EPA Region 10
Supplemental Risk Assessment Guidance for Superfund

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FOREWORD

The purpose of the *EPA Region 10 Supplemental Risk Assessment Guidance for Superfund* 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 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 *Risk Assessment Guidance for Superfund, Volumes I and II* (RAGS) (EPA 1991c&d, EPA 1989c&d) and other national EPA guidance documents related to the conduct of risk assessments (EPA 1992a, EPA 1994a). National supplements to RAGS are separate from this regional guidance document and may be obtained from the relevant national office listed in section 7.3 of this document.

This regional guidance applies solely to risk assessments conducted at region 10 National Priorities List (NPL) sites. While this guidance is primarily intended to clarify and extend the national RAGS, as interpreted and applied by Region 10, in some cases (e.g., human health contaminant screening), as noted within the text, regional guidance will not be consistent with national RAGS. In such cases, unless other wise agreed upon with the regional project manager (RPM), regional guidance should prevail.

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 risk assessment guidance issued from the Office of Environmental Assessment and Superfund in Region 10. Copies of regional guidance materials may be obtained from the Office of Environmental Assessment Risk Evaluation Unit (206/553-8209).

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 Risk Assessment Guidance for Superfund* should help to create scientifically sound, technically defensible and consistent risk assessments in Region 10.

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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
EPA	[United States] Environmental Protection Agency
ERA	ecological risk assessment
FS	feasibility study
HEAST	Heath Effects Assessment Summary Tables
HHEM	Human Health Evaluation Manual of the RAGS
HHRA	human health risk assessment
HI	hazard index
HQ	hazard quotient
IRIS	Integrated Risk Information System
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
RBC	risk-based concentration
RfC	reference concentration
RfD	reference dose
RI	remedial investigation
RME	reasonable maximum exposure
ROD	record of decision
RPM	regional project manager
SARA	Superfund Amendments and Reauthorization Act of 1986
TRV	toxicity reference value
TQ	toxicity quotient
UCL	upper confidence limit
UTL	upper tolerence level

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. Updates from the previous (1992) version of the Region 10 guidance