EPA Region 10
Supplemental Ecological Risk Assessment Guidance for Superfund

EPA 910-R-97-005

June 1997

Prepared by:
US EPA Region 10
Office of Environmental Assessment
Risk Evaluation Unit

FOREWORD

The purpose of the *EPA Region 10 Supplemental Ecological Risk Assessment Guidance for Superfund* is to summarize and highlight important concepts and steps of the Remedial Investigation/Feasibility Study (RI/FS) relevant to the risk assessment. Also, it is designed to identify specific deliverables that should be submitted to Region 10 during the development of the baseline risk assessment. This guidance is a supplement to the national *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessment (EPA 1996a), Risk Assessment Guidance for Superfund, Volume II* (RAGS) (EPA 1991c&d, EPA 1989c&d) and the *Framework for Ecological risk Assessment* (EPA 1992a).

This regional guidance applies solely to risk assessments conducted at region 10 National Priorities List (NPL) sites. This guidance is primarily intended to clarify and extend the national RAGS, and unless other wise agreed upon with EPA Region 10 project manager (RPM), and/or risk assessors, the regional guidance should prevail.

Region 10 guidance is intended for use by RPMs and risk assessors preparing human health and ecological risk assessments for CERCLA NPL sites in Region 10. Other uses (e.g., risk assessments conducted at RCRA facilities) may be appropriate, but should first be approved by the RPM.

This guidance does not constitute rule-making by the Agency, and may not be relied on to create a substantive or procedural right enforceable by any other person. Region 10 reserves the right to take action that is at variance with this guidance. Contextually appropriate application of the concepts presented in *EPA Region 10 Supplemental Ecological Risk Assessment Guidance for Superfund* should help to create scientifically sound, technically defensible and consistent risk assessments in Region 10.

Updates to this guidance relating to specific technical issues and/or regarding particular relevant case study examples will be issued in the form of the *Region 10 Risk Report*, a new, intermittent regional publication. This guidance document, and subsequent issues of the *Region 10 Risk Report*, supersede all previous Ecological Risk Assessment Guidance issued from the Office of Environmental Assessment and Superfund in Region 10. Copies of the regional guidance and other related documents may be obtained from the Environmental Protection Agency, Region 10 homepage **(http://www.epa.gov/r10earth/r10.html).**

*** * * * * * ***

For questions regarding this regional guidance, contact:

Julius U. Nwosu, Region 10, Risk Evaluation Unit, 206/553-7121.

E-mail:Nwosu.Julius@epamail.epa.gov.

Table of Contents

1.0 INTRODUCTION 1

1.1 Regional Technical Guidance 2
1.2 Focus of Risk Assessment 4
1.3 Scheduling of Deliverables 5

2.0 RI/FS PROJECT PLANNING 10

2.1 Preliminary Phase (Steps 1 & 2) 10
2.2 Conceptual Site Model 11
2.3 Preliminary Remediation Goals 14

2.3.1 List Expected Contaminants 15
2.3.2 Identify Potential ARARs *16*
2.3.3 Identify Risk-based Concentrations *16*
2.3.4 Present PRG Information in a Table 17

2.4 Consideration of Risk Assessment Data Needs in the Work Plan 17

2.4.1 Use of Sampling Data for the Risk Assessment 18
2.4.2 Analytes and Detection Limits 18

3.0 Preliminary Data Analysis 19

3.1 Scheduling of Risk Assessment Deliverables During Preliminary Data Analysis 19
3.2 Evaluation of Laboratory Contaminants and Natural Background 20

3.2.1 Site Related Contaminants 21
3.2.2 Natural Background 21
3.2.3 Identification of Contaminants of Concern (COPCs) 23

3.3 Ecological Risk-based Screening 23

4.0 BASELINE ECOLOGICAL RISK ASSESSMENT 27

4.1 Introduction 27

4.1.1 Chapter Objective 28

4.1.2 Roles of Parties Involved in the Ecological Risk Assessment 28

4.2 Step 3: Problem Formulation 28

4.2.1 Refinement of Contaminants of Concern 29
4.2.2 Further Characterization of Ecological Effects 29
4.2.3 Review & Refinement of Contaminant Fate and Transport, Exposure Pathways, and Ecosystems at Risk 29
4.2.4 Selection of Assessment Endpoints 30
4.2.5 Refinement of Conceptual Site Model and *Testable Hypotheses* 30
4.2.6 Literature Search 31

4.3 Step 4*:* Selection of Study Design & Data Quality Objectives 32

4.3.1 Selection of Measurement Endpoints 32
4.3.2 The Relationship Between Measurement Endpoints and Assessment Endpoints 33
4.3.3 *Lines of evidence* 35

5.0 Step 5: Site Assessments (Verification of Field and Sampling Plan) 36

5.1 Sampling and Analysis Plan 36
5.2 Verification of Exposure Pathways 36
5.3 Estimation of Exposure Point Concentrations 36
5.4 Toxicity Tests 39
5.5 Toxicity Bioassays 39

6.0 Step 6: Analysis Phase (Field Investigation and Data Analysis) 40

6.1 Field Studies 42
6.2 Analysis of Ecological Exposures and Effects 42

7.0 Step 7: Risk Characterization 44

7.1 Risk Estimation and Uncertainty Analysis 45
7.1.1 Risk Estimation 45
7.1.2 Risk Description 46
7.1.2.1 Current Adverse Effects 47
7.1.2 .2 *Future Adverse Effects* 47
7.1.3 Risk Calculation 47
7.1.4 Uncertainty Analysis 50
7.1.5 Interpretation of Uncertainty 51

7.2 *Interpretation of Ecological Significance* 52

7.2.1 Conclusion with Evaluation of Ecological Significance 53

8.0 Step 8: Risk Management 54

9.0 RISK ASSESSMENT TASKS FOR THE FS 55
9.1 Risk Evaluation of Remedial Alternatives 55
9.2 Scheduling of Risk Assessment Deliverables for the FS 55

10.0 ECOLOGICAL RISK ASSESSMENT RESOURCES 56

10.1 General Guidance 56
10.2 Screening Values 57
10.3 Uncertainty References 57
10.4 Where to Obtain Documents 58

11.0 REFERENCES 59

APPENDICES

Appendix A Background Determination for Inorganics in Soils

Appendix B (I) Bioavailability of Inorganic Contaminants in soil
(ii) Oak Ridge Toxicological Benchmark Values

Appendix C ***Risk Report*** ("Tool Box")
Technical Issues:
Radionuclide Exposure Parameters for Ecological Receptors

Appendix D ***Risk Report*** Case Study Summaries

ATTACHMENTS

Attachment 1

List of Common Risk Assessment Acronyms

ARAR	applicable or relevant and appropriate requirement
AWQC	ambient water quality criteria
BTAG	biological technical assistance group
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act of 1980 (Superfund)
COPCs	contaminants of potential concern
CSM	conceptual site model
DQO	data quality objectives
EPA	[United States] Environmental Protection Agency
ERA	ecological risk assessment
FS	feasibility study
HI	hazard index
HQ	hazard quotient
IAEA	International Atomic Energy Agency
LD_{50}	dose which produces a 50% mortality rate in a given species
LOAEL	lowest observed adverse effects level
MCL	maximum contaminant level
MCLG	maximum contaminant level goal
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NPL	National Priorities List
NOAEL	no observed adverse effects level
PRG	preliminary remediation goal
PRP	potentially responsible party
RAGS	EPA Risk Assessment Guidance for Superfund
RAO	remedial action objectives
RBC	risk-based concentration
RI	remedial investigation
ROD	record of decision
RPM	regional project manager
SAP	sampling and analysis plan
SARA	Superfund Amendments and Reauthorization Act of 1986
SMDP	scientific management decision point
TRV	toxicity reference value
TEF	toxic equivalency factor
TEQ	toxicity equivalence

List of Common Risk Assessment Acronyms (cont'd)

UCL	upper confidence limit
UTL	upper tolerance level
WP	work plan

Lists of Exhibits & Text-boxes

List of Exhibits

Exhibit 1-1 Ecological Risk Assessment Framework 3
Exhibit 1-2 Eight-step Ecological Risk Assessment Process for Superfund . 7
Exhibit 1-3 Ecological Risk Assessment In the RI/FS Process 9
Exhibit 6-1 Analysis Phase 41
Exhibit 7-1 Risk Characterization Phase 43

List of Text-boxes

Text-box 1-1 Highlights of Region 10 Guidance 1
Text-box 1-2 Ecological Risk Assessment Steps & Decision Points 4
Text-box 1-3 Integrated Risk Assessment Deliverables in RI/FS Process 6
Text-box 2-1 Risk Assessment Interim Deliverables During RI/FS Process . . 10
Text-box 2-2 Steps Involved in Preliminary Ecological Risk Assessment . . . 10
Text-box 2-3 Steps in the Development of PRGs 14
Text-box 2-4 Guidelines on the Presentation of PRGs Values 17
Text-box 2-5 Other Issues Related to DQO Determination 17
Text-box 3-1 Risk Assessment Interim Deliverables During Prelim. Phase . . 20
Text-box 3-2 Ecological Risk-based Screening 24
Text-box 3-3 Ecological Toxicity & Exposure References 25
Text-box 4-1 Potential Sources of Ecological Effects & Toxicity Data 31
Text-box 4-2 Components of the Work Plan & Sampling and Analysis Plan . 32
Text-box 4-3 Suggested Measurement Endpoints 33
Text-box 4-4 Characteristics of Assessment & Measurement Endpoints . . . 34
Text-box 5-1 Possible Toxicity Tests & Bioassays 39

1.0 INTRODUCTION

As stated in the foreword, the purpose of the Region 10 guidance is to summarize important concepts from national risk assessment guidance, highlight steps of the Remedial Investigation/Feasibility Study (RI/FS) relevant to the risk assessment, and identify specific deliverables that should be submitted to Region 10 during development of the baseline risk assessment. Highlights of the Region 10 guidance are in Text box 1-1. The anticipated users of the regional guidance are project managers, who need to identify stages of the remedial process in which a risk assessor should be involved, as well as technical staff who write or review risk assessments.

Text Box 1-1 Highlights of Region 10 Guidance

- Screening Level Ecological Risk Assessment (Sections 3.4)
- Baseline Ecological Risk Assessment (Section 4)
- Radionuclide Exposure Formulas and Equations (Appendix A)
- Ecological Benchmark Screening Values (Appendix B)
- Updated Resources and References (Section 7.0)
- Technical Issue Papers Section (Appendix C)
- Case Studies Section (Appendix D)

Ecological Risk Assessment is 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 (EPA 1992a). Ecological risk assessment is an integral part of the Remedial Investigation and Feasibility Study (RI/FS). The three components of the Remedial Investigation (RI) process are: (1) characterization of the nature and extent of contamination; (2) ecological risk assessment; (3) human health risk assessment. The investigation of the nature and extent of contamination determines the chemicals present at the site, as well as the distribution and concentration of the chemicals. The ecological and human health risk assessments determine the potential for adverse effects to the *environment* and *human health*, respectively.

The current EPA approaches to ecological risk assessments for Superfund are based on the human health risk assessment format, but modified for the increased complexity of organisms encountered and their interactions in the ecosystem. The purpose of ecological risk assessments may vary within programs, but they generally serve to provide risk managers with an estimate of the extent and magnitude of adverse effects on the ecosystem of concern.

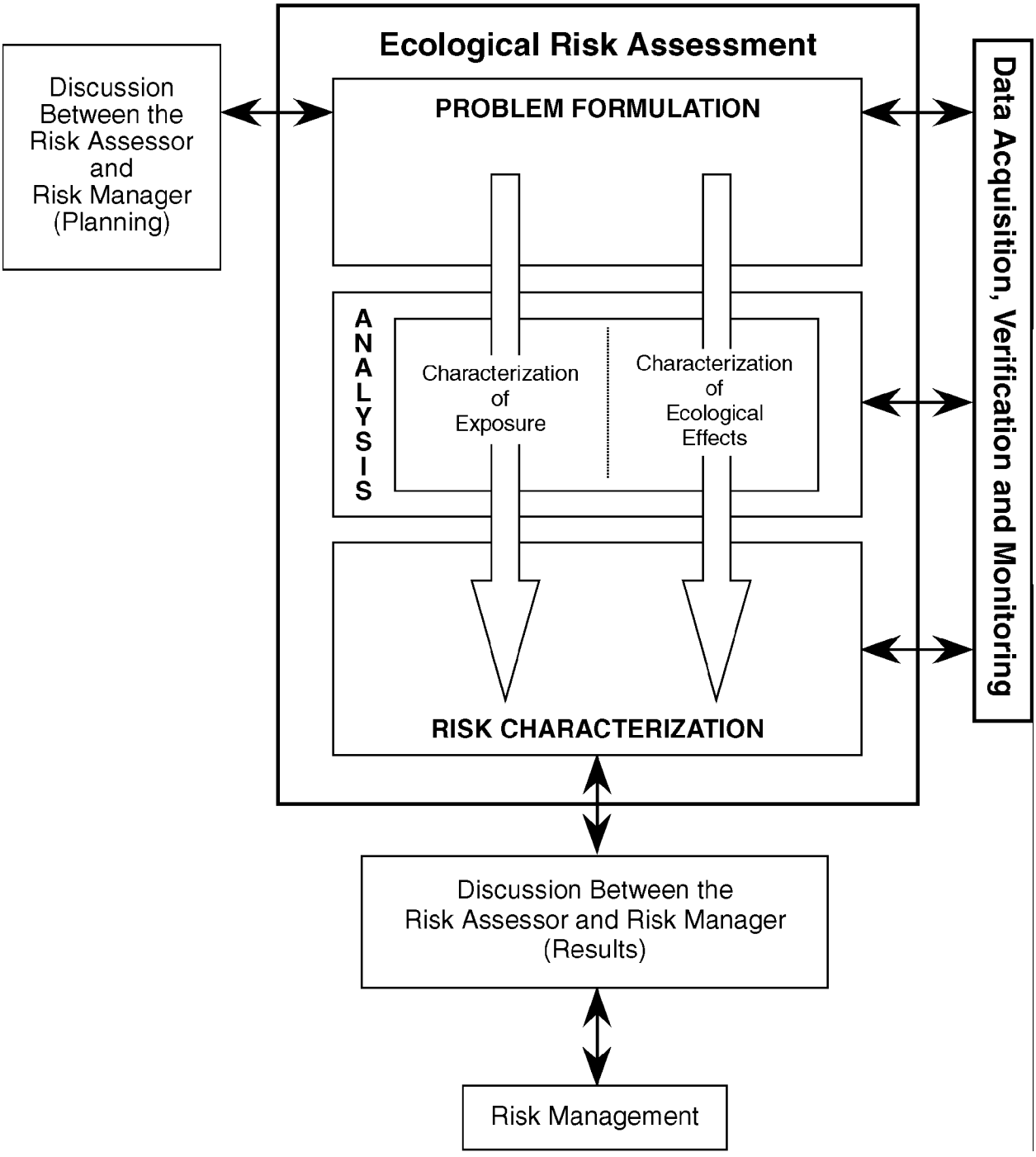
The Region 10 supplemental guidance is a region-specific document that outlines the process and tools used for conducting ecological risk assessments at Superfund sites. This document borrows heavily from the EPA headquarters documents: *Ecological Risk Assessment for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (EPA 1996a), the *Proposed Guidelines* for *Ecological Risk Assessment* (EPA 1996b), the *Framework for Ecological Risk Assessment* (EPA 1992a), the *Review of Ecological Assessment Case Studies* (EPA 1993b & 1994c) and other EPA regional ecological risk assessment documents. Exhibit 1-1 outlines the major components of the ecological risk assessment process.

1.1 Regional Technical Guidance

The region will issue an update to this guidance to address evolving risk assessment technical issues. The *Region 10 Risk Review* will be released intermittently in response to selected ecological risk assessment technical issues. It will be a separate publication from the Region 10 *Risk Assessment News*, and will provide more in-depth, technical discussions than the *News*. Issues of the *Region 10 Risk Review* will be placed under Appendix C, "The Tool Box," of this document. Appendix D will similarly be comprised of special releases of the *Region 10 Risk Review* which will focus on actual case studies related to ecological risk assessments.

This guidance is intended as a supplement to the upcoming EPA headquarters *Ecological Risk Assessment for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (EPA 1996a). It focuses on issues related to Superfund sites in Region 10. Furthermore, this document does not determine the scale of the ecological risk assessment or give specific details about investigative techniques which may be used in the ecological risk assessment. It provides the tools (e.g., toxicity bioassays) and examples (site-specific case studies) that will enable risk assessors and site managers to make sound decisions which are technically defensible and cost effective.

EXHIBIT I-1
Ecological Risk Assessment Framework (U.S. EPA, 1992a)



1.2 Focus of Risk Ecological Assessment

Text box 1-2 summarizes the associated steps and the pert-inent decision points and; Exhibit 1-2 outlines the eight-step ecolo-gical risk assessment process for superfund. Table 1-1 shows these decision points in relation to corresponding deliverables.

Text Box 1- 2 Ecological Risk Assessment Steps and Decision Points

- Preliminary Problem Formulation and Ecological Effects Evaluation.
- Preliminary Exposure Estimates and Risk Calculation (DECISION POINT # 1).
- Problem Formulation: Selection of Assessment Endpoints and Development of Testable Hypothesis (DECISION POINT # 2).
- Development of Conceptual Model, Selection of Measurement Endpoints and Study Design (DECISION POINT # 3).
- Site Assessments: Confirmation of Ecological Sampling and Analysis Plan & Verification of Exposure Pathways (DECISION POINT # 4).
- Field Investigations: Site Investigation Consistent with Work plan.
- Risk Characterization.
- Risk Management (DECISION POINT # 5).

