (ug/L)	Source	Ref No.
94441: Water flea Daphnia magna	S	1.00	EC50			18 mg/L		707
20989: Water flea Daphnia magna	S	1.00	LC50	MOR		14000		5718
33460: Fathead minnow Pimephales promelas	F	4.00	EC50	BEH		460		926
122681: Fathead minnow Pimephales promelas	F	4.00	EC50	BEH		460		926
40134: Fathead minnow Pimephales promelas	S	1.00	LC50	MOR		4200		6021
40136: Fathead minnow Pimephales promelas	S	1.00	LC50	MOR		>3200		6021
40138: Fathead minnow Pimephales promelas	S	1.00	LC50	MOR		3000		6021
115906: Rotifer Brachonus calyciflorus	S	2.00	EC50	REP		4000		3963
115907: Rotifer Brachionus calyciflorus	S	2.00	LC50	MOR		9100		3963
115905: Rotifer Brachionus calyciflorus	S	2.00	LOEC	REP		5000		3963
115904: Rotifer Brachionus calyciflorus	S	2.00	NOEC	REP		2300		3963
SALTWATER								
36220: Harpacticoid copepod Tigriopus califomicus	S	3.00		MOR		2500		2476
36221: Harpacticoid copepod Tigriopus califomicus	S	3.00		MOR		1000		2476

Species Common Name Species Latin Name	Ex Ty	Dur (days)	End point	Effect	Conc Type	Conc (ug/L)	Source	Ref No.
36222: **Pacific oyster** **Crassostrea gigas**	**S**	**4.00**		**MOR**		**5000**		**2476**
36223: Pacific oyster Crassostrea gigas	S	4.00		MOR		10000		2476

CITATION INFORMATION

REFERENCE NUMBER: 707

Bringmann, G. and R. Kuhn

1982

Results of Toxic Action of Water Pollutants on Daphnia magna Straus Tested by an Improved Standardized Procedure

Z. Wasser-Abwasser-Forsch. 15(l): l-6 (GER) (ENG ABS)

REFERENCE NUMBER: 926

Smock, L.A., D.L. Stoneburner, and J.R. Clark

1976

The Toxic Effects of Trinitrotoluene (TNT) and its Primary Degradation Products on Two Species of Algae and the Fathead Minnow

Water Res. 10(6):537-543

REFERENCE NUMBER: 2463

Bringmann, G. and R. Kuhn

1978 A

Limiting Values for the Noxious Effects of Water Pollutant Material to Blue Algae (Microcystis aeruginosa) and Green Algae Scenedesmus...

Vom Wasser 50:45-60 (GER) (ENG ABS)

REFERENCE NUMBER: 2476

Won, W.D., L.H. Disalvo, and J. Ng

1976

Toxicity and Mutagenicity of 2,4,6-Trinitrotoluene and its Microbial Metabolites

Appl. Environ. Microbial. 31(4):576-580

REFERENCE NUMBER: 3963

Snell, T.W. and B.D. Moffat

1992

A 2-D Life Cycle Test with the Rotifer Brachionus calyciflorus

Environ. Toxicol. Chem. 11(9):1249-1257

REFERENCE NUMBER: 5087

Pearson, J.G., J.P. Glennon, J.J. Barkley, and J.W. Highfill

1979

An Approach to the Toxicological Evaluation of a Complex Industrial Wastewater

In: L.L. Marking and R.A. Kimerle (Eds.), Aquatic Toxicology and Hazard Assessment, 2nd Symposium, ASTM STP 667, Philadelphia, PA:284-301 (Author Communication Used)

REFERENCE NUMBER: 5303

Bringmann, G. and R. Kuhn

1980 A

Comparison of the Toxicity Thresholds of Water Pollutants to Bacteria, Algae, and Protozoa in the Cell Multiplication Inhibition Test

Water Res. 14(3):231-241 (Author Communication Used)

REFERENCE NUMBER: 5718

Bringmann, G. and R. Kuhn

1977

Results of the Damaging Effect of Water Pollutants on Daphnia magna

Z. Wasser-Abwasser-Forsch. 10(5):161-166 (GER) (ENG ABS)

REFERENCE NUMBER: 5719

Bringmann, G., R. Kuhn, and A. Winter

1980

Determination of Biological Damage From Water Pollutants to Protozoa. III. Saprozoic Flagellates

Z. Wasser-Abwasser-Forsch. 13(5): 170-173 (GER) (ENG ABS)

REFERENCE NUMBER: 6021

Liu, D.H.W., R.J. Spanggord, and H.C. Bailey

1976

Toxicity of TNT Wastewater (Pink Water) to Aquatic Organisms

Contract No. DAMD 17-75-C-5056, Defense Technical Information Center, No. ADA031067, U.S. Army Med. Res. Develop. Command, Washington, D.C.:33 p.