National Priority List (NPL) sites in Region 10 vary in size from a few acres to square miles, vary in number and type of sources of contamination, and vary in presence of ecological receptors or in potential for exposure to human populations. The risk assessment process and the report produced will not be exactly the same for all sites, rather the process will be modified as needed for any site. Best professional judgement (BPJ) of the project manager, risk assessor, and reviewers will always be used to determine the level of effort to be devoted to risk assessment and to specific aspects of the risk assessment.

Ideally, the risk assessment process will be iterative, with results of early steps (scoping, calculation of preliminary remediation goals, and screening steps) used to focus subsequent work on information needed by decision-makers and on important chemicals, pathways, and issues. For example, the RPM and risk assessor may find that not as much precision is needed in the baseline risk assessment for a site where remedial action is clearly triggered, based on criteria in the National Contingency Plan (NCP) (EPA 1990d) and the *Role of the Baseline Risk Assessment* memo (EPA 1991e), although detailed analysis might go into setting remediation goals for such

a site. For a site where preliminary calculations show risks near the upper boundary of the risk range, more effort and precise information for the baseline risk assessment might be needed to support risk management decisions. Some NPL sites will be managed as multiple operable units, or as projects of several phases, including early or interim actions, rather than with a single RI/FS. Appropriate modifications of the risk assessment process to meet the needs of decision-makers will be important for these sites (see Exhibit 1-3). Instead of a single "baseline" risk assessment, the risk assessment deliverables might include one or more focused risk assessments, addressing a single source area or medium. The focused risk assessment would be used to justify a specific action. This type of approach is discussed in the guidance for CERCLA Municipal Landfills, on pages 3-39 and 3-40:

> ...it may be possible to streamline or limit the scope of the baseline risk assessment in order to initiate remedial action on the most obvious landfill problems... Ultimately, it will be necessary to demonstrate that the final remedy, once implemented, will address all pathways and contaminants of concern, not just those that triggered the need for remedial action (EPA 1991a).

Sites where early action or operable unit actions are taken based on focused risk assessment or other criteria will later require a comprehensive risk assessment, considering all sources, pathways, and contaminants, to justify final actions or "no further action" decisions. At a partially remediated site, the risk assessment should evaluate the site in its present physical condition. The RPM and risk assessor should decide how to factor ongoing actions into the risk assessment.

1.3 Scheduling of Deliverables

The organization of this regional risk assessment guidance is consistent with the *Region 10 Policy, Conduct of Remedial Investigations and Feasibility Studies* (EPA 10, 1990). This regional risk assessment guidance identifies certain items as risk assessment interim deliverables which should be submitted in advance of the baseline risk assessment. Risk assessment interim deliverables can be included as parts of the Site Characterization, Work Plan, and Preliminary Data Analysis documents (see Text box 1-3), or may be submitted as separate technical memos, according to the needs of the particular project. The EPA RPM will determine the specific schedule of deliverables for a site. The information from interim deliverables will ultimately be incorporated in the baseline risk assessment, elsewhere in the RI/FS, or as appendices to these documents.

The intent of requesting early submittal of interim deliverables for review is to facilitate the progress of the risk assessment, to encourage discussion, and to clarify reasoning in decisions affecting risk assessment and ultimately risk management. Hence, the interim deliverables requested by region 10 relate to decision points in the risk assessment process (e.g., Which contaminants potentially pose significant concerns? What exposure pathways are involved?). Deliverables are discussed here in the sequence in which they will be subm-itted, as outlined in Text box 1-2. Further discu-ssion of scheduling of risk assessment deliverables is pro-vided in sections 1.1, 2.1, 3.1, 3.2 and 4.1. Headquarters' guidance (EPA 1991f) also addre-sses scheduling of deliverables for sites at which a potentially responsible party (PRP) will conduct the RI/FS but the EPA will conduct the risk assessment.

Text Box 1- 3 Integration of Risk Assessment Deliverables in RI/FS Process

Phase I. RI/FS Project Planning

Scoping

Conceptual Site Model (2.2)
Preliminary Remediation Goals (2.3)

RI/FS Work Plan

Outline of the Risk Assessment

Phase II. Preliminary Data Analysis / Site Characterization Summary

Evaluation of Site Contaminants and Natural Background (3.2)
Risk-Based Screening of Contaminants (3.3)
Conceptual Site Model/Exposure Pathways (4.2.3)
Problem Formulation (4.2)
Ecological Endpoints Selection (4.2.4 & 4.3.1)

Phase III. Remedial Investigation and Feasibility Study Reports

Remedial Investigation Report

Baseline Risk Assessment (4.0)

Feasibility Study

Risk Evaluation of Remedial Alternatives (9.1)

*Note: **Bold** items are risk assessment deliverables. Parenthetical references indicate relevant sections of this guidance document.*

EXHIBIT I-2
Eight-step Ecological Risk Assessment Process for Superfund

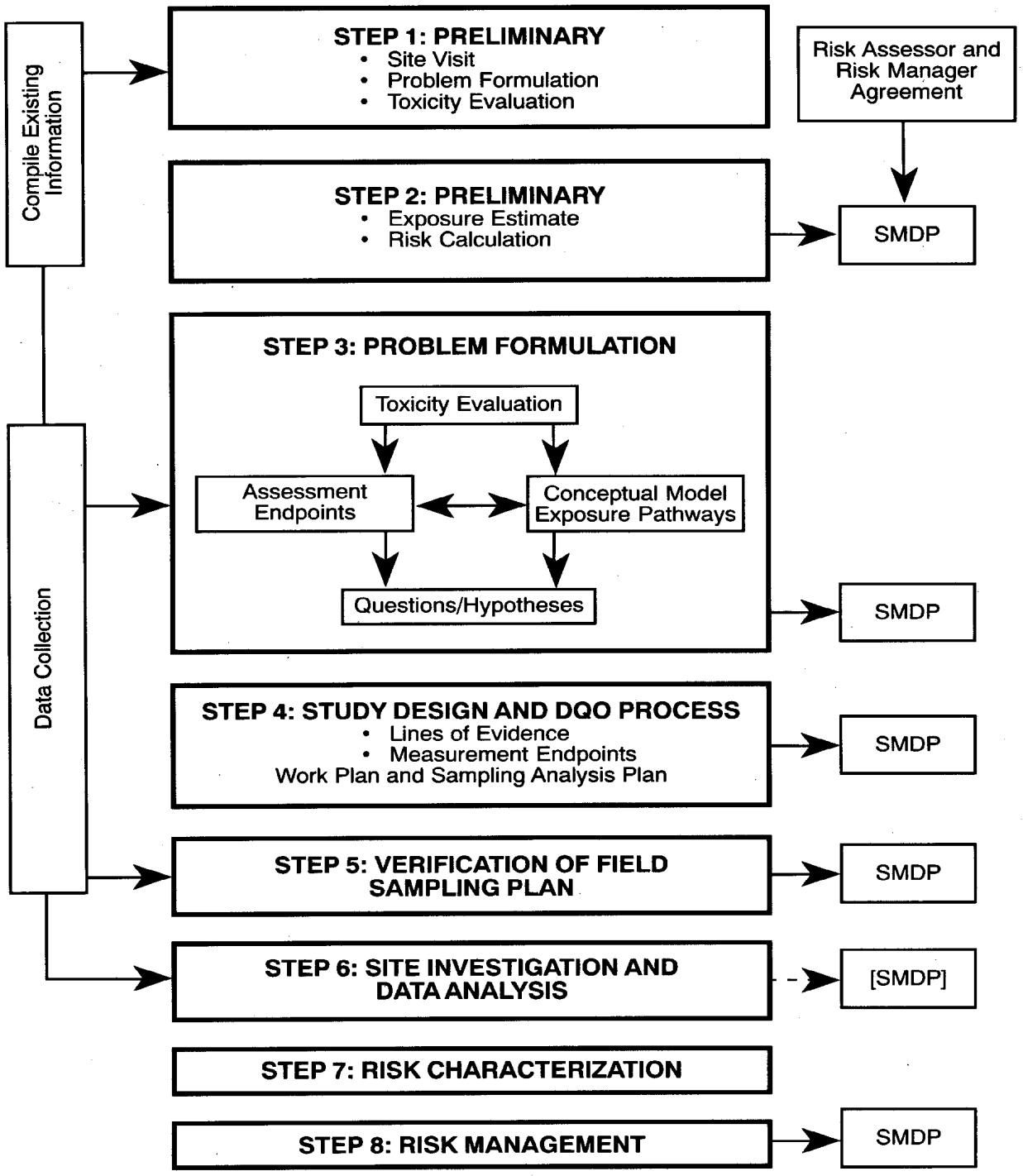
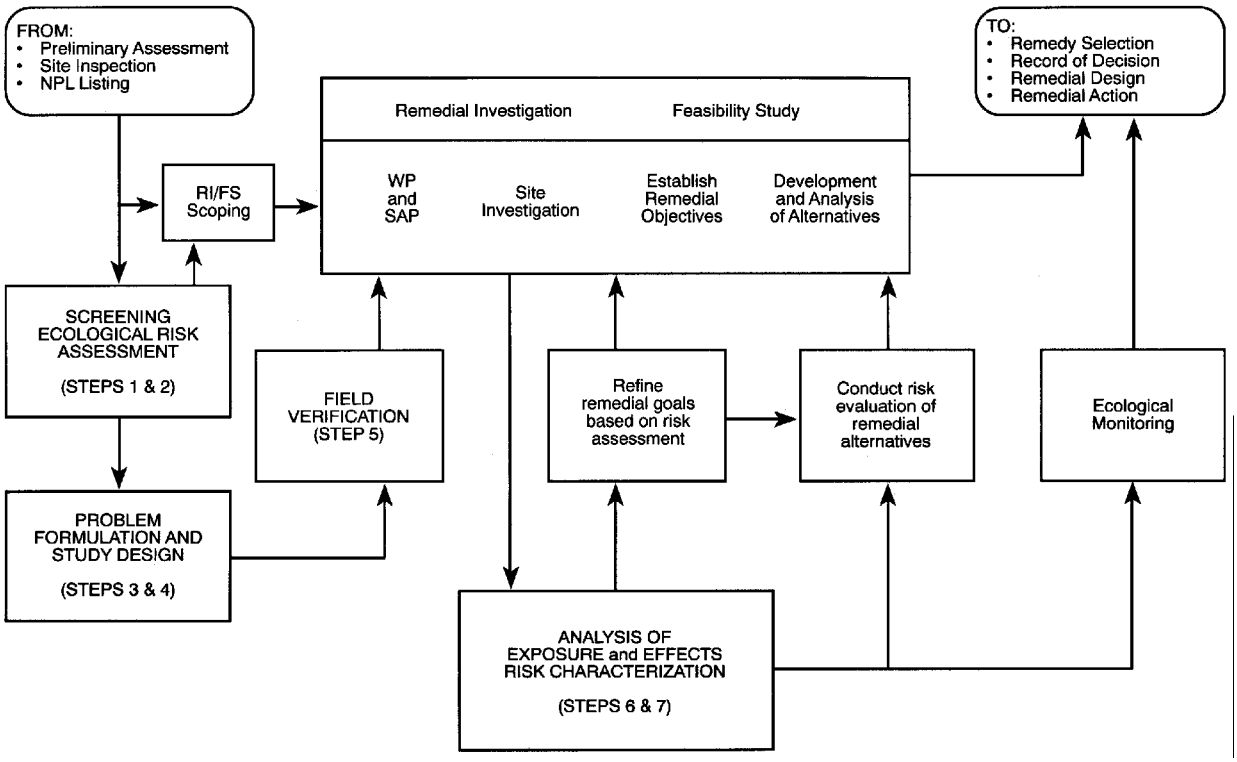


Table 1-1 Decisions Points and Corresponding Deliverables

Section which concludes with Decision Points	Decision to be Made	Deliverables
Preliminary Phase	Determine whether or not a significant ecological threat may exist.	• Screening level risk calculations • Table of COPCs • Map of sample locations • Other relevant site maps
Problem Formulation	Agree on objective(s), testable hypotheses and selection of both assessment and corresponding measurement endpoints	• Objective(s) • Testable Hypotheses • Suspected ecological effects of COPCs • Endpoints table
Problem Formulation (with Conceptual Site Model)	Agree on exposure pathways, development of conceptual site model, the risk assessment Work plan, sampling and analysis plan (SAP), a site investigation and methods of data analysis.	• Conceptual Site Model • Draft Work Plan
Site Assessment	Agree on any changes, resulting from information from the field study, in the Work Plan or SAP.	• final Work plan and/or SAP
Risk Management	Determine and initiate remedial actions for the site and develop the Record of Decision (ROD).	• Baseline Ecological Risk Assessment with: Remedial Action Objectives (RAOs) and Risk Characterization

EXHIBIT I-3
Ecological Risk Assessment in the RI/FS Process



WP: Work Plan
SAP: Sampling and Analysis Plan

2.0 RI/FS PROJECT PLANNING

Text Box 2-1 Risk Assessment Interim Deliverables During RI/FS Project Planning

- Conceptual Site Model (2.2)
- Preliminary Remediation Goals (2.3)

The risk assessment information considered in the RI/FS project planning is often included in primary documents, such as a scoping document and work plans (see Exhibit 1-3). The interim deliverables specified in Text box 2-1 should be submitted for review in advance of the larger documents, and the information later incorporated into these larger documents (i.e., the baseline risk assessment). The specific schedule is up to the discretion of the RPM. However, since both the finalized Conceptual Site Model and the Preliminary Remediation Goals will impact the progress of the risk assessment, these deliverables will correspond to decision points in the risk assessment process and should be submitted in a timely fashion. For sites where the potentially responsible party (PRP) will be conducting the RI/FS while an EPA contractor will be doing the risk assessment, it will probably be necessary to submit separate risk assessment deliverables. For example, the risk assessor will need the list of expected contaminants, submitted by the PRP, in order to prepare preliminary remediation goals (PRGs). In turn, the exposure pathways from the conceptual site model will have to be presented in time for the PRP to consider risk assessment data needs in preparing the RI/FS work plan. (See also the directive on risk assessment for PRP sites (EPA 1991f)).

2.1 Steps 1 & 2: The Preliminary Phase

Text Box 2-2 Steps Involved in Preliminary Ecological Risk Assessment (Steps 1 & 2)

- Site Visit
- Preliminary Problem Formulation
- Toxicity Evaluation
- Exposure Estimation
- Risk Calculation

(See U. S. EPA 1996a for Details)

The components addressed within these two initial steps are listed in Text box 2-2. These components include site visit, preliminary problem formulation, toxicity evaluation, exposure estimation and risk calculation. The preliminary ecological risk assessment efforts involve the first two steps (**steps 1 & 2**) of the ecological risk assessment process. These first two steps are often referred to as screening steps as it is during these steps that the media, exposure pathways, receptors and contaminants on which the risk assessment will focus are selected and others are determined of lesser or no risk.

See Steps 1 and 2 of the EPA headquarters *Ecological Risk Assessment for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (EPA 1996a), for a full description of these components. Ecological risk assessment is an iterative process which mandates increasingly specific levels of investigations as data are acquired. The preliminary process must be thorough in its scope, but not overly detailed. Overly detailed screening can encourage limited areas of focus; and this step should provide a complete picture of all potential ecological concerns present at the site. If available information indicates the need for further investigations, such should be conducted within the following ecological risk assessment process.

2.2 Conceptual Site Model

The Site Characterization Document, or another document used during the scoping stage, should present and discuss a conceptual site model for both current and potential future site use. This should be in the form of a flow chart showing site characteristics, including contaminant sources, release mechanisms, transport routes, receptors, and other information as appropriate. Iterations of this model will be carried through the work plan and baseline risk assessment report. As stated on page 2-9 of the Guidance for Conducting Remedial Investigations and Feasibility Studies (RI/FS guidance) (EPA 1988b):

> The conceptual site model should include known and suspected sources of contamination, types of contaminants and affected media, known and potential routes of migration, and known or potential human and environmental receptors. This effort, in addition to assisting in identifying locations where sampling is necessary, will also assist in the identification of potential remedial technologies.

A generic conceptual site model diagram taken from the RI/FS guidance is presented as figure 2-1. This may be used as a starting point, although other effective formats, graphical or pictorial, are possible, for example figures 2-2. The generic model should be modified to include as much *site specific* information as possible. Text accompanying the diagram should sufficiently address specific sources and receptors at the site.

The development of the conceptual site model will provide a basis for preliminary identification of exposure scenarios to be evaluated in the baseline risk assessment. If possible, human and ecological components of the conceptual site model should be shown in a single diagram. This will allow both the risk assessor and the risk manager to put potential ecological

threats in perspective as well as to avoid redundancy in evaluating the different components connected with the ecological threat (e.g., contaminant uptake by fish which may become prey items for Bald Eagles). Ecological exposure scenarios are discussed in the *Wildlife Exposure Factors Handbook* (EPA 1993a).

A written presentation of ecological exposure scenarios and pathways that will be evaluated in the risk assessment should be prepared during RI/FS planning. The exposure scenarios and pathways will be used in developing the work plans so that risk assessment data needs are addressed. Selection of exposure pathways will rely heavily on the conceptual site model.

Presentation of selected exposure pathways may simply be notes or text accompanying the conceptual site model, and should include reasoning for including and excluding various pathways. Discussion of exposure scenarios may, when appropriate, be accompanied by site maps showing locations of sources and receptors, or can refer to maps in the scoping report or work plan.

Identification of exposure scenarios and pathways at this stage in the process may be detailed, or may be more general, depending on the amount of information about the site available from the scoping process. Scenarios and pathways may be modified as more information is collected during the RI. Due to the increased complexity of the ecosystem and the interaction of organisms, the ecological exposure pathways and scenarios present may be more complex than the human health exposure pathways. Hence, to clearly communicate the potential ecological exposure pathways present at the site without excessive detail regarding the various components of ecosystem interactions that may occur at the site, it may be helpful to discuss the different components of the ecosystem that will become the backbone of the conceptual site model and ecological assessment endpoints. The final version of the exposure scenarios and pathways presentation will appear again in the exposure assessment section of the baseline risk assessment.

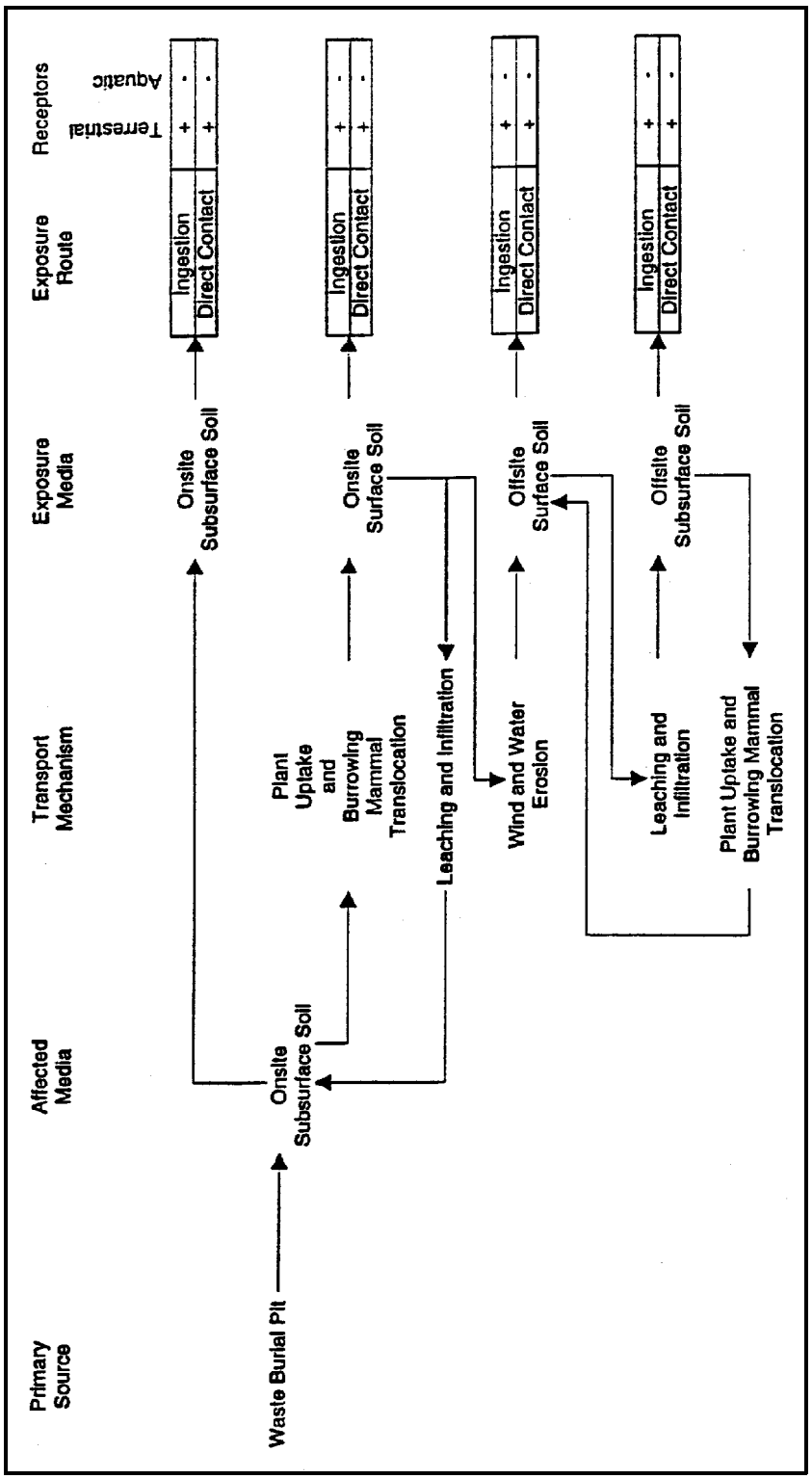


Figure 2-1 Graphical Conceptual Site Model

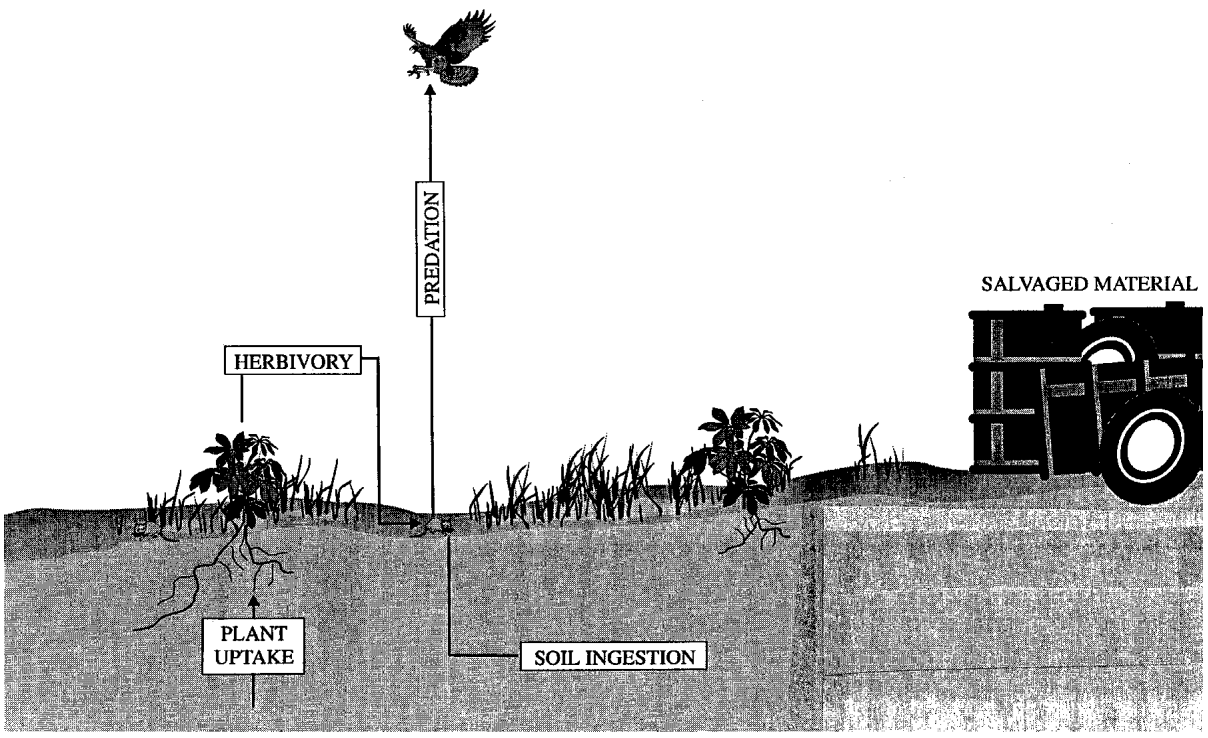


Figure 2-2 Schematic Conceptual Site Model

2.3 Preliminary Remediation Goals

Preliminary remediation goals (PRGs) are categorized in two ways: (1) ecological and human health endpoints, and (2) risk-based (e.g. RBCs) and regulatory (e.g. ARARs). The latter separation is not always distinct (e.g., some regulatory levels, such as AWQC, may be established from risk-based analyses). Regardless of the source of a potential ARAR, it should be accompanied by a description noting whether it is based on ecological or human health protection and whether it is a regulatory value and/or a risk-based value. It is important that as

Text Box 2- 3 Steps in the Development of PRGs

- List expected contaminants
- Identify potential ARARs
  - determine applicable sources
  - calculate "risk at ARAR"
- Identify RBCs
  - assemble toxicity Information
  - compile/calculate RBCs
- Present information in a table

much information available for both ecological and human heath threats be presented in this context.

Steps involved in developing PRGs are presented in Text box 2-3. Values for a limited number of contaminants, which take into account the additional transport pathway of migration of contaminants in soil to groundwater, may be found in the *Soil Screening Guidance* (EPA 1994b). Ecological risk information may be found in a variety of reference materials, such as those listed in Text box 3-3, so it is essential to clearly cite sources. Other references for ecological values may be found in section 10. The Regional *Policy on Conduct of RI/FS* (EPA 10 1990) emphasizes that preliminary remedial action objectives be developed at the initial scoping group meeting.

The primary function of the completed PRG table will be to anticipate the range of risk-based concentrations that may become goals for site clean up action. Early consideration of these numbers allows planning and evaluation of remedial alternatives to begin before the remedial investigation report and baseline risk assessment are complete. It is expected that the PRG table will also be referred to by managers and technical personnel at various stages of the RI/FS process, for various purposes. An important use is evaluation of adequacy of analytical methods to provide data for risk assessment: method detection/quantitation limits can be compared to risk-based concentrations. Also, as RI data become available, actual concentrations of contaminants in site media can be compared to risk-based concentrations to identify contaminants of concern for sampling in subsequent phases. The risk-based concentrations will also be used in screening contaminants for the baseline risk assessment.

2.3.1 List Expected Contaminants

The first step in developing PRGs is to assemble a list of potential site-related contaminants. Based on the site history, and on analytical results from Site Investigation, Preliminary Assessment, or other sampling efforts prior to the RI, a list of chemicals expected or known to be present can be compiled. Resource materials identifying contaminants expected to be associated with specific industries or sources can be consulted. (Resources include Appendix II of the *Data Useability Guidance* (EPA 1990b) and guidance for specific categories of sources.) A written discussion of site information used to obtain the list of contaminants should be provided and the discussion should be part of the scoping document or conceptual site model, or may accompany the table of PRGs. The list may be long for sites with multiple source areas. Chemicals may be added to or deleted from the list as additional information becomes available

during the RI.

2.3.2 Identify Potential ARARs

Chemical-specific standards for soil, water, and air, as specified in federal or state regulations that may become ARARs, are identified for each potential contaminant. (ARAR guidance is provided in EPA 1988a). In the interest of limiting effort during scoping, the RPM may determine that identification of the obvious federal standards, Maximum Contaminant Levels and Maximum Contaminants Level Goals (MCLs and MCLGs) for water and Ambient Water Quality Criteria (AWQC) for surface water, is sufficient at this stage. Note that ARARs under the Washington State Model Toxics Control Act (MTCA) (WDOE 1991) include some concentrations defined in the regulation, and some concentrations calculated using toxicity information. If toxicity information is not available for contaminant(s) in question, therefore, a quantitative structure activity relationship (QSAR) type of approach may be used. The use of QSAR approach to estimate toxicity to aquatic organisms is described by EPA's Office of Toxic Substances (EPA 1988f).

2.3.3 Identify Risk-based Concentrations*

Ecological risk-based screening values are available for many contaminants. Ecotox threshold values are listed in a recent *EcoUpdate* (EPA 1996c), but when using these values, care should be taken to insure that they are adequately conservative for site-specific conditions. Also, screening values may be found in the literature as well as many of the resources listed in Text box 3-3. (See also sections 3.3 and 4.2.)

*Note that risk-based concentrations provided in Attachment 1 do not protect for ecological effects, migration of contaminants to groundwater or inhalation exposure pathways. Soil characteristics, geological and meteorological conditions at the site, as well as chemical and physical properties of contaminants affect their fate and transport. These factors, along with site use, determine the relative importance of various routes of release, receptors of concern and exposure pathways (release to air, migration to groundwater, incidental ingestion, dermal contact) in determining risk-based goals for soil.

2.3.4 Present PRG Information in a Table

The risk assessor should gather information, perform necessary calculations and present information, separated by media (soil, groundwater, surface water, and sediment) in tabular form in accordance with guidance provided in Text-box 2-4. Up-front agreement with the RPM on which risk-based PRGs will be used for comparison and risk characterization purposes in the risk assessment is essential in order to avoid unnecessary backtracking at later stages of the risk assessment. Although ARARs are not part of the baseline risk assessment, it is often useful for some of the management-related purposes noted below, to present these numbers together with the risk-based concentrations.

Text Box 2- 4 Guidelines on Presenting PRG Values in Tabular Format

- Contaminant exposure point concentrations,
- Regulatory PRG(s) (ARARs) for each pathway of concern,
- Risk at ARAR(s) (ecological risk-based), and
- Risk-based PRG(s) (RBCs) for each pathway of concern.

2.4 Consideration of Risk Assessment Data Needs in the Work Plan

Sampling and analysis activities undertaken during the remedial investigation should provide adequate data to evaluate all potential and appropriate exposure pathways, and chosen ecological endpoints for the risk assessment. The sampling plan should be designed keeping in mind how the data will be used, and how it will affect the risk assessment. Therefore, the risk assessors must be involved in the development of data quality objectives related to the risk assessment. Development of data quality objectives (DQO) is not limited to concerns for the precision, accuracy, representativeness, completeness and comparability of the data. Text-box 2-5 outlines other issues that are related to Data quality objectives. Specific risk assessment aspects of data quality objectives are discussed in the subsections below.

Text-Box 2- 5 Other Issues Related to DQO Determination

- Types of laboratory analysis used,
- Sensitivity of the analytical technique,
- Detection limits,
- Confidence limits, and
- The resulting data quality (ATSDR, 1994).

2.4.1 Use of Sampling Data for the Risk Assessment

The work plan should show that the data needed to evaluate each exposure pathway identified for the site will be collected. In the section of the work plan that discusses the risk assessment, the association of each pathway with specific samples should be spelled out. The information provided should answer the following types of questions: Will groundwater concentrations be averaged over time for risk assessment? If so, how many rounds of data will be collected? Are ecological receptors chosen for evaluation/monitoring found in adequate numbers at the site? Will soil samples be averaged or composited to describe an area? Will exposures to soil be considered using samples taken at the surface, at depth, or both? Were locations for soil samples selected using a random, systematic, or other designs? Are sampling plans adequate to distinguish site contamination from natural background?

For pathways and receptors that will be evaluated using estimates of potential release and/or models of fate and transport, specific models chosen for the site assessment should be identified in the work plan. The *Framework for Ecological Risk Assessment* (EPA 1992a) and other EPA documents provide guidance on selection of models. Physical data needed for model(s), such as meteorological data or soil data, should be identified, and appropriate methods to be used in data collection should be included in the sampling plan.

2.4.2 Analytes and Detection Limits

Selection of analytical methods involves consideration of many site-specific factors, including site history and contaminants. The RPM, chemist and risk assessor should evaluate the advantages of available methods. Appendix III of the *Data Useability Guidance* (EPA 1990b) compiles information on various analytical methods and detection limits, listed by chemicals. Information gathered during the scoping process, particularly RBCs and PRGs for expected site contaminants, should be consulted when choosing methods. For samples that will be used to establish exposure point concentrations for risk assessment, results are more useful if detection limits meet risk-based concentrations. The adequacy of detection limits should be evaluated in the work plan by presenting a table listing expected contaminants and comparing the method detection or quantitation limit for each compound with the appropriate risk-based goal for that chemical in that medium. This does not mean that every sample must be analyzed with the method achieving the lowest possible detection limits. For example, at locations where concentrations are known or expected to be high, the most sensitive method may not be

necessary.

3.0 Preliminary Data Analysis

Extensive discussion on evaluation of data for use in risk assessment is provided in the *Data Useability Guidance* (EPA 1990b). Judgement regarding the needs of a particular project should be used in interpreting this guidance. At many Superfund sites, several chemicals are detected in site media. The ecological threats posed by these contaminants vary in degree and distribution. Some contaminants, often referred to as the "drivers" will pose greater and/or more threats than others, and will steer the direction of the risk assessment. Elimination from the baseline risk assessment of common laboratory contaminants, natural background elements, and chemicals that pose minimal risk should be conducted in a systematic manner, as presented in sections 3.2 and 3.3 below, or using other acceptable rationale approved by EPA Region 10. It is suggested that this step be carried out in advance of the baseline risk assessment.

3.1 Scheduling of Risk Assessment Deliverables During Preliminary Data Analysis

Section 3 describes the content of deliverables, listed in Text box 3-1, that will be submitted after RI sampling results are available but before the RI/FS and baseline risk assessment are submitted. All of the information called for in section 3 can be compiled and submitted to the RPM in one package, along with other data reports, if convenient.

The timing and length of these deliverables will vary depending on the needs of the site. If additional sampling events will be planned based on results of early rounds, timely reporting of risk-based screening and revised exposure scenarios will be important. These should be submitted as soon as possible after data are available. Risk-based screening can also be used to identify unusually high risks, for which the RPM might want to consider early action. Documentation of the logic used in reducing the number of contaminants to be carried through the baseline risk assessment must be included in the final risk assessment. This can be accomplished by including a copy of the risk-based screening and other deliverables from the preliminary data analysis as an appendix to the baseline risk assessment.

For some projects the preliminary data analysis deliverables may be omitted entirely. This may occur when previously agreed-upon schedules do not allow for additional rounds of document

review. Also, some of the interim deliverables called for below may not be necessary if no additional sampling is anticipated, and if the conceptual site model and identification of exp-osure scenarios and pathways in the work plan are acceptable and do not require revision. In these cases, the information called for in section 3 below will be submitted as part of the baseline risk assessment. The Region 10 risk assessment staff *does not* recommend skipping the "Risk-based Screening" and "Revised Conceptual Site Model/Exposure Pathways" interim steps. The potential problem is that if risk-based screening and specific exposure and toxicity information is not submitted and approved, gaps will be carried through the baseline risk assessment. For PRP-lead sites, the specifics of the schedule may be different. RI sampling results should be provided as a deliverable to the risk assessor before the risk assessment data analysis tasks can proceed.