REFERENCE NUMBER: 6041

Pederson, G.

1970

Sanitary Engineering Special Study No. 24-007-70/71

Evaluation of Toxicity of Selected TNT Wastes on Fish Phase I-Acute Toxicity of alpha-TNT to ...

Army Environ. Hygiene Agency, Edgewood Arsenal, MD:35 p.

(U.S. NTIS AD-725572)

REFERENCE NUMBER: 6502

Bailey, H.C. and D.H.W. Liu

1980

Lumbriculus variegatus, a Benthic Oligochaete, As a Bioassay Organism

In: J.C. Eaton, P.R. Parrish, and A.C. Hendricks (Eds.), Aquatic Toxicology and Hazard Assessment, 3rd Symposium, ASTM STP 707, Philadelphia, PA:205-215

REFERENCE NUMBER: 7453

Bringmann, G. and R. Kuhn

1977 A

Limiting Values for the Damaging Action of Water Pollutants to Bacteria (Pseudomonas putida) and Green Algae (Scenedesmus quadricauda) in the...

Z. Wasser-Abwasser-Forsch. 10(3/4):87-98 (GER) (ENG ABS)

REFERENCE NUMBER: 8065

Fitzgerald, G.P., G.C. Gerloff, and F. Skoog

1952 B

Stream Pollution: Studies on Chemicals with Selective Toxicity to Blue-Green Algae

Sewage Ind. Wastes 24(7):888-896 (Author Communication Used)

REFERENCE NUMBER: 8706

Schott, C.D. and EC. Worthley

1974

The Toxicity of TNT and Related Wastes to an Aquatic Flowering Plant, 'Lemna perpusilla' Torr. Edgewood Arsenal Tech. Rep. EB-TR-74016, Edgewood Arsenal, Aberdeen Proving Grd., MD:18 p. (U.S. NTIS AD-778158) (Used Ref 9184)

REFERENCE NUMBER: 10141

Bailey, H.C. and R.J. Spanggord

1983

The Relationship between the Toxicity and Structure of Nitroaromatic Chemicals

In: W.E. Bishop, R.D. Cardwell, and B.B. Heidolph (Eds.), Aquatic Toxicology and Hazard Assessment, 6th Symposium, ASTM STP 802, Philadelphia, PA:98-107

REFERENCE NUMBER: 15134

Bringmann, G. and R. Kuhn

1978 B

Testing of Substances for Their Toxicity Threshold: Model

Organisms Microcystis (Diplocystis) aeruginosa and Scenedesmus quadricauda

Mitt. Int. Ver. Theor. Angew. Limnol. 21:275-284 (Author Communication Used)

Appendix G
Benchmark Studies

DEPARMENT OF THE ARMY
U.S. ARMY CENTER FOR HEALTH PROMOTION AND PREVENTIVE MEDICINE (PROVISIONAL)
ABERDEEN PROVING GROUND, MARYLAND 21010-5422

REPLY TO ATTENTION OF MCHB-DL-EE

EXECUTIVE SUMMARY

STUDY NO. 75-23-YS50-94
FINAL REPORT
HEALTH RISK ASSESSMENT OF CONSUMING DEER PROM ABERDEEN PROVING GROUND, MD
MAY 1995

Aberdeen Proving Ground (APG) is a United States Army installation located on the western banks of the upper Chesapeake Bay, Maryland. The APG has been in operation for over 75 years with a primary mission of research, development, and testing of munitions and military vehicles. As a results of APG being on the National Priorities List, an installation-wide he&h risk assessment is currently underway. As part of this h&h risk assessment, all potential human exposure pathways are being investigated to include the food chain. Hunters harvest approximately 800 whitetail deer from AJG annually. To assure public safety, a study was completed by the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) to identify any potential human health hazards associated with consumption of deer harvest&d from APG.

During the 1993 hunting season, scientists from USACHPPM collected 150 deer samples (muscle and liver) from hunters. These samples were analyzed for several explosives and breakdown products, polychlorinated biphenyls (PCBs), heavy metals, and organochlorine pesticides (DDT, DDD, DDE). For background and comparison purposes, deer were also sampled from areas off the installation within in the state of Maryland. Data from the chemical analyses revealed no detectable levels of explosives, PCBs, or organochlorine pesticides. However, low concentrations of several heavy metals were identified in deer from both APG and off post. These values were compressed statistically, but no consistent patterns or trends between the sites and metal tissue levels were seen.