Text Box 3-1 Risk Assessment Interim Deliverables During Preliminary Data Analysis

- Evaluation of Site Contaminants and Natural Background (3. 2)
- Risk-based Screening of Contaminants (3.3)
- Revised Conceptual Site Model/Exposure Pathways (4.2.3) & (4.2.5)
- Revisions to Work Plan (4.3)
- Problem Formulation (4.2)
- Ecological Endpoints Selection (4.2.4) & (4.3.1)

3.2 Evaluation of Site Related Contaminants and Natural Background

Differentiation of background concentrations from site- related contaminants are necessary for the identification of COPCs and also for the characterization of nature and extent of contamination in the ecological risk assessment. To determine the type of risk posed by site contaminants, it is necessary to compare contaminant levels to background concentrations. Comparison with natural background levels should only be used for inorganic chemicals, because organic chemicals found at most Superfund sites do not occur naturally (even though they may be ubiquitous). The presence of organic chemicals in background samples may be an indication that samples were collected in an area influenced by the site. Unless a strong case can be made for the naturally occurring organics, these chemicals should not be excluded from evaluation in the ecological risk assessment.

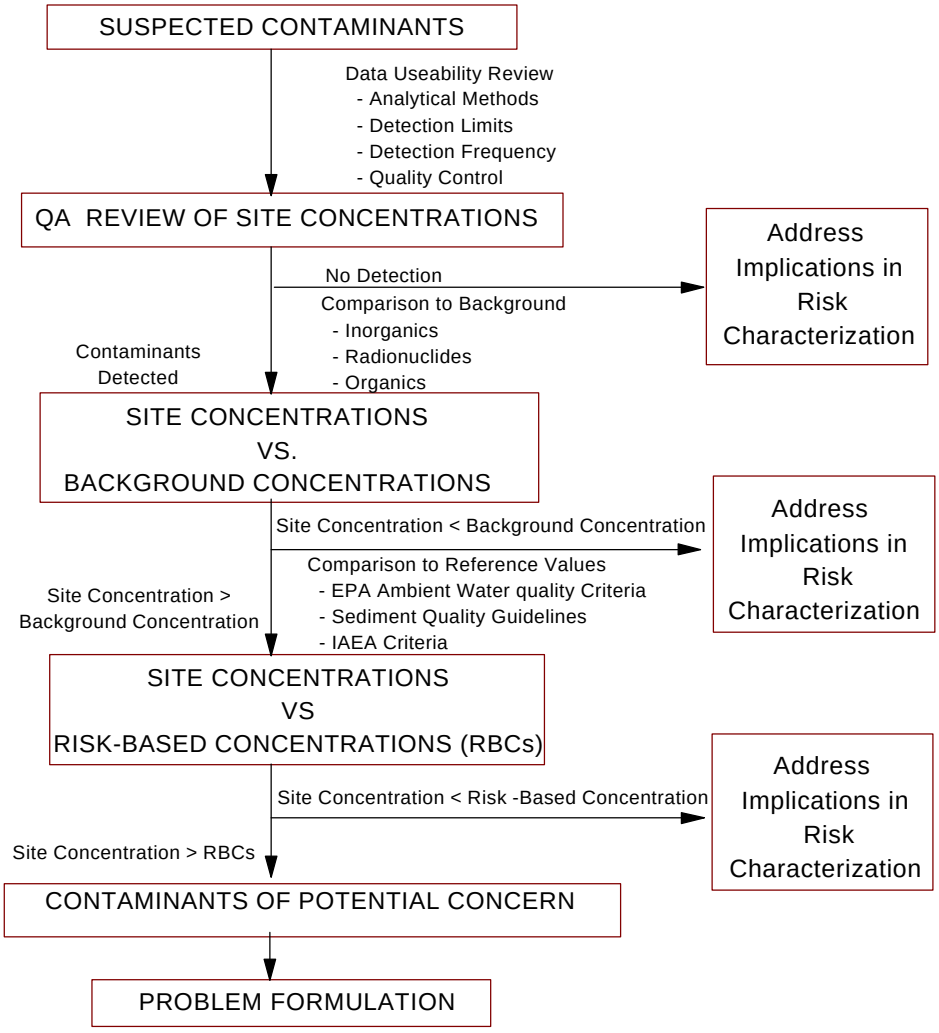
3.2.1 Site Related Contaminants

Chemicals reliably associated with site activities based on historical information whose data are of sufficient quality should be retained and evaluated in the risk assessment. However, certain organic chemicals (for example, acetone, toluene, methylene chloride, 2-butanone and the phthalate esters) are commonly used in the laboratory which may be introduced into the sample due to cross contamination that are not from the site, should be excluded from the risk assessment (See RAGS Part A, HHEM, Chapter 5 for details).

3.2.2 Natural Background

Determining whether detected concentrations of inorganics represent natural background in a medium is a site-specific issue. Appropriate number and locations of background samples are determined by the RPM and geologists. Interpreting site data compared to background data should be discussed among project managers and scientists and addressed in the RI report. If it is unclear at the time the preliminary data analysis is conducted whether inorganics are natural or anthropogenic in origin, they should be carried through the baseline risk assessment, with further consideration of the issue of background in the FS. *Although natural background elements may be excluded from the baseline risk assessment, at some sites the risk from natural background elements may be included in the baseline risk assessment, presented separately from the site-related risks, at the option of the RPM*. Further discussion regarding the application of background concentrations to ecological risk assessments may be found in Appendix C and in other relevant documents listed in sections 9 and 10.

Figure 3 -1. Selection of Contaminants of Potential Concern (COPCs)



Adapted from INEL, 1994

3.2.3 Identification of Contaminants of Concern (COPCs)

The screening of contaminants should compare the maximum concentration of each contaminant detected at the site to a risk-based concentration calculated using a conservative target risk, based on values derived from toxicity studies and exposure scenarios. Figure 3-1 is provided to illustrate the selection process. At this stage the list of contaminants which was initiated in the screening stage of the risk assessment, must be finalized utilizing all available data. Some factors to consider when establishing this list include: environmental concentrations in all media, frequency of occurrence, background levels, bioavailability, physical/chemical properties, potential for bioaccumulation or bioconcentration, potency and organism-experienced effects (EPA 1989b). Once the above information has been gathered, the type of analysis to be performed should be determined. The risk assessor may also re-evaluate each contaminant eliminated, to insure that cumulative hazard is not overlooked. Basic steps of this process are outlined in Text box 3-2.

3.3 Ecological Risk-based Screening

Ecological screening process includes the identification of contaminants of potential concern. Text box 3-2 outlines the ecological screening process. Unlike the human health risk assessments for which the receptor is implicit to the process, in ecological risk assessment the receptor(s) are not preselected. Hence, the ecological screening process involves the initial identification of both contaminants and receptors. The risk assessment is focused on those contaminants that may pose significant threats to the ecosystem. Therefore, the risk-based screening will indicate whether or not any potential threats to ecological components exist at the site. Contaminants found at concentrations not indicative of significant threat to the ecosystem should be eliminated and no longer evaluated in the ecological risk assessment, but should be retained for risk characterization. The uncertainty section of the risk characterization phase should analyze the uncertainty about the predicted risk(s) [or lack of] from such contaminants.

The first phase of the screening revolves around potential exposure pathways and transport mechanisms identified earlier in the RI. All potential pathways identified should be discussed: incomplete pathways should be documented as such; pathways which may exist, but are not yet confirmed, should be listed as such, with specific detail regarding the unconfirmed points on the pathway; and, complete pathways should be listed, detailing each step of the pathway and how it was confirmed. The second stage of the screening level relies on

comparisons and calculations. Site concentrations must be measured and toxicity values for corresponding contaminants determined. Ecological toxicity values may be found in the literature as well as many of the references listed in Text box 3-3. For the many contaminants for which ecological risk-based concentrations are not available, toxicity reference values must be determined and subsequent hazard calculations executed. See section 1.3 (Step 1) [Screening-Level Ecolog-ical Effects Evalu-ation] of EPA head-quarters' *Ecological Risk Assessment for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (EPA 1996a) for preferred ecotoxicological screening values.

Text Box 3-2 Ecological Risk-based Screening

CONTAMINANTS

- List maximum concentration of each chemical in each medium.
- Compare to risk-based concentration
- Eliminate chemicals if
  - concentration exceeds screening concentration for given medium

  OR
  - HQ<1 *and* all relevant HIs<1.
- Carry remaining chemicals through baseline risk assessment.

RECEPTORS

- List all potential ecological receptors and receptor groups.
- Determine if complete exposure pathways exist for each source medium of concern.
- Eliminate receptors/receptor groups if all relevant exposure pathways for each medium of concern are incomplete.
- Carry remaining receptors through baseline risk assessment.

NOTE: *Under the summary presented in risk characterization all contaminants and receptors must be presented along with rationale for eliminations made during screening.*

The risk-based concentrations and toxicity reference values will then be used for comparison with site concentrations. The risk-based numbers calculated for the screening process should be conservative and will be modified during the subsequent steps as more site-specific and less uncertain parameter data become available. Section 4.7.1.3 outlines toxicity calculations to be used in risk-based screening of site-related contaminants. Also, see Step 2 (Screening-Level Exposure Estimates and Risk Calculation) of EPA headquarters *Ecological Risk*

Assessment for Superfund: Process for Designing and Conducting Ecological Risk Assessments (EPA 1996a).

A table presenting site-related contaminants, site contaminant concentrations and toxicity values, accompanied by a site map indicating sampling sites, should be included in the screening stage interim deliverable to the RPM.

At the conclusion of the screening stage of the risk assessment, the results should be submitted to the remedial project manager. The results submitted must include a list of all contaminants present at the site. A table should be provided, giving the following information for each contaminant in all corresponding media. Table 3-1 is presented as an example. A site map indicating sampling sites and location should accompany the table. Additional site maps showing the spatial distribution of particular contaminants of concern at the site should be provided only if they further elucidate site conditions.

Background data may be employed in the screening process to determine which site-related contaminants, particularly inorg-anics, exist on site at concen-trations elevated above surrounding natural background levels. Plann-ing for background sampling should occur early in the RI. The collection and use of soil background data for ecological risk assessments is discussed in Appendix C; other relevant references are also listed in Appendix C.

Text Box 3- 3 Ecological Toxicity and Exposure References

- USFWS Contaminant Hazard Reviews (e.g. *Zinc Hazards to Fish, Wildlife, and Invertebrates: Asynoptic Review.* Fish and Wildlife Service, US Department of the Interior. Biological Report 10; Contaminant Hazard Reviews Report 26: April 1993.)
- AWQC values (e.g., Ambient Water Quality Criteria for lead EPA 440/5-84-027, 1985)
- NOAA Screening Guidelines (NOAA Homepage)
- AQUIRE database (EPA Ecotoxicology Data System)
- *Wildlife Exposure Factors Handbook* (EPA 1993a)
- Current *ECO Updates (EPA 1996c)*
- *Summary of Guidelines for Contaminated Sediments* (WDOE, Publication #95-308)
- *Screening Benchmarks for Ecological Risk Assessment* (Oak Ridge National Laboratory)

Table 3-1
Sample Summary Table for Contaminants of Concern
(after initial risk-based screening)

Contaminants	Maximum Detected Levels (ppb)	Risk-Based Concs (ppb)	Frequency of Samples Exceeding Screening Criteria	Background Values (ppb)	Frequency of Samples Exceeding Background
Inorganics					
Arsenic	4.73	0.038	41/57	3.4	4/57
Chromium	3050	180	4/57	4	7/57
Lead	18.1	NA	1/57	5	4/57
Nickel	453	730	0/57	5	16/57
Organics					
1,1,2,2-Tetrachloroethane	0.2	0.052	1/101	NA	NA
Chloromethane	7.5	1.4	8/95	NA	NA
Bis(2-ethylhexyl)phthalate	170	4.8	11/101	NA	NA
Trichloroethene	7	1.6	9/101	NA	NA
Chloroform	0.5	0.15	7/101	NA	NA
Dibromo-chloromethane	0.5	0.13	1/101	NA	NA
Pesticides/PCBs					
Aldrin	0.08	0	3/82	NA	NA
Aroclor 1254	1.18	0.01	3/101	NA	NA
Dieldrin	0.01	0	2/101	NA	NA
DDT	0.4	0.2	1/101	NA	NA

The contaminant portion of the screening process is somewhat prescriptive; the screening process for receptors, although somewhat complex, is not so established. Receptor screening should simply identify potential receptors and/or receptor groups on site. The first step is to catalog the plants and wildlife on the site. The second, is to determine which of these organisms may be exposed to the contaminants, via any exposure pathway(s), at the site.

Screening may be organized by species or functional groups or even by specific populations. It should be well documented, allowing for tracking of those organisms determined *not* to be potential receptors as well as those which are. Assistance from local plant and wildlife experts may help to identify less common receptors. The end result of this process should be a compilation of potential receptors, species or groups and justification for each determination provided. This compilation of potential receptors, species or groups should assist in the development of the conceptual model for the site.

At the conclusion of the ecological risk-based screening, an interim deliverable should be submitted to the remedial project manager (RPM). The deliverable should list all contaminants of concern present at the site, site concentrations of these contaminants, the toxicity and/or background data used in the screening, the source of this data and the number of site concentration exceedances above the chosen screening value. For contaminants found to be elevated only in certain areas (hot spots), a map identifying these areas should be provided. Also, a list of potential receptors and identified (complete) exposure pathways should be provided. Relevant concentration-based distributional maps which illustrate fate and transport and/or exposure pathways for selected contaminants should also be included.

4.0 BASELINE ECOLOGICAL RISK ASSESSMENT

4.1 Introduction

The methodology recommended for use in developing the baseline ecological risk assessment is described in the *Risk Assessment Guidance For Superfund, Volume II, Environmental Evaluation Manual* (EPA 1989c). Additional guidance for ecological risk assessment can be found in the following EPA publications: *Framework for Ecological Risk Assessments* (EPA 1992a), *Ecological Risk Assessment for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (EPA 1996a) and the *Proposed Guidelines* for *Ecological Risk Assessment* (EPA 1996b).

4.1.1 Chapter Objective

This chapter covers all aspects of step 3 in the eight-step process outlined in the EPA headquarters Superfund ecological risk assessment guidance (EPA 1996a). While the baseline ecological risk assessment report is the final deliverable for the risk assessment, a set of interim deliverables may be crucial in conducting an effective ecological risk assessment. Such interim deliverables can help to insure that all parties involved in the risk assessment are in agreement at certain critical decision points, and thus prevent backtracking to these points at later times when it becomes clear that differences of opinion exist.

4.1.2 Roles of Parties Involved in the Ecological Risk Assessment

Decisions regarding the risk assessment for a given site should be made by the remedial project manager (RPM) for that site. The RPM will also serve as the liaison between the contractor performing the risk assessment and the EPA risk assessment staff. Prior to the decision-making, the RPM may establish a Biological Technical Assistance Group (BTAG) for consultation. In Region 10, a BTAG is an ad hoc group comprised of members invited to serve by the RPM; Region 10 BTAGs are specific to given sites or projects. A BTAG usually consists of EPA staff specializing in environmental sciences, ecology and ecotoxicology as well as individuals representing the trustees such as the U.S. Fish and Wildlife Service (USFWS), the National Oceanic and Atmospheric Administration (NOAA) and related state agencies (e.g.,WDOE). These members function in an advisory and review capacity to assist the RPM with the risk assessment process. The RPM may consult with specific EPA staff members as well as the BTAG team, if one has been established. Communication between the contractor and/or risk assessor with the BTAG is essential in the ecological risk assessment process. This open line of communication will help generate agreement and consistency among all parties involved.

4.2 Step 3: Problem Formulation[†]

Problem formulation at Step 3 should involve the following activities:

- Refining preliminary list of COPCs;
- Further characterization of ecological effects;

[†](See EPA 1996a, for details).

- Review and refinement of contaminant fate/transport, exposure pathways and ecosystems potentially at risk;
- Selection of **assessment endpoints;** and
- Refinement of Conceptual Site Model and development of testable hypotheses or questions that the site investigation will address.

4.2.1 Refining Preliminary List of COPCs

Because of the conservative nature of the screening phase, some of the Initial list of contaminants identified or suspected to be site related in Steps 1 and 2 should be re-evaluated to eliminate those that pose negligible ecological risk. The risk assessor at this stage should review the assumptions used in the screening phase and compare them to literature values. For example, if 100 percent bioavailability was used in the screening phase and literature values report only 65 percent, then the change in percent bioavailability should affect the HQ. Those contaminants with HQs below 1 should be considered for elimination from the risk assessment (the risk assessor should discuss this with the risk manager before reaching any conclusion).

4.2.2 Further Characterization of Ecological Effects

Literature search used in the screening phase should be expanded to obtain additional information needed for the baseline risk assessment. Procedures for further characterization of ecological effects are outline in the EPA Headquarters guidance (EPA 1996a).

4.2.3 Review and Refinement of Contaminant Fate/Transport, Exposure Pathways and Ecosystems Potentially at Risk

These activities involve compiling additional data on:

- Environmental fate/transport of contaminants;
- Ecological setting at the site (habitat and potential receptors);
- Magnitude and Extent of Contamination (spatial and temporal scales).

Procedures for review and refinement of contaminant fate/transport, exposure pathways and ecosystems potentially at risk are outline in the EPA Headquarters guidance (EPA 1996a).

4.2.4 Selection of Assessment Endpoints

Selection of assessment endpoints for the baseline risk ecological assessment must be based on the ecosystems, communities and species observed at the site. This selection should take into consideration the following:

- Concentration of contaminant present in media of concern
- Toxicity mechanisms of contaminants to potential receptors at the site
- Susceptibility of receptors to contaminants at the site
- Existence of complete exposure pathways to potential receptors

4.2.5 Refinement of Conceptual Site Model and Development of Testable Hypotheses

Refinement of the conceptual site model will help to identify additional data requirements which may influence the model. The conceptual model should provide a functional framework for evaluating potential exposures of ecological receptors using or inhabiting the site.

Ecological receptors are those organisms that may be currently exposed to contaminants at the site or may be exposed in the future. Those species that occupy a niche considered fundamental to the function of the larger ecosystem should be documented clearly as such within the risk assessment report. Site-specific ecological receptors of concern can be selected for a site according to the following hierarchy of considerations. First, the receptor should be exposed, directly or indirectly to the contaminants, as the assumption is usually made that an organism not exposed to a given contaminant is not at risk from that contaminant. Second, changes in the community structure, as marked by standard indices, when linked to exposure, may indicate changes in potential receptors. Third, if a prey organism serves as a source of exposure to predators (based on body burden and sample model), the predators may also be potential receptors on the food chain.

Although individual changes may sometimes be considered significant when threatened or endangered species are among the receptors, ecological risk assessments focus on effects to the overall ecosystem at the site (e.g., such as population changes). Impact on critical species on the food chain structure can affect the entire ecosystem. While organisms higher in trophic levels often attract the most attention, effects of contaminants on lower trophic levels (e.g., decomposers, detritus feeders) must also be considered. For example, a contaminant may be

toxic to microorganisms at very low concentrations, and if microbial or invertebrate populations are disrupted, decomposition of dead plant and animal matter may not occur. This in turn, may reduce the mineralization process needed to sustain the plant community. Eutrophication may also result from similar mechanisms in the aquatic system, causing the depletion of oxygen that is vital for aquatic life forms.

A complete exposure pathway includes a source, a mechanism of contaminant release, retention and/or transport influences, a biotic exposure point, and an exposure pathway at the ecological exposure point. Only complete pathways are expected to produce a significant exposure to the receptors. All exposure pathways documented in the risk assessment should be accompanied by a related description of the aforementioned properties. These pathways will help to determine appropriate measurements for evaluation of chosen assessment endpoints.

4.2.6 Literature Search

Literature must be the primary source of data at some point before finalizing the risk assessment. Therefore, the search should be conducted as soon as the problem formulation phase is completed. In fact, it should be started during the screening phase of the risk assess-ment. Inadequate literature searches can result in unnecessary toxicity testing as well as delays in the over-all process due to a lack of data. Literature search may provide ecolo-gical effects data for particular conta-minants and species. Possible sources of ecological risk-based values such as LD50s, LC50s, NOAELs and LOAELs are listed on Text box 4-1. Data obtained from the search can be compared to site-specific data, to fully characterize associated risks from a site (EPA 1989b). At the conclusion of the literature search, data gaps may be identified, therefore, it should be decided at this point whether toxicity tests and field

Text Box 4-1 Potential Sources of Ecological Effects &Toxicity Data

primary literature

- Registry of Toxic Effects of Chemical Substances
- Hazardous Substances Database
- Radiotoxicological Benchmarks for Wildlife at Rocky Flats
- Agency for Toxic Substances and Diseases Registry
- Phytotox Database
- Aquatic Information Retrieval (AQUIRE)
- Chemical Evaluation Search and Retrieval System
- Fish and Wildlife Service Contaminant Hazard Reviews
- Oak Ridge National Laboratory Screening Values
- Washington State DOE Sediment Screening Values

studies are needed. **4.3 Step 4: Selection of Study Design & Data Quality Objectives**

The problem formulation step (step 3) concludes with the development of the conceptual model which includes assessment end-points, exposure pathways and questions to be addressed in the risk assessment (see Section 3.6.2 of EPA 1996a, and Text-box 4-2, for more details). Step 4 of the ecological risk assessment establishes what the measurement end-points should be, followed by the study design and what type of data will be need to address the risk question (hypotheses). The product of this step (Step 4) is the Work plan (WP) and sampling and analysis plan (SAP) for the risk assessment. Any additions or changes necessary for conducting the specialized tasks indicated in the Work plan should be determined.

Text Box 4-2 Components of the Work plan & Sampling and Analysis Plan

The **Work plan** (WP): Assessment endpoints, exposure pathways, questions (testable Hypotheses), define the relationship between measurement endpoints and assessment endpoints, and uncertainty analysis.

The **Sampling and Analysis Plan** (SAP): Data needs, study design that is scientifically feasible, study methods and sampling techniques, data reduction and quality assurance.

4.3.1 Selection of Measurement Endpoints

A good measurement endpoint will have a clear relationship to an assessment endpoint and should be predictive of the assessment endpoint. Measurement endpoints must be "measurable" using practical and economic means; and they must be appropriate to all relevant considerations including the scale of the site, the exposure pathway of concern, and the time scale of concern (EPA 1989e). More details regarding characteristics of good endpoints can be found in Chapter 2 of *Ecological Assessment of Hazardous Waste Sites* (EPA 1989e). Text box 4-3 lists potential measurement endpoints. Notice that the list of assessment endpoints is essentially a subset of the list of measurement endpoints, which includes more specific qualities such as characteristics of "individuals".

4.3.2 The Relationship Between Measurement Endpoints and Assessment Endpoints

Text Box 4-3 Suggested Measurement Endpoints

Individual
- Death
- Growth
- Fecundity
- Overt symptomology
- Biomarkers
- Tissue Concentrations
- Behaviors

Population
- Occurrence
- Abundance
- Age/size class structure
- Yield/Production
- Frequency of gross morbidity
- Frequency of mass mortality

Community
- Number of species
- Species evenness/dominance
- Species diversity
- Pollution indices
- Community quality indices
- Community type

Ecosystem
- Biomass
- Productivity
- Nutrient Dynamics

SOURCE: EPA 1989e

The relationship between measurement and assessment endpoints can be complex. Assessment endpoints can sometimes also serve as measure-ment endpoints. Endpoints are identifiable environ-mental characteristics designed to help assess ecological integrity in an objective and straight-forward fashion. Endpoints should be determined by careful examination of the ecological components being evaluated and the overall implication to the ecosystem in question. Endpoints are discreet components of the complex interdependent relations of an ecosystem. These endpoints may come from various levels of the system. For example, an assessment endpoint may be a functional group (raptors) or a particular species (coho salmon). Regardless of the level the assessment endpoints occupy in the ecosystem, the measurement endpoints will fall at or below that level (i.e., they will be at least or more concrete and able to be evaluated more directly).

An assessment endpoint, as defined by G. Suter III in Chapter 2 of *Ecological Assessment of Hazardous Waste Sites* (EPA 1989e), is "a formal expression of an actual environmental value to be protected. It is an environmental characteristic, which, if found to be significantly affected, would indicate a need for remediation." While the highest assessment to be made in the overall ecological aspects of the RI/FS process is an evaluation of the ecological integrity of the site, the assessment endpoints are usually the highest level values at the site which can be assessed *objectively*.

Text Box 4- 4 Characteristics of Good (a) Assessment and (b) Measurement Endpoints

(a) Assessment Endpoints

- biological relevance
- measurable or predictable
- susceptible to the hazard
- logically related to decision
- social relevance

(b) Measurement Endpoints

- correspond to or predictive of assessment endpoints
- readily measured
- appropriate to scale of site
- appropriate to exposure pathway
- appropriate temporal dynamics
- low natural variability
- diagnostic
- broadly applicable
- standard
- existing data series available

SOURCE: *adapted from* EPA 1989e

Measurement endpoints are "quantitative expressions of observed or measured effects of a hazard; and, these measurable environmental characteristics are related to the valued characteristics chosen as assessment endpoints (EPA 1989e)." Measurement endpoints are those criteria which have been selected to serve as indicators of assessment endpoints.

It is imperative that all assessment endpoints have appropriate corresponding measurement endpoint(s) to facilitate accurate evaluation. Conversely, each measurement endpoint should be directly related to an assessment endpoint. It is not reasonable to collect data under the guise of "measurement endpoints" when the data collected are unrelated to assessment needs. Such data will not aid in the risk characterization or remediation processes. Text box 4-4 presents characteristics of good assessment and measurement endpoints. Table 4-1 presents a sample summary (examples) of assessment and measurement endpoints.

Table 4-1 Sample Summary of Endpoints

Assessment Endpoints	Measurement Endpoints	Alternate Measurement Endpoints
Population flux of American peregrine falcon in Kitsap County, WA (*biological relevance: control of rodent population)*.	Peregrine falcon egg-shell thinning.	Level of DDT in tissue of field mice
	Seasonal peregrine falcon reproductive fecundity	Number of peregrine falcon nests
Coho salmon populations in the Duwamish River basin (*societal relevance: food source).*	Reproduction rates in coho salmon	Sediment available for spawning
	Visible lesions on the coho salmon	Dissolved oxygen levels in stream

4.3.3 Lines of Evidence

The conclusion of a risk assessment may be authenticated by using lines of evidence to interprete risk estimates. Lines of evidence may be derived from several sources or by different techniques relevant to adverse effect on the assessment endpoints, such as quotient estimates, modeling results, field experiments and observations. Some of the factors that should be evaluated by a risk assessor in a risk assessment to establish lines of evidence should include:

- The relevance of evidence to assessment endpoints
- The relevance of evidence to the conceptual model
- The sufficiency and data quality and study design used in the key studies
- The strength of the cause and effect relationships
- The relative uncertainties associated with the lines of evidence and their direction

For additional guidance on the application of **lines of evidence** in ecological risk assessments, see (EPA 1996a and EPA1996b)

5.0 Step 5: Site Assessments (Verification of Field and Sampling Plan)

The site assessment is the confirmatory step on the magnitude of exposures of receptors to contaminants at the site. The site-sampling and measurements required for this step are both diverse and specific; a number of different skills will be needed. These skills and the corresponding measurements should have been determined at the decision point following the problem formulation.

5.1 Sampling and Analysis Plan: Quantification of Release, Migration and Fate of Contaminants

Sampling design should be clearly laid out in the Work plan as influenced by the decisions made and the associated deliverables at the problem formulation step. Sampling should be based on sound judgement taking into consideration all the variables and relevant data needs about the site. Direct sampling of media is not the only method available, but it is useful and will help to identify the current migration of contaminants as well as the transport mechanisms. These data will also help to predict future migration patterns of the contaminants from the site. Also, any sampling for background data and the areas involved should be included in the Sampling and Analysis Plan.

5.2 Verification of Exposure Pathways: Characterization of Receptors

Characterization of receptors should be limited to site receptors, and may further be limited to those which are directly associated with the measurement and assessment endpoints. Information to be collected in this step includes: species' feeding habits, life histories, habitat preference, and other attributes related to sensitivity to the contaminants at the site (EPA 1989b). This information should be available in published literature, but some field observations may also be essential. All pertinent data should be assembled here to insure proper assessment of the potential effects of contaminants on given receptors to minimize uncertainty.

5.3 Estimation of Exposure Point Concentrations

This step will depend on which receptors are associated with the measurement (and assessment) endpoints. Media which are the potential sources of exposure of receptors to site contaminants should be sampled and analyzed to determine the levels of contamination. To

establish the exposure point concentrations, more data will be needed to facilitate the estimation of intake rates for the exposed group of receptors. This information may include: properties of the contaminant, ecological effects, the nature of the receptors and the physical and chemical properties of the media (EPA 1989b). Table 5-1 contains the intake parameters for deer mouse and Table 5-2 shows sample intake calculations. In the case of bioaccumulation of contaminants, biota samples from at least two trophic levels should be collected from the site and evaluated to determine the site-specific bioconcentration and bioaccumulation rates.

Table 5-1 Sample Intake Calculations for the Deer Mouse

DEER MOUSE PARAMETERS

Soil Concentration Lead	=	150 mg/kg
Body Weight	=	20g (.02 kg) deer mouse
Bioconcentration Factor$_{(invertebrates)}$	=	0.65
Percent Invertebrate in Diet	=	38%
Food Intake/Day	=	.007 kg/day dry wt.
Concentration of Pb in Seed	=	8.6 mg/kg (Hypothetical) dry wt.
Percent Seed in Diet	=	40% dry wt.
Daily Intake$_{plant}$	=	2 mg/kg-BW-day dry wt.
Concentration of Pb in Leaf	=	16.3 mg/kg dry wt.
Percent of leaf in Diet	=	14% dry wt.

Table 5-2 Sample intake Calculations for the Deer Mouse

Chemical of Concern	Concentration (soil; mg/kg)	Daily Intake Soil (mg/kg-day)	Daily Intake Invertebrate (mg/kg-day)	Daily Intake Plant (mg/kg-day)	Daily Intake Total (mg/kg-day)
Lead	150	6.4	18.3	2.0	26.7

Where:

Daily Intake Soil = (Concentration$_{soil}$ x soil ingestion rate)/body weight
= (150 mg/kg x 0.0006 kg/day)/0.02 kg body weight
= 4.5 mg Pb/kg-BW-day

Daily Intake Invertebrates = (Concentration$_{soil}$ x bioconcentration factor$_{invertebrate}$ x % invertebrates in diet x food/day)body weight
= (150 mg Pb/kg x 0.65 x 0.38 x 0.007 kg/day)/0.02
= 12.97 mg Pb/kg-BW-day
Note: Bioconcentration factor for invertebrates are estimated from literature.

Daily Intake Plants = (((Concentration$_{seed}$ x % seed in diet) + (concentration$_{leaf}$ x % leaf in diet)) x food/day/body weight
= (((8.6 mg Pb/kg x 0.40) + (16.3 x 0.14)) x 0.007)/0.02
= 2.00 mg Pb/kg-BW-day
Note: Concentration of seed and leaf tissue measured at site are hypothetical.

Daily Intake Total = Daily intake$_{soil}$ + daily intake$_{invertebrate}$ + daily intake$_{plant}$
= (4.5 + 12.97 + 2.0) mg/kg-day
= 19.47 mg Pb/kg-BW-day

Note: All concentrations are on dry wt. Basis.

5.4 Toxicity Tests

Toxicity tests are used to measure the degree of response by exposed organisms to a specified concentration of chemicals or other agents compared to an unexposed control. Toxicity tests should only be conducted for measurements which are directly pertinent to the objective(s) of the study from the perspectives provided by the assessment and measurement endpoints. If not, toxicity testing can prolong (and increase the cost of) the risk assessment, while clouding the true aims of the risk assessment and providing virtually no helpful information. Text box 5-1 lists possible toxicity tests for different media.

Text Box 5-1 Possible Toxicity Tests and Bioassays

Aquatic
- *Microtox®*
- Fathead minnow
- Rainbow trout
- Sheephead minnow
- *Daphnia magna*
- Fetal Embryo Assay (FETAX)
- Root Elongation/Seed Germination

Terrestrial (Soil Contact Tests)---
Earthworm Bioassay
- Seed Germination
- Plant Uptake (For Food Chain Transfer Potential)
- Microtox® (solid phase)

Soil Elutriate Tests
- Microtox®
- *Daphnia magna*
- Root Elongation
- Sediment Elutriate Tests
- *Ceriodaphnia dubia*
- *Daphnia magna*

Bulk Sediment Tests
- *Hyalella azteca*
- Sand dollar assay
- Bivalves (pacific oysters)
- Rhepoxinius
- Sea cucumber
- Sea urchin reproductive assay