To determine ifthese metal levels posed a hazard to consumers, a health risk assessment was completed. Actual consumption data obtained from a hunter's questionnaire was used to define exposure (eg. how much venison harvested from APG do the hunters and their families actually consume per year). Arsenic, cadmium, chromium, and mercury levels were evaluated using the U.S. Environmental Protection Agency (EPA) Guidance for Risk Assessment at Superfund Sites. Arsenic levels were also compared to established standards - Applicable or Relevant and Appropriate Requirements (ARARs). At the moment, there are no standard EPA methods to evaluate lead and no ARARs for comparison. So lead levels were evaluated using a similar method used by the U.S. Food and Drug Administration (FDA) for lead in shellfish. A synopsis of the findings and associated uncertainties is presented below.

Following the standard EPA risk assessment methodology, cadmium, chromium, and mercury levels in APG deer posed no significant risk to consumers but initially, arsenic levels appeared to contribute the most to the potential risk. However, this risk may be overestimated because ofthe conservative assumptions and uncertainties associated with the toxicity values for arsenic. Also, most reported toxicity values are derived for the inorganic form of arsenic as opposed to the less toxic organic form; but the actual forms of arsenic in deer is unknown at this time. It has been reported in the literature that only 10% of the arsenic found in shellfish is in the inorganic form.

Due to the inherent uncertainties associated with arsenic, levels were also compared to establish standards or Applicable or Relevant and Appropriate Requirements (ARARs). Arsenic levels in deer were compared ***to FDA*** arsenic standards for tolerable residues exposures in beef and pork (0.5 mg/kg and 0.7 mg/kg respectively) associated with arsenic used as a feed additive and the use of arsenical pesticides. Again, most of these values have been established for the inorganic form of arsenic. Levels in deer from APG and offpost sites were similar or slightly higher than these values. Additionally, calculated intake levels of arsenic by hunters eating deer from APG, were compared to acceptable daily intake values for arsenic established by the World Health Organization (WHO). None of the arsenic intake values based on the 95% Upper Confidence Limits exceeded any of the WHO criteria.

Currently, there are no standard EPA methods available to evaluate lead in edible tissue. Therefore, the FDA method for evaluating lead in shellfish was applied in this study. Maximum lead levels of concern were based on exposure factors (EPA standards and hunter consumption data collected during the study) and on provisional tolerable total intake levels for general and sensitive populations (ie. adults, pregnant women, school age children, and children under 6 years). Lead levels in deer tissue were compared to these acceptable maximum levels. Overall the lead levels in deer from both APG and offpost were within the acceptable safe Emits.

Based on these data and considering the conservatism and uncertainty related to the current risk assessment process, the health risk associated with consuming meat from APG deer is no greater than that associated with consuming meat from offpost deer. Therefore, consumption of ARG deer following the current practices identified in this report should not present an elevated human health hazard.

DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010-6522

REPLY TO
ATTENTION OF

HSHB-MO-T

EXECUTIVE SUMMARY
HEALTH RISK ASSESSMENT FOR CONSUMPTION OF DEER MUSCLE AND LIVER FROM JOLIET ARMY AMMUNITION PLANT

Joliet Amy Ammunition Plant (JAAP) is a Government-owned installation currently maintained in a nonproducing, caretaker status by a modified caretaker contractor (Alliant Tech Systems, Inc.). The primary activities included munition production, assembly, storage, and demilitarization. As a result of contamination from past manufacturing activities and pesticide use, a study was initiated to investigate the potential contamination of deer harvested from JAAP.

During the 1992 hunting season, samples of deer liver and muscle were obtained from hunters and analyzed for explosives, PCBs, metals, and organochlorine pesticides. Deer from an offpost site were sampled as a control. Data from chemical analyses revealed no detectable levels of explosives, PCBs, or organochlorine pesticides. Some tissue concentrations of metals were identified in muscle, liver, kidney, and bone.

A human health risk assessment following the U.S. Environmental Protection Agency's Risk Assessment Guideline showed that there were no significant risks associated with consuming deer meat from JAAP due to explosives accumulation. Detectable levels of arsenic, cadmium, chromium, mercury, and lead were found. Arsenic posed a potential health risk; however, the arsenic in offpost reference deer were higher than the JAAP deer. In all instances, the arsenic levels meet acceptable residue levels established by the US Food and Drug Adminstration for food.