5.5 Toxicity Bioassays

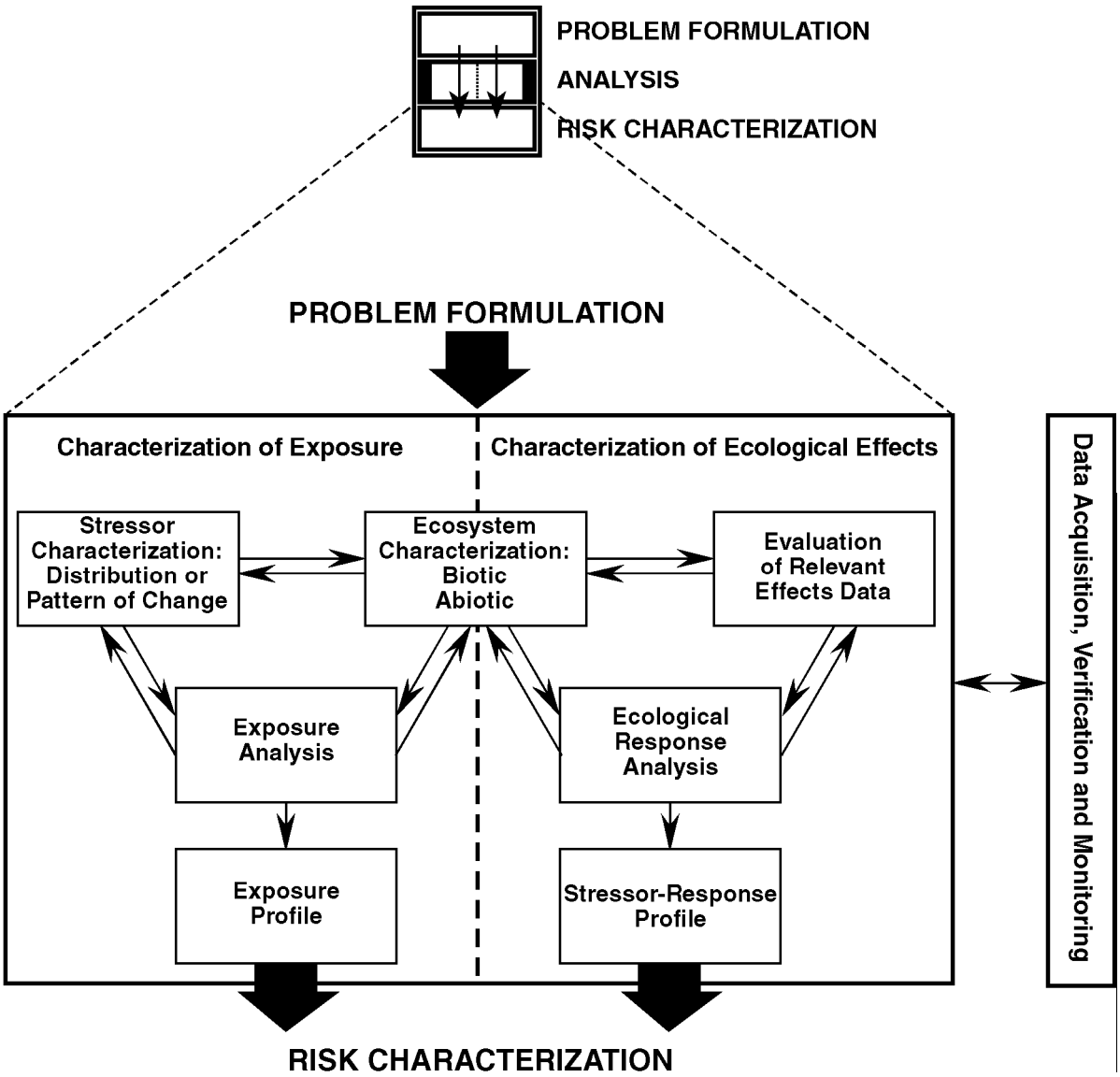
Toxicity bioassays are used to measure the relative potency of chemicals and other agents by comparing the effects on living organisms with the effects on a standard preparations on similar organisms. Toxicity bioassays can be performed for each matrix (water, sediment, and soil). Text box 5-1 lists possible bioassays for different media. The screening level bioassay will yield qualitative information, essentially identifying whether the matrix "passes" (the organism being

tested does not exhibit adverse effects) or "fails" (the organism exhibits adverse effects) (WDOE 1994). If the matrix "fails" the bioassay, it must be carried through the risk assessment and more analyses must be conducted to evaluate which contaminants are contained within the matrix. If the matrix "passes" the bioassay, it may not require further analysis, but should be retained for risk characterization and uncertainty analysis. However, before making such a determination, the nature of the potential contaminant(s) must be evaluated using information from the literature or other laboratory methods such as chemical tests. For example, a particular contaminant may be suspected to exist at levels of concern in a given medium. A screening bioassay may be administered on that medium using an organism likely to be effected by the contaminants and the medium may "pass" this bioassay test. A chemical analysis revealing the presence of no significant amount of the contaminants in that medium could then be used in conjunction with the bioassay to conclude that the medium in question does not pose significant threat to the ecosystem. Hence, the bioassay for each medium of concern can serve 1) to indicate the presence of a potential stressor in the media and 2) to validate chemical analyses corresponding to each medium.

6.0 Step 6: Analysis Phase (Field / Site Investigations and Data Analysis)

Exhibit 6-1 illustrates the components of the analysis phase (Step 6). The analysis phase of the ecological risk assessment is designed to bring all issues related to the study design, sample collection, data quality objectives and data reduction together. However, in some cases, modifications are warranted to the original study design. Therefore, if any unforeseen events require a change in the WP or SAP, all changes must be agreed upon at the decision point. The result of the analysis phase are used to characterize ecological risk in Step 7 (as illustrated on Exhibit 7-1).

EXHIBIT 6-1
Analysis Phase



6.1 Field Studies

A well-conducted field study can provide a valuable link between site contaminants and the potential ecological effects. The field study will help to determine the conditions of the organisms within the site. Several "endpoints" are considered evidence of an adverse toxic effects. Such evidence includes:

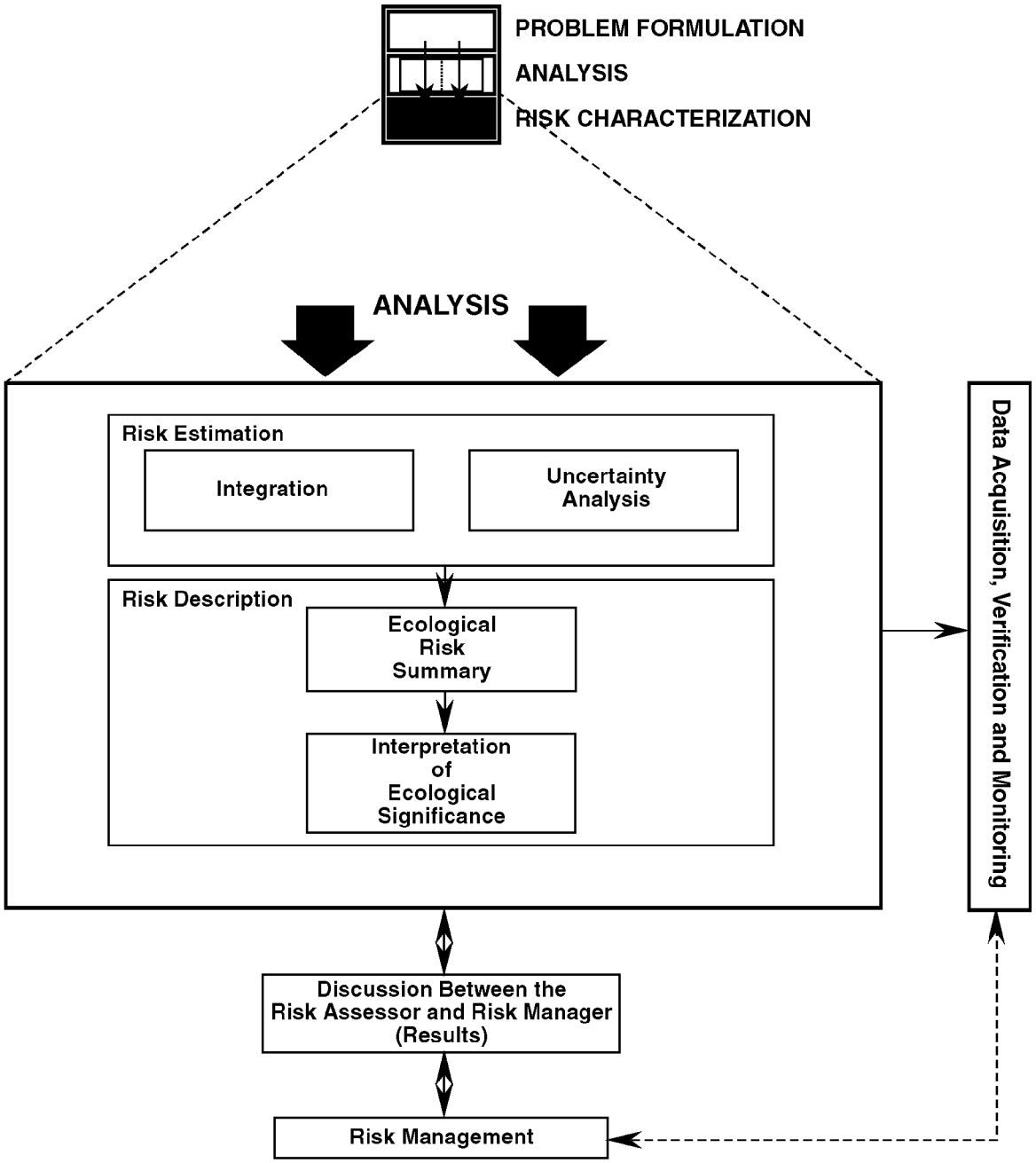
- reduction in species population,
- absence of species known to inhabit the area,
- presence of plant or animal species associated with "stressed habitats,"
- changes in community balance or trophic structure, and
- frequency of lesions, tumors or other pathological conditions in individuals.

Literature sources are an expedient means of referencing pertinent toxicity information. However, often they do not contain species-specific data needed. Although field studies involve additional time and cost, but they may provide site-specific and species-specific data needed.

6.2 Analysis of Ecological Exposures and Effects

This step provides a link between exposure to contaminants and observed effects on receptors at the site. It focuses on dose-response relationships. Some of this information may be found in the literature, some can be determined from laboratory toxicity tests and some will need to be measured in the field. Regardless of the source of the data, there will be some degree of uncertainty associated with it; it is important that as data are collected, the uncertainty associated with it be clearly understood and documented. This will be extremely useful in the risk characterization phase. For additional detail, see EPA headquarters guidance (EPA 1996a).

EXHIBIT 7-1
Risk Characterization



7.0 Step 7: Risk Characterization

Exhibit 7-1 illustrates the components of the risk characterization phase (Step 7). Risk characterization is the final step in the risk assessment process. All calculations and data from exposure and ecological effects assessments can be related to the objective(s) of the risk assessment through the conceptual model and the assessment and measurement endpoints. The ecological effects and exposure assessments should have been guided by the measurement endpoints, thereby providing a link to the assessment endpoints. All relevant information should be presented in this section of the risk assessment. Both current and potential future adverse effects must be addressed. The predicted adverse effects should then be discussed in the context of the conceptual site model, the uncertainty encountered and the ecological significance implied.

A recent memorandum (EPA 1995a) issued by the EPA Administrator articulates the importance of good risk characterization, emphasizing "transparency, clarity, consistency and reasonableness." All analyses, conclusions, resulting decisions and criteria employed to arrive at such decisions must be made obvious and be clearly presented.

Basic assumptions and scientific policies should be consistent and grounded in science, with care taken to avoid overly conservative approaches. Sources of uncertainty must be clearly presented and explained. The memorandum outlines three guiding principles to direct risk characterization:

1 *The risk characterization integrates the information from the hazard identification, dose-response, and exposure assessments, using a combination of qualitative information, quantitative information, and information regarding uncertainties.*

2 *The risk characterization includes a discussion of uncertainty and variability.*

3 *Well-balanced risk characterizations present risk conclusions and information regarding the strengths and limitations of the assessment for other risk assessors, EPA decision-makers, and the public (EPA 1995a).*

Risk characterization guidance, expanding on the aforementioned memorandum, and more specifically directed towards ecological risk assessments, is currently being developed within upcoming *Guidelines for Ecological Risk Assessment*, by EPA's Risk Assessment Forum.

Risk characterization should answer the following basic question: Are ecological receptors at the site expected to be exposed to site contaminants at levels capable of causing harm to the overall ecosystem, or to particular valued species within that ecosystem, now or in the future? An analysis of data gathered during the risk assessment process will enable the risk assessor to determine risk estimate(s) related to the conceptual site model and the chosen assessment endpoints. Subsequent discussion regarding uncertainty and ecological significance will help to put risk estimates into a perspective allowing for sound remedial decisions. Discussion of risk estimates should identify the strengths and limitations of the risk conclusions in such a way as to provide a "complete, informative and useful" set of information for decision makers (EPA 1995a).

7.1 Risk Estimation and Uncertainty Analysis

Data analysis focuses on the first phase of risk characterization, risk estimation. The ground work for data analysis is laid long before the risk characterization stage during the development of the conceptual site model and in the choice of assessment and measurement endpoints. These steps guide the data analysis by focussing efforts on preselected representative component(s) of the ecosystem. Such components should account for sensitive subpopulations and specific individuals, as appropriate, as well as the overall health of the site's ecosystem. In what ways these components are indicative of the overall health of the site should be summarized in the ecological significance portion of the risk description.

7.1.1 Risk Estimation

Risk estimates should integrate exposure and toxicity information in a way that supplies a measurement of adverse risks. Such a measurement may be a qualitative description, such as "high," "medium," or "low" or it may be a quantitative value or set of values such as a quotient or range. The type of data evaluation employed in the screening stages of the risk assessment may or may not be appropriate for the final risk estimation. For contaminants which were "screened out" of the more in-depth data gathering event of the risk assessment, the conservative screening estimate may be discussed in the risk characterization phase. For those contaminants "screened in" to subsequent stages of the risk assessment, additional data to supplement screening level information should be used to help characterize the risk.

If a hazard quotient is to be used to estimate risks at the site, refined data from the site-specific exposure and toxicity investigations associated with steps 4-6 should be used to calculate

the hazard quotient. The dose in equation 7-1 may be modified from a simple exposure point concentration to a site- and receptor-specific intake value. The TRV may be modified from a benchmark concentration to a receptor-specific toxicity value. A further modification may be the construction of distributions of effects. In situations in which such data are available, a distribution will help provide a better representation of the conditions present at the site than a single value.

Integration of field studies and computer-aided simulations, in addition to the conceptual site model, into the risk estimate process will also help to provide a better understanding of the potential risks present at the site. Such combination of methods may be used with a single value quotient risk estimate, a distribution of estimated risk or even a more qualitative type of estimate.

To fully characterization the potential risks at a contaminated site, all data should be presented clearly, and in the context of the associated endpoints embodied in the conceptual site. For example, whether a point estimate of intake represents a maximally exposed receptor or an average-exposed receptor must be clearly stated; or if a change was made to the conceptual model, it should be clearly stated before related data are discussed. All extrapolations made to apply toxicity data across species should be clearly stated. Essentially, the "**lines of evidence**" leading to the risk estimates should be presented. Such an analysis is necessary for both quantitative and qualitative risk estimations. Toxicity and exposure parameters, any professional judgements and any inferences applied to the data, and sources should be described.

The time scale for effects predicted by risk estimation to occur should also be noted. It may be presented as an absolute value (e.g. number of days or years); and it may also be presented in the context of the life cycle of receptor(s) effected. Deforestation may take decades, while depletion of microbial faunal communities may take days. Similarly, the time for a system to potentially recover from the projected/observed effects is also relative.

7.1.2 Risk Description

Risk description provides information that will enable risk managers make decision on the **likelihood** and the **ecological significance** of the estimated risks. For additional detail regarding risk description, see EPA headquarters' Guidanace (EPA 540-R-97-006)**.**

7.1.2.1 *Current Adverse Effects*

Although data associated with the risk estimate(s) may be complicated, the information sought is straightforward: are ecological receptors currently exposed to site contaminants at levels capable of causing harm to the overall ecosystem or to particular valued species within that ecosystem? As discussed above, a qualitative or quantitative risk estimate based on evaluation of assessment endpoints in the context of the conceptual model should be presented. Any assumptions, equations and/or professional judgements utilized should be clearly presented as such. Any adverse effects predicted by the risk estimate(s) should be detailed with the types, extent and severity of the effects (EPA 1989b).The time for such effects to occur, as well as the time for such effects to be eradicated/mitigated, should be discussed.

7.1.2.2 *Future Adverse Effects*

As with the Current Adverse Effects section, this information too should be presented in a straightforward fashion. The question is essentially the same: are ecological receptors at the site expected to be exposed to site contaminants at levels capable of causing harm to the overall ecosystem or to particular valued species within that ecosystem in the future? Again, a risk estimate should be presented along with any relevant qualifications/clarification of the data. Anticipated adverse effects should be described regarding types, extent and severity (EPA 1989b). A time line for effects and recovery should also be included.

7.1.3 Risk Calculation [‡]

Ecological risk calculations primarily involve the hazard quotient (HQ), which is sometimes referred to as the toxicity quotient (TQ). Equation 7-1 shows how to calculate the HQ.

[‡]Risk calculations may be used during screening as well as later stages of the risk assessment process. When used in the screening process such calculations must be based on conservative estimates (worst-case-scenario). These results will not be used to set remedial or cleanup goals, rather they will assist the project manager in making risk decisions about the site. In the screening phase, they are used to determine which contaminants will be carried through the risk assessment.

$$HQ = Dose/TRV$$

HQ = hazard quotient
Dose = level of contamination to which an organism is exposed expressed in mg-contaminant/kg-body weight/day
TRV = toxicity reference value (an approved Risk-Based Concentrations or a NOAEL-related value)

Equation 7-1 The Hazard Quotient

(a) NOAEL = Acute or Subchronic LOAEL/10

(b) NOAEL = Chronic LOAEL/5

(c) NOAEL = LD50/50

(d) NOAEL = $NOAEL_{\text{different family-same order}}/2$ (for non-protected species)

(e) NOAEL = $NOAEL_{\text{different order-same class}}/2$ (for non-protected species)

(f) NOAEL = $NOAEL_{\text{related non-protected species}}/2$ (for protected species)

SOURCES:Calabrese & Baldwin, 1993; EPA, 1986b; Newell et al., 1987

Equation 7- 2 Extrapolating to NOAEL from (a) acute/subchronic LOAEL; (b) chronic LOAEL; (c) LD_{50}; NOAEL of related (d) family, (e) order, or (f) nonprotected species.

During the risk calculations, if no risk-based concentration values are available, the no-observed-adverse-effect-level (NOAEL) should be used as the toxicity reference value (TRV). To extrapolate to the NOAEL from a related value, equations 7-2 (a-f) may be applied. When no related values are available, screening level bioassays may be appropriate. A lack of data cannot be used to justify the elimination of a contaminant from the risk assessment; a screening level qualification of "insufficient evidence available" should be noted and the contaminant should be further examined during the risk assessment process.

In cases where related contaminants are found at the same site, and a cumulative effect is suspected or known, the HI should be calculated. In the absence of any knowledge of interactive effects, the HI is simply the summation of all HQ's corresponding to the particular contaminants for all pathways for each media as shown in equation 7-3. Hazard Quotient (HQ) values greater than or equal to one indicate a likelihood of risk. Contaminants with an HQ 1 should continue to be evaluated throughout the following stages of the ecological risk assessment.

$$HI = \sum HQ$$

HI = Hazard index
$\sum$HQ = The summation of all hazard quotients of related effects and mode of action of contaminants of concern

Equation 7- 3: The Hazard Index

Contaminants with an HQ < 1 should be retained only for consideration in the uncertainty analysis and risk characterization of the ecological risk assessment. Exceptions to the latter include (1) single contaminants with HQ < 1 which contribute to one or more HI 1; and (2) contaminants with the potential to bioaccumulate. Contaminants which may bioaccumulate include, but are not limited to, PCBs, PAHs, cadmium and mercury. Enough information about the nature and extent of contamination must be provided to enable the project manager (with guidance from Regional BTAG) to decide which contaminants should be carried through the ecological risk assessment. The hazard index (HI) is evaluated on the same principle as the HQ. An HI of greater than or equal to one indicates a need for concern. An HI of less than one indicates that contributing contaminants may be set aside for risk characterization and uncertainty analysis. Best professional judgement must be employed in a hazard-quotient-based screening process.

7.1.4 Uncertainty Analysis

Invariably, uncertainty will be associated with a quantitative risk assessment. Uncertainty is introduced at many points along the progression of the risk assessment and its extent varies greatly. Uncertainty is present in the values obtained, the model chosen and the scenarios chosen. Regardless of origin or extent, uncertainty must be documented. One of the most common criticisms of ecological risk assessments is inadequate discussion of associated uncertainties (EPA 1992b). Masking or omission of uncertainty does not lend a higher credibility to the data presented, it simply hampers the subsequent decisions by preventing an informed evaluation of the data. Sources of uncertainty include natural variability, measurement error, sampling error, human error, extrapolation mandated by an incomplete knowledge base and

incorrect assumptions and oversimplification. Each contributor to the uncertainty of a value or decision must be documented in the risk assessment at the point where the data are introduced; and all uncertainty associated with data presented in the risk characterization should be summarized here.

A sensitivity analysis of parameters may help to identify which ones have the most significant impact upon the risk estimate. Further, those uncertainty factors with the highest potential for reduction may be discerned. If data uncertainty, including that attributable to scientific assumptions, professional judgement, and possible error are tracked during the preceding stages of the risk assessment, the risk characterization will be simpler to assemble.

Uncertainty analysis is used to quantify some of the uncertainty associated with the prediction of a risk assessment by describing the uncertainty of the inputs to the risk assessment. The uncertainty described may be due to variability, due to an input that varies over time or by the individual selected, or the uncertainty may be due to lack of knowledge of the correct value for a model input value. This second source may be reduced by further study.

A popular tool for uncertainty analysis is the Monte Carlo uncertainty analysis technique. With this technique, some of the uncertainties in the risk assessment are described by distributions and then carried through the assessment to yield a probability distribution as the risk assessment prediction. Refer to EPA policy paper on Monte Carlo analysis (EPA 1997). This technique is discussed further in the next.

7.1.5 Interpretation of Uncertainty

Overall, there are three important considerations related to uncertainty which must be presented in the risk assessment report. Foremost, the risks must be identified; second, they must be quantified to the extent possible; third, they must be explained (or qualified). Regardless of any uncertainty analysis method used, these three steps must be adhered to for all relevant values, calculations and assumptions presented within the risk assessment. Such data should have been presented throughout the risk assessment as it arose. In this section, key uncertainties may be reiterated. Most importantly, how the uncertainties impact risk assessment results should be discussed. Figure 7-1 shows an example of results from a Monte Carlo uncertainty analysis. It examines the uncertainty in the exposure model prediction, due to uncertainty in the model

inputs. The chart shows the range of possible values; a cumulative chart derived from this output would show that about 80% of the values predict a hazard quotient below one.

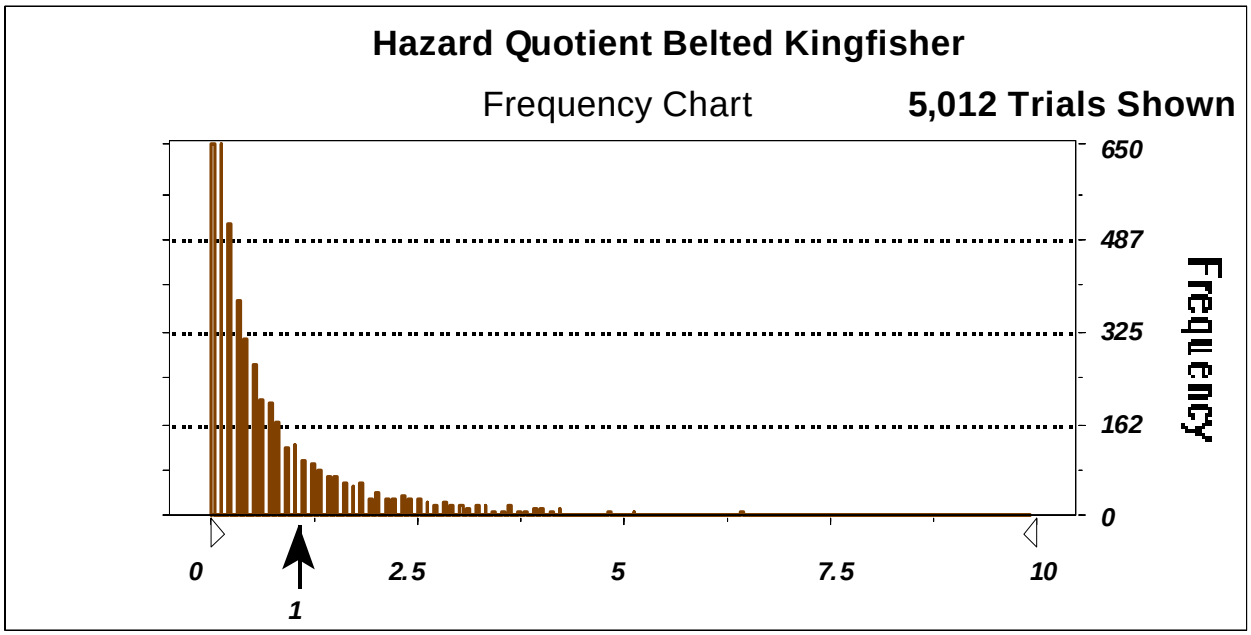


Figure 7- 1 Frequency Chart of the Hazard Quotient for the Belted Kingfisher.

. The Monte Carlo method has the benefits of better describing some of the risk assessment uncertainties verses a qualitative description. It also forces a closer look at all of the model input parameters in order to assign distributions. However, this technique has the disadvantages of added effort in its application and the possibility of being misapplied or possibly misrepresenting the risk assessment uncertainties.

The use of Monte Carlo uncertainty analysis is encouraged in appropriate cases. Because of the potential to complicate the risk assessment, before a Monte Carlo uncertainty analysis is conducted, the contractor must present, through the RPM, its proposed use of Monte Carlo to the ERA reviewer for approval. Documentation of the proposed use and its projected advantages should be provided. Some of the requirements for its usage include:

- A description of all assumptions to be used in the application of the method;

- A full description of distributions used in the analysis and the basis for each, including possible alternatives;
- A sensitivity analysis describing important model parameters;
- A description of the uncertainties that are not described by the Monte Carlo analysis; *Is it variability and/or uncertainty that is being described?*
- A computer disk of the risk model and assumptions made in the uncertainty analysis.

The Monte Carlo analysis is not necessarily appropriate for all situations; however, if it appears to offer a better analysis of data for a given site, the above information should be provided to the RPM and a discussion initiated to facilitate a timely and informed decision.

7. 2 Interpretation of Ecological Significance

Once calculations are made, and accompanying uncertainty presented and analyzed, conclusions must summarized. What do the numerical results imply? What ecological risks are present at the site. Utilizing the conceptual site model and the endpoint analysis strategy, can a clear relationship of cause and effect be shown for between given contaminants and specific effects on the ecosystem? What are the implications of the various uncertainties? These are the types of focusing questions which should be answered in this final section of the risk assessment. If site risks are to be compared to background risks, a discussion of the outcome of this comparison, qualitative or quantitative, should be articulated here also.

7.2.1 Conclusion with Evaluation of Ecological Significance

Ecological Significance encompasses changes in both structure and function of an ecosystem; and a discussion of these changes is the concluding portion of the risk description. Risk estimates should have been determined during data analysis, a discussion of the lines of evidence leading to these estimates should have been initiated during data analysis and continued into the uncertainty assessment. Remaining is an interpretation of the ecological significance of the estimates. Such an interpretation should follow naturally from the conceptual site model and the assessment endpoints chosen to evaluate the site.

This section should begin with a brief recapitulation of the conceptual site model and any

modifications made to it in the course of the subsequent stages of the risk assessment. The hypotheses chosen to evaluate this model should be described, applying the assessment endpoints for evaluation. For select key hypotheses and endpoints which were rejected, a brief explanation in support of this decision should be offered. Any critical assumptions or gaps of information should be identified, as should any points for which a consensus was never reached. (Such instances should be rare, but may, upon occasion, occur. In such cases, the risk manager will direct how to proceed on the risk assessment, and this may be noted in the risk characterization.) Inevitably, professional judgement will be used to assess ecological significance; such instances should be noted as such.

The ecological significance of risks presented should include an evaluation of intensity of effects, scale, both spatial and temporal, of effects and potential for recovery of the ecosystem (EPA 1989b). Measures for evaluating the ecological significance of the risks presented at a site should have been developed in the problem formulation and conceptual site model design steps of the ecological risk assessment. An evaluation of assessment endpoints, accounting for intensity, scale and recovery should be the center of the ecological significance discussion. What a “recovered” ecosystem implies should be somewhat implicit in the values represented by the chosen endpoints. A more detailed picture can be drawn from these.

The information provided in this section will be used to guide prioritization of the site remediation. Clarity and completeness are essential. The analysis presented here must be connected to the assessment endpoints selected for the risk assessment. This will insure that individuals reading the assessment understand both its purpose and its results, thereby providing a clear perspective of the ecological impacts experienced by or projected for the site.

8.0 Step 8: Risk Management

Risk management is a process that ensues when the baseline risk assessment is complete. Risk management decisions are the responsibility of the project manager (risk manager), not the risk assessor. However, the project manager utilizes the risk assessment in conjunction with available remedial options to select a preferred remedy for a site. It is imperative that the project manager understand the risk assessment, including uncertainties and other limitations. This understanding is crucial to the project managers ability to select the best remedial action for a site. For instance, a risk assessment based on field study data which includes species of concern can be appropriately weighted higher in the risk management decision in comparison to a risk

assessment built around a literature search and/or toxicity studies on surrogate species. It is essential that all uncertainty linked to all risk assessment data be clearly documented.

9.0 RISK ASSESSMENT TASKS FOR THE FS

9.1 Risk Evaluation of Remedial Alternatives

Depending on the results of the risk assessment, these alternatives may be based on ecological concerns, human health concerns, or a combination of the two. Parts B and C of the Risk Assessment Guidance for Superfund, HHEM provide guidance on calculation of human health risk-based remediation goals and risk evaluation of remedial alternatives. However, because these processes involve the integration of risk assessment with management and feasibility concerns, specific deliverables and level of effort will be determined according to the needs of each site.

9.2 Scheduling of Risk Assessment Deliverables for the FS

Risk assessment tasks for the FS must be integrated in the FS process. The risk assessor will need to provide risk-based concentrations, as developed during scoping or modified based on the baseline risk assessment, to engineers working on remedial alternatives. Engineers will need to provide estimates of time to complete remediation, of expected treatment residuals, and of potential for releases during remedial activities to the risk assessor, for evaluations of long-term and short-term risks. These pieces of information may be called for as separate deliverables at the discretion of the RPM. This would probably be necessary for PRP-lead sites.

At some sites, incineration of hazardous materials is considered as a remedial alternative. In such cases, there are risk assessment related tasks which must be performed. A list of guidance documents, addressing both screening level evaluations and baseline risk assessment activities, is provided in section 10 of this document. Region 10 has also recently developed a screening level conceptual model and accompanying computer spreadsheet for screening level risk assessment of human indirect exposure to air emissions sources, including hazardous waste incinerators. For more information about this model, contact the Region 10 Risk Evaluation branch in the Office of Environmental Assessment.

10.0 Ecological Risk Assessment Resources

10.1 General Guidance

Framework for Ecological Risk Assessment. 1992. EPA/630/R-92/001

A Review of Ecological Assessment Case Studies from a Risk Assessment Perspective. 1992. EPA/630/R-92/005.

Risk Assessment Guidance for Superfund, Volume II, Environmental Evaluation Manual. 1989. Office of Solid Waste and Emergency Response. EPA 540/1-89/001A.

Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference. 1989. EPA/600/3-89-013.

Guidance for Data Useability in Risk Assessment. 1992. Office of Emergency and Remedial Response, Office of Solid Waste and Emergency Response, Directive No. 9285.7-09A and B.

The following recent publications contain information of interest for ecological risk assessment. Copies may be obtained from the addresses indicated.

- *Ecological Risk: A Primer for Risk Managers* (EPA/734-R95-001). January 1995. Office of Prevention, Pesticides & Toxic Substances; US EPA; (H7507C) Crystal Mall II (CM-2); 1921 Jefferson Davis Hwy; Arlington, VA 22202.

- *Summary of Guidelines for Contaminated Sediments* (WDOE, Publication # 95-308). March 1995. Washington Department of Ecology; Publication; Distribution Office; P. O. Box 47600; Olympia, WA 98504-7600; (360) 407-7472

- *Protocol for the Derivation of Canadian Sediment Quality Guidelines for the Protection of Aquatic Life* (Canadian Council of Ministers of the Environment, Report CCME EPC-98E). March 1995. Guidelines Division; Evaluation and Interpretation Branch; Environment Canada; Ottawa, Ontario, K1A 0H3; CANADA

- U.S. Environmental Protection Agency (EPA). 1994. *Ecological Risk Assessment for*

Superfund: Process for Designing and Conducting Ecological Risk Assessments, review draft. Edison, NJ: Environmental Response Team.

- U.S. Environmental Protection Agency (EPA). 1995. *Draft Proposed Guidelines for Ecological Risk Assessment.* Risk Assessment Forum, Washington, D.C., EPA/630/R-95/002.

- U.S. Environmental Protection Agency (EPA). [Soon to be released.] *Superfund Mine Waste Reference Document. (This document will have an ecological risk assessment chapter geared towards mining sites, but also an appendix covering the general ecological risk assessment process.)*

10.2 Screening Values

Batts, D. And J. Cubbage. 1995. *Summary of Guidelines for Contaminated Freshwater Sediments.* Washington State Department of Ecology. *NOTE: This reference has good screening values, but site-specific data may be more appropriate, as conditions vary.*

Screening Benchmarks for Ecological Risk Assessment. Environmental Sciences and Health Sciences Research Divisions Oak Ridge National Laboratory, Oak Ridge, Tennessee. *NOTE: These are "benchmark" values and are useful if other information is lacking; the basis for each value should be critically evaluated before it is used.*

US EPA. January 1996. Ecotox Thresholds. *ECO Update* **3**(2). Intermittent Bulletin of Office of Emergency and Remedial Response. *NOTE: These values may not be appropriate in all situations; particular attention should be given to applicability to site conditions.*

10.3 Uncertainty References

Frey, H.C., *Quantitative Analysis of Uncertainty and Variability in Environmental Policy Making*, American Association for the Advancement of Science, Washington. DC. 1992.

Burmaster, D.E. and Anderson, P.D., "Principles of Good Practice for the Use of Monte Carlo Techniques in Human Health and Ecological Risk Assessments." *Risk Analysis*, Vol 14, pp. 477-481, 1994.

MacIntosh, D.L., Suter, G.W., and Hoffman, F.O., “Use of Probabilistic Exposure Models in Ecological Risk Assessments of Contaminated Sites,” *Risk Analysis*, Vol 14. pp. 405-419, 1994.

US EPA. May 15, 1997. Policy for use of Probabilistic analysis in risk assessments: *Guiding principles for Monte Carlo Analysis.* EPA/630/R-97/001.

10.4 Where to Obtain Documents

- *IRIS User Support* (513-569-7254). This resource can provide information about how to access IRIS on-line through vendors. IRIS is also available on PC-compatible diskettes from NTIS.

- *National Technical Information Service*, Springfield, VA (703-487-4650). NTIS distributes many government publications including EPA documents.

- *National Risk Management Research Laboratory* (formerly, CERI), Cincinnati, Ohio (513-569-7562). Depending on availability, NRMRL can provide free single copies of ORD guidance documents, primarily those identified with EPA/600, and some other documents.

- *Superfund Docket* (703) 603-8917. Limited source for guidance identified as "OSWER Directive # XXXXX."

- *Region 10 EPA Library* (206-553-1289). The library will loan EPA publications (and ATSDR Toxicity Profiles) to the public.

- Safe Drinking Water Hotline (800-426-4791). This hotline is staffed from 9 am to 5:30 pm EST.

11.0 REFERENCES

Calabrese, E. J., and L. A. Baldwin. 1993. Uncertainty factors for ecological risk assessment. In: E.J. Calabrese and L. A. Baldwin (eds.), Performing ecological risk assessment. Lewis Publishers, Boca Raton, Florida, Chapter 4.

Newell, A. J., D. W. Johnson and L. K. Allen. 1987. *Niagara River Biota Contamination Project: Fish Flesh Criteria for Piscivorous Wildlife.* Technical Report 87-3, division of Fish and Wildlife, Bureau of Environmental Protection, New York State Department of Environmental conservation.

US Environmental Protection Agency(EPA) 1997. *Policy for use of Probabilistic analysis in risk assessments: Guiding principles for Monte Carlo Analysis.* EPA/630/R-97/001.

U.S. Environmental Protection Agency (EPA). 1996a. *Ecological Risk Assessment for Superfund: Process for Designing and Conducting Ecological Risk Assessments, review draft.* Edison, NJ: Environmental Response Team.

U.S. Environmental Protection Agency (EPA). 1996b *Proposed Guidelines* for *Ecological Risk Assessment*, Risk Assessment Forum, Washington, D.C . EPA/630R-95/002B.