BADGER ECOLOGICAL RISK ASSESSMENT

Background: A tier 1 screening level ecological assessment was performed at Badger Army Ammunition Plant, using simplified assumptions regarding chemical concentrations in prey organisms, to determine the need for further action at the site.

Methods: Abiotic sampling and simple modeling (hazard index) were performed for heavy metal contaminants found in site soils. No biota sampling was performed during this first portion of the study. Chemical concentrations in invertebrate prey organisms were assumed to be identical to measured soil concentrations (i.e., 100% bioavailability was assumed).

Results: Based on the results of the modeling, the potential for adverse risk was identified for three organisms (garter snake, meadowlark and vole) due to heavy metal contamination.

Conclusions: The unacceptably high hazard indices identified for three organisms, based on presumed uptake of heavy metal contaminants, was used as a basis for recommending further investigation at the site. Because of the highly conservative, unrealistic assumptions used in this screening evaluation, the hazard index values may not be indicative of actual site hazard. In order to confirm or refute the findings of the tier 1 study, it has been proposed that potential prey organisms (ants, ground-dwelling insects, flying insects and earthworms) be collected and analyzed for contaminants. If contaminants are found in the prey organisms, the model will be modified using measured concentrations (instead of assuming soil concentrations are equivalent to prey tissue concentrations).

Applications: This study serves as an example of how to perform a simplified, tier 1 screening level ecological evaluation, and how to use the results of the evaluation to design a tier 2 study that will identify the presence or absence of potential hazard to selected ecological receptor populations.

ABERDEEN PROVING GROUND
SNAPPING TURTLE (Chelydra serpentina)
CONTAMINATION SURVEY WORKPLAN

and

ABERDEEN PROVING GROUND
SNAPPING TURTLE CONTAMINATION SURVEY

Background: Aberdeen Proving Ground (APG), located in northeastern Maryland on the Chesapeake Bay, was established in 1917 as the Ordnance Proving Ground and was established as a munitions post in 1919. The primary mission of APG has been the development and testing of munitions, including chemical warfare agents. As a result, large areas have been impacted by chemical contaminants. Aberdeen Proving Grounds is considered a former hazardous waste site and is listed on the National Priorities List.

Many of the chemicals of concern identified at APG are known to bioconcentrate in aquatic systems and have been found in bodies of water on or adjacent to the site. Chemicals of Ecological Concern

(COECs) found or suspected to occur onsite included PCBs, organochlorine pesticides, metals, explosives and trichlorophenylurea (TCPU). At the present time snapping turtles found in these bodies of water are harvested by local fishermen for human consumption. Because these turtles are the top predators in the local aquatic ecosystem, and because many of these compounds are known to bioconcentrate, the concern existed that ingestion of turtles could constitute a potential threat to human health. Given these concerns and the fact that bioconcentration is difficult to reproduce in the laboratory, a tier 2 study was conducted whereby turtles were collected and the tissues analyzed for COECs. The analytical results were then evaluated quantitatively in a human health risk assessment.

Methods: Tissue sampling of snapping turtles was conducted to determine whether chemicals of concern identified in the existing Baseline Ecological Risk Assessment were bioconcentiating to a significant extent. Four sampling locations were selected to evaluate contaminant uptake (three contaminated areas and one reference area), based on contamination potential and snapping turtle trapper use. The potentially contaminated areas included 1) Carroll Island, used as a chemical agent test site, 2) Watson Creek, located adjacent to a hazardous waste and ordnance disposal area, and 3) Canal Creek, which receives water from lab waste disposal sites, mustard disposal pits, and various production facilities. The reference area was located approximately 5 miles upstream from APG at the Van Bibber drinking water treatment facility, an area thought to be free of site-related contaminants and unlikely to contain turtles impacted by the downstream areas.

An analysis of turtle populations and annual harvest of turtles from each of the areas was conducted to identify an optimum sample size for the study. It was estimated that 25% of the annual harvest (approximately 10 turtles per area) would provide optimum data; however, after evaluation of study areas and turtle populations, it was determined that 15% of the annual harvest (6 turtles per area) was the highest attainable number of turtles that could be collected without severely depleting the Van Bibber population. Six turtles were collected from the 3 sampling areas, and 5 were collected from the reference area. Animals were weighed, sacrificed, and tissue collected for analysis. Muscle tissue (e.g., edible tissue) was analyzed for metals, PCBs, pesticides, TCPU and explosives (see Table G-l for a list of specific analytes).