U.S. Environmental Protection Agency (EPA). 1996c. *Ecotox. ECO Update, Intermittent Bulletin, Volume 3, Number 2.* Washington, DC: Office of Emergency and Remedial Response, Hazardous Site Evaluation Division; Publ. 9345.0-12FSI.

U.S. Environmental Protection Agency (EPA). 1995a. *Risk Characterization Memorandum*. Washington, DC: EPA Administrator; March 1995.

U.S. Environmental Protection Agency (EPA). 1995b. *Exposure Factors Handbook, Internal Review Draft.* Washington, D.C.: NCEA; Publ. NCEA-W005.

U.S. Environmental Protection Agency (EPA). 1995c. *Health Effects Assessment Summary Tables* (HEAST). Office of Solid Waste and Emergency Response, Office of Emergency and Remedial Response 9200.6-303. NTIS No. PB91-921100.

U.S. Environmental Protection Agency (EPA). 1995d. *Integrated Risk Information System* (IRIS). On-line database.

U.S. Environmental Protection Agency (EPA). 1994a. *Ecological Risk Assessment for Superfund: Process for Designing and Conducting Ecological Risk Assessments, review draft.* Edison, NJ: Environmental Response Team.

U.S. Environmental Protection Agency (EPA). 1994b. *Soil Screening Guidance.* Office of Solid Waste and Emergency Response; EPA/540/R-94/101.

U.S. Environmental Protection Agency (EPA). 1994c. *A Review of Ecological Assessment Case Studies from a Risk Assessment Perspective, Volume II*. Washington, DC: Risk Assessment Forum; EPA/630/R-94/003.

U.S. Environmental Protection Agency (EPA). 1993a. *Wildlife Exposure Factors Handbook, Volumes I and II.* Washington, DC: Office of Research and Development; EPA/600/R-93/187A&B.

U.S. Environmental Protection Agency (EPA). 1993b. *A Review of Ecological Assessment Case Studies from a Risk Assessment Perspective, Volume I*. Washington, DC: Risk Assessment Forum; EPA/630/R-93/005.

U.S. Environmental Protection Agency (EPA). 1992a. *Framework for Ecological Risk Assessment.* Washington, DC: Risk Assessment Forum; EPA/630/R-92/001.

U.S. Environmental Protection Agency (EPA). 1992b. *Peer Review Workshop Report on a Framework for Ecological Risk Assessment.* Washington, DC: Risk Assessment Forum; EPA/625/3-91/022.

U.S. Environmental Protection Agency (EPA). 1991a. *Conducting Remedial Investigations/Feasibility Studies for CERCLA Municipal Landfill Sites.* Office of Emergency and Remedial Response. OSWER Directive No. 9355.3-11.

U.S. Environmental Protection Agency (EPA). 1991b. *Interim Guidance for Dermal Exposure Assessment.* Office of Research and Development, Office of Health and Environmental

Assessment. OHEA-E-367.

U.S. Environmental Protection Agency (EPA). 1991c. *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part B, Development of Risk-based Remediation Goals.* Office of Solid Waste and Emergency Response. OSWER Directive No. 9285.7-01B.

U.S. Environmental Protection Agency (EPA). 1991d. *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part C, Risk Evaluation of Remedial Alternatives.* Office of Solid Waste and Emergency Response. OSWER Directive No. 9285.7-01C.

U.S. Environmental Protection Agency (EPA). 1991e. *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions.* Office of Solid Waste and Emergency Response. OSWER Directive No. 9355.0-30.

U.S. Environmental Protection Agency (EPA). 1991f. *Supplemental Guidance on Performing Risk Assessments in Remedial Investigations/Feasibility Studies Conducted by Potentially Responsible Parties*. Office of Solid Waste and Emergency Response. OSWER Directive No. 9835.15a.

U.S. Environmental Protection Agency (EPA). 1991g. *The Role of BTAGs in Ecological Assessment. ECO Update, Intermittent Bulletin, Volume 1, Number 1.* Washington, DC: Office of Emergency and Remedial Response, Hazardous Site Evaluation Division; Publ. 934.0.05I.

U.S. Environmental Protection Agency (EPA). 1991h. *Risk Assessment Guidance for Superfund, Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors.* Office of Emergency and Remedial Response, Office of Solid Waste and Emergency Response, Directive No. 9285.6-03.

U.S. Environmental Protection Agency (EPA). 1990a. *Air Pathway Analysis Procedures for Superfund Applications. Office of Air Quality Planning and Standards.* EPA/450/1-89/001,002,003,004.

U.S. Environmental Protection Agency (EPA). 1990b. *Guidance for Data Useability in Risk Assessment. Office of Emergency and Remedial Response.* EPA/540/G-90/008.

U.S. Environmental Protection Agency (EPA). 1990c. *Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions.* EPA 600/6-90/003.

U.S. Environmental Protection Agency (EPA). 1990d. *National Oil and Hazardous Substances Pollution Contingency Plan; Final Rule.* Federal Register, Vol. 55, No. 46, pages 8665-8865.

U.S. Environmental Protection Agency (EPA). 1989a. *Development of a Risk Assessment Methodology for Land Application and Distribution and Marketing of Municipal Sludge.* EPA 600/6-89/001.

U.S. Environmental Protection Agency (EPA). 1989b. *Ecological Assessment of Superfund Sites: An Overview. ECO Update, Intermittent Bulletin, Volume 1, Number 2.* Washington, DC: Office of Emergency and Remedial Responses, Hazardous Site Evaluation Division; Publ. 9345.0.0-5I.

U.S. Environmental Protection Agency (EPA). 1989c. *Risk Assessment Guidance for Superfund: Volume 2 - Environmental Evaluation Manual, Interim Final.* Washington, DC: Office of Solid Waste and Emergency Response; EPA/540/1-89/001A.

U.S. Environmental Protection Agency (EPA). 1989d. *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part A, Baseline Risk Assessment.* Office of Solid Waste and Emergency Response. OSWER Directive No. 9285.7-01A. EPA 540/1-89/002.

U.S. Environmental Protection Agency (EPA). 1989e. *Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference.* Corvallis, OR: Office of Research and Development, Environmental Research Laboratory; EPA/600/3-89/013.

U.S. Environmental Protection Agency (EPA). 1988a. *CERCLA Compliance with Other Laws Manual, Interim Final, Volumes, I and II.* Office of Emergency and Remedial Response. OSWER Directive No. 9234.1-01 and 9234.1-02. EPA/540/6-89-009.

U.S. Environmental Protection Agency (EPA). 1988b. *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA.* Office of Emergency and Remedial Response. OSWER Directive No. 9355.3-01.

U.S. Environmental Protection Agency (EPA). 1988c. *Estimating Exposures to 2,3,7,8-TCDD.* Office of Health and Environmental Assessment. EPA 600/6-88/005A.

U.S. Environmental Protection Agency (EPA). 1988e. *Superfund Exposure Assessment Manual*. Office of Remedial Response. EPA 540/1-88/001.

U.S. Environmental Protection Agency (EPA). 1988f. *Estimating Toxicity of Industrial Chemicals to Aquatic Organisms Using Structure Activity Relationships.* Office of Toxic Substances; EPA/560/688/001.

U.S. Environmental Protection Agency (EPA). 1986a. *Risk Assessment Guidelines of 1986*. Office of Health and Environmental Assessment. EPA/600/8-87-045. (Also published in the Federal Register, September 24, 1986, 55 FR 33992-34054.)

U.S. Environmental Protection Agency (EPA). 1986b *Standard Evaluation Procedure , Ecological Risk Assessment*. EPA/600/8-87-045. Hazard Evaluation Division. EPA 540/9-86/167. D. J. Urban and N. J. Cook, Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, D.C.

U.S. Environmental Protection Agency, Region III (EPA III). 1994. *Interim Ecological Risk Assessment Guidelines.* Philadelphia, PA: Hazardous Waste Management Division, Superfund Program Branch; Publ. 19107-4431.

U.S. Environmental Protection Agency, Region IV (EPA IV). 1995a. *Data Collection and Evaluation, Supplemental Guidance to RAGS: Region 4 Bulletins: Human Health Risk Assessment.* Atlanta: Waste Management Division; Bulletin 1.

U.S. Environmental Protection Agency, Region IV (EPA IV). 1995b. *Toxicity Assessment, Supplemental Guidance to RAGS: Region 4 Bulletins: Human Health Risk Assessment.* Atlanta: Waste Management Division; Bulletin 2.

U.S. Environmental Protection Agency, Region IV (EPA IV). 1995c. *Exposure Assessment, Supplemental Guidance to RAGS: Region 4 Bulletins: Human Health Risk Assessment.* Atlanta: Waste Management Division; Bulletin 3.

U.S. Environmental Protection Agency, Region IV (EPA IV). 1995d. *Risk Characterization, Supplemental Guidance to RAGS: Region 4 Bulletins: Human Health Risk Assessment.* Atlanta: Waste Management Division; Bulletin 4.

U.S. Environmental Protection Agency, Region X (EPA X). 1990. *Region 10 Policy, Conduct of Remedial Investigations and Feasibility Studies.* Region 10 Hazardous Waste Division.

Van Horn, R.L., N.L. Hampton, T.A. Bensen and C.S. Staley (INEL). 1994. *Guidance Manual for Conducting Screening Level Ecological Risk Assessment of the INEL, draft.* Idaho Falls, ID: Idaho National Engineering Laboratories.

Washington State Department of Ecology. 1991. *Model Toxics Control Act Cleanup Regulation.* Chapter 173-340 WAC.

Appendix A

(Determination of background Levels for Soils)

This document is being reviewed

Appendix B

(I)Region 10 Guidelines for determining the bioavailability of inorganic contaminants in soil for human health and ecological risk assessments

For evaluations of the soil and dust ingestion pathway in human and animal exposure assessments, it may be appropriate to adjust the percentage of uptake of some inorganic contaminants. Physical and chemical properties of metals such as solubility and speciation, may affect bioavailability. Metals in the environment do not occur in pure form, instead they form compounds with other chemical elements, like carbon, phosphorus, silicon and sulfur. Also, characteristics of the soil matrix may decrease the bioavailability of these contaminants into the body from 100 percent. Additionally, biological and behavioral features of the receptor such as conditions in the stomach, lungs and intestines (in human or animal), may also decrease the uptake from 100 percent. However, there is no evidence to suggest that in all circumstances the bioavailability of inorganic soil contaminants will always be less than 100 percent.

This Region 10 risk assessment guidance provides default options for specific inorganic contaminants in soil. If non-default options are desired, further guidance is provided regarding the acceptable approaches.

I. Guidelines for specific inorganic contaminants in soil:

A. Arsenic

1. If contamination is associated with the application of pesticides/herbicides, wood treatment processes and/or fossil fuel combustion, assume 100% bioavailability.

2. If the site is a smelter site and its appears likely that the arsenic exists primarily as finely-grained oxides from smelter stack emissions, assume 80% relative bioavailability. This value is supported by a conservative interpretation of the scientific literature (EPA, 1992).

3. If the site is primarily impacted by mineralogical activities such as mining, milling, tailings and other activities and no associated smelting activities, assume 60% relative bioavailability.

   This value is the ***lower 95%*** *confidence limit* derived from the Region 10 oral dosing study of immature swine. Swine were dosed with residential soils collected from a smelter-impacted site at Ruston, Tacoma in Washington state. This study has been scientifically peer reviewed and the complete report is available (EPA 910/R-96-002). Based on results from several scientific, peer reviewed reports it is reasonable to assume that the lower confidence limit of results based on smelter wastes (i.e. 60%) is unlikely to be less than the mean of a study based on site-specific mining wastes. However, 60% relative bioavailability is likely to be within the 95% confidence limits of the mean of results from a study based on mining wastes, if such a site-specific study existed.

B. Lead

1. If the assessment is for childhood exposures, use the default bioavailability parameter incorporated in the Integrated Exposure Uptake Biokinetic (IEUBK) Model for Children (version 0.99d), or the most current model version.

2. If the assessment is for adult exposures, use the default bioavailability parameter incorporated in the USEPA "Recommendations of the Technical Review Workgroup for Lead for an Interim Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil" (December 1996), or the most current version.

3. If alternate bioavailability values are proposed (based either on *in vivo* studies, blood lead studies or other studies) for use in the IEUBK model or the Adult model, the proposed values should be

submitted to the Technical Review Workgroup (TRW) for Lead for review and/or should be compared to current guidance regarding use the IEUBK, blood lead studies and other studies. Review by the TRW is intended to assure national consistency in lead exposure and risk assessment.

II. Guidelines for inorganic contaminants in soil

If non-default options for arsenic or lead are desired, or bioavailability for other inorganic contaminants is being considered in the risk assessment, the following guidance is provided regarding acceptable approaches.

A. Based on the toxicological data available and the basis for the cancer slope factor or Reference Dose, determine whether bioavailability data should represented as “absolute” or “relative”. Consultation with the regional toxicology staff should be sought when making this determination.

The choice of appropriate bioavailability factors should be discussed with the regional toxicology staff during the planning and scoping phases of the baseline risk assessment. This will assure that the proper environmental samples are collected and that the site manager is briefed regarding the significance of bioavailability at the site under consideration, and the uncertainties associated with the various types of data discussed below.

B. If *in vivo* data on the extent of uptake of a specific inorganic contaminant from site-derived wastes are available, these data should be qualitatively or quantitatively utilized in the exposure assessment. Quantitative use of the data should be dependent on the scientific merit of the study, the degree of confidence that site-specific exposure parameters have been appropriately addressed in the study design and that the results of the study are applicable to the exposure assessment under consideration. When *in vivo* data are not adequate for quantitative use, the data may be used in the risk assessment report’s discussion regarding uncertainties

of the exposure assessment, to design further *in vivo* studies and/or to design other types of laboratory studies.

C. If site-specific *in vivo* data on bioavailability are lacking but mineral speciation or petrological data are available, and those data indicate that the site-derived wastes are sufficiently similar to materials used in an appropriate *in vivo* study (see above), then the “absolute” or “relative” bioavailability, whichever is appropriate, may be used from the *in vivo* study. The cons-traints on the use of the *in vivo* data are the same as stated in #2, above.

D. If mineralogical or petrological data are not available from site-derived wastes, if available data are inadequate, if site samples are not sufficiently similar to samples utilized in an *in vivo* study, or if the *in vivo* data are inapp-ropriate for the site under consideration then 100 percent bioavailability should be assumed in the exposure assessment. (See above for specific defaults for arsenic and lead.)

Glossary:

Absolute-bioavailability. This is the situation where the *absorbed fraction* of a specific compound in a particular medium is identical to the bioavailable form. For example, if sodium arsenate was 80 percent absorbed from drinking water and arsenic sulfide was 40 percent absorbed from the same water, then the *absolute* bioavailability of these compunds would be 80 percent and 40 percent, respectively **.**

Relative-bioavailability. This is the situation where the absorption of a particular compound in a particular medium is compared to some other reference point. For example, in the case above, if sodium arsenate in drinking water was the reference point, then the *relative* bioavailability of arsenic sulfide in drinking water would be 80 divided by 40, which would be equal to 0.50 or 50 percent.

References:

USEPA. 1996. Bioavailability of arsenic and lead in environmental substrates I. Results of an oral dosing study of immature swine. February 1996, EPA 910/R-96-002.

USEPA. 1994. Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK). EPA/540/R-93/083. Office of Emergency and Remedial response, Washington, D. C.

USEPA. 1992.< Baseline Risk Assessment Ruston/ North Tacoma Operable Unit Commencement Bay Nearshore/Tideflats Superfund Site, Tacoma, Washington.

II.Oakridge Toxicological Screening Benchmark Values

(To download this document, please visit the Oak Ridge National Laboratory Homepage at:
http://www.ornl.gov/

Appendix C

"The Tool Box"
Region 10 Risk Report Technical Issues
(Guidelines for Screening Radionuclides for Eco-effects)

See Radiotoxicological Benchmarks for Wildlife at the Rocky Flats Environmental Te - Programs and Capabilities Database No. 607-024. RADIOTOXICOLOGICAL BENCHMARKS FOR WILDLIFE AT THE ROCKY FLATS ENVIRONMENTAL TECHNOLOGY (RFET) SITE.... --**http://www.anl.gov/LabDB/Current/Ext/H607-text.024.html**

Appendix D

Region 10 Risk Report, Special Release Case Study Summaries

Office of Environmental Assessment

June 1997
Release Number 1

Region 10 Risk Report

focus: eco risk

1200 Sixth Avenue
Seattle, WA 98101
(206) 553-8209

An intermittent publication of the US EPA Region 10 Risk Evaluation Unit, this report is intended as a technical case study illustration to supplement the regional Superfund risk assessment guidance (Jan 96) and can be nested in Appendix C of that document.

(Insert Soil Background Issue Paper)

Office of Environmental Assessment

June 1997
Release Number 2

Region 10 Risk Report

Special Release: Case Study

focus: eco risk

1200 Sixth Avenue
Seattle, WA 98101
(206) 553-8209

An intermittent publication of the US EPA Region 10 Risk Evaluation Unit, this report is intended as a technical case study illustration to supplement the regional Superfund risk assessment guidance (Jan 96) and can be nested in Appendix IV of that document.

(Insert Soil Background Case Study Excerpts from Region 10 Sites)

Office of Environmental Assessment

June 1997
Release Number 3

Region 10 Risk Report

Special Release: Case Study

focus: eco risk

1200 Sixth Avenue
Seattle, WA 98101
(206) 553-8209

An intermittent publication of the US EPA Region 10 Risk Evaluation Unit, this report is intended as a technical case study illustration to supplement the regional Superfund risk assessment guidance (Jan 96) and can be nested in Appendix D of that document.

(Insert Ecological Risk Assessment Case Study)

Attachments