Results: No military chemicals (TCPU or explosives) were found in any turtles. Low levels of pesticides and PCBs were found in several turtles from two of the contaminated areas, but not the third area. Iron and zinc were found in turtles from all areas (including the reference area). Other metals, including mercury, silver, copper, magnesium, aluminum, chromium and nickel, were found in one or more turtles from the contaminated areas. A quantitative risk assessment of potential ingestion of turtle meat by human receptors indicates that the concentrations of contaminants in turtle tissue do not pose an unacceptable risk to human health.

Conclusions: Because snapping turtles are the top predators in the aquatic ecosystem at APG, and because they are known to bioaccumulate a number of chemicals of concern, this evaluation provided a worst-case look into bioaccumulation of APG-related contamination. Explosives and ureas associated with did not accumulate in tissue. Metals, pesticides and PCBs were found in turtle tissue below any levels of concern for human health. Based on these results, current turtle harvesting practices at APG do not need to be altered to protect human health.

Applications: Although the primary concern for this study was protection of human health, the methodologies used to identify chemicals of concern, analytical sample sizes, areas of concern and top predators can be applied to other aquatic systems where bioaccumulation is of potential concern. This study is particularly relevant in situations where military chemicals may have entered aquatic systems via runoff, groundwater seeps, or direct discharge.

TABLE G-l
ANALYTE LIST - ABERDEEN PROVING GROUND

Metals:
- Aluminum
- Antimony
- Arsenic
- Barium
- Beryllium
- Boron
- Cadmium
- Chromium
- Copper
- Iron
- Lead
- Manganese
- Mercury
- Nickel
- Selenium
- Silver
- Thallium
- Zinc

Pesticides:
- Dieldrin
- DDT (total)
- PCB (total)
- Hexachlorobenzene
- Chlordane

Explosives:
- Trinitrotoluene (TNT)
- 2,4-Dinitrotoluene @NT)
- 2,6-Dinitrotoluene @NT)
- RDX
- 1,3,5-Trinitrobenzene (TNB)
- 1,3-Dinitrobenzene (DNB)
- Tetryl

Ureas:
- Trichlorophenylurea (TCPU)

RESIDUE ANALYSIS AND HUMAN HEALTH RISK ASSESSMENT OF DEER FROM JAAP ARMY AMMUNITION PLANT

Background: Joliette Army Ammunition Plant (JAAP) is a government-owned installation that was extensively used from World War II to 1977 for munitions production, assembly, storage and demilitarization. The site is currently maintained in a nonproducing, caretaker status. Deer hunting is currently allowed onsite; however, questions have been raised concerning the safety of eating deer from military installations. Because of these potential human health concerns, a study was undertaken to evaluate the potential for bioaccumulation of site-related contaminants in deer tissues. Results of the bioaccumulation study were then used to evaluate potential human health risks associated with ingestion of deer tissue. Although similar studies have been conducted in the past (Alabama Army Ammunition Plant and Badger Army Ammunition Plant), the analytical detection limits in these previous studies were not sufficiently low to allow an accurate estimation of the levels of explosives that had bioaccumulated.

Methods: Tier 1 studies (abiotic sampling) had previously demonstrated that soils, sediment, surface water and groundwater were contaminated by a number of munitions-related chemicals. Chemicals of potential concern that were identified in the remedial investigation included a number of metals, explosives, PCBs and organochlorine pesticides. Muscle and liver tissues were collected from deer harvested at the JAAP during the deer hunting season and were analyzed for compounds identified during the remedial investigation with known bioaccumulative and/or toxic properties (Table G-2). Tissues were analyzed for PCBs, organochlorine pesticides, mercury, lead, arsenic, chromium, and cadmium. In addition, explosives analysis was conducted because of the limited information in the literature concerning potential biouptake and bioaccumulation of these compounds. Animals were harvested from four areas:

- Load, Assemble and Pack Area (20 animals).
- Manufacture Area (20 animals).
- Background (8 animals).
- Off-Post Natural Area (12 animals).

The sample size of 20 animals was deemed adequate to detect a change of one standard deviation from background with a power of 80%. Residue data were analyzed statistically using a multiway ANOVA.

A human health risk assessment was performed on chemicals detected in deer tissue (both liver and muscle) using standard USEPA methodology. Exposure factors used in the human health evaluation were modified using data from a hunter's survey.

Results: No PCBs, organochlorine pesticides or explosives were found in any tissue samples, but metal residues were found in both liver and muscle tissue. All metals except arsenic were found at comparable concentrations in deer tissue from onsite and background and offpost areas. Arsenic was found at the statistically highest concentrations in deer from the offpost nature area. A quantitative evaluation of human risk associated with ingestion of deer tissue indicated that unacceptably high risks could occur if deer tissue from either the offpost area or the manufacture area were ingested on a regular basis (potential cancer risks as high as 3.5 E-4, hazard index 1.1). The primary contributor to site risk was arsenic.

Conclusions: Although potentially unacceptable human health risks were identified for individuals eating arsenic-contaminated deer from the site, it is likely that arsenic in these tissues was due to naturally occurring background arsenic rather than site contamination. Other site contaminants, including PCBs, pesticides, explosives and metals (other than arsenic) were not found to bioaccumulate in deer tissue at concentrations that could threaten human health.

Applications: Although the primary concern for this study was protection of human health, the methodologies used to evaluate potential bioaccumulation, analytical sample sizes, areas of concern, tissues to be analyzed, and comparison to background should be relevant to other sites. This study is particularly relevant in situations where chemicals (metals, PCBs, pesticides, explosives) may enter

the human food chain through ingestion of deer (or other site herbivores, including domestic animals).

TABLE G-2
ANALYTE LIST AND REPORTING LIMITS (MC/KG)
JOLIETTE ARMY AMMUNITION PLANT (JAAP)

Metals:
- Arsenic (0.025)
- Cadmium (0.025)
- Chromium (0.025)
- Lead (0.025)
- Mercury (0.020)

Aroclors:
- 1242 (0.40)
- 1016 (0.40)
- 1248 (0.40)
- 1254 (0.70)
- 1260 (0.70)

Pesticides:
- o,p'-DDD (0.01)
- p,p'-DDD (0.0 1)
- o,p'-DDE (0.01)
- p,p'-DDE (0.01)
- o,p'-DDT (0.015)
- p,p'-DDT (0.10)

Explosives:
- 2,4,6-Trinitrotoluene (0.10)
- 2,4-Dinitrotoluene (0.05)
- 2,6-Dinitrotoluene (0.10)
- 2-Amino-4,6-Dinitrotoluene (0.20)
- 4-Amino-2,6-Dinitrotoluene (0.20)
- RDX (0.10)
- HMX (5.0)
- 1,3,5-Trinitrobenzene (0.05)
- 1,3-Dinitrobenzene (0.05)

PLANT UPTAKE OF RDX AND TNT UTILIZING SITE-SPECIFIC CRITERIA FOR THE CORNHUSKER ARMY AMMUNITION PLANT (CAAP), NEBRASKA

Background: At CAAP an underground plume of groundwater contaminated with low levels of RDX and TNT has been identified, located, and is being tracked. This plume occurs onpost, but extends offpost as well. Concern has been raised by the regulating agencies (USEPA and the State of Nebraska) that even low levels of RDX and TNT in groundwater may become substantially bioconcentrated in irrigated crops and home gardens. Previous investigations of RDX and TNT uptake by plants have not addressed uptake of these compounds from irrigation waters (previous studies focused on uptake from highly contaminated soils). The purpose of this study, which is currently ongoing, is to evaluate potential uptake and bioconcentration of RDX and TNT into edible plants, using irrigation water containing these compounds at concentrations similar to that found in groundwater.

Methods: Common food crop plants will be grown in CAAP soil under controlled, greenhouse conditions, using RDX/TNT contaminated irrigation water. Control plants will be grown under similar conditions, using uncontaminated irrigation water. Crop plants chosen for the study include common field crop species (alfalfa, soybean and corn) and garden crop species (root species - radish; seed

species - green bean; leaf species - lettuce; fruit species - tomato). Shoots and seeds of field crops and edible portions of garden crops will be evaluated for the amount of contaminants present, and growing plants will be evaluated for the presence of adverse symptoms. Chemical concentrations in plant tissues will be compared to the amount of extractable RDX and TNT in soil and the amount of RDX and TNT provided from irrigation water.

Results: Not applicable - study currently ongoing.

Conclusions: Not applicable - study currently ongoing.

Applications: Because most plant uptake studies for explosives are based on models that use highly conservative assumptions regarding biouptake/accumulation, the results of this study should provide a more realistic estimate of the degree of uptake of explosives into plant tissues. This can be useful for both human health and ecological food chain studies. Additionally, this information can be used when calculating site remediation goals that are protective of human health and the environment

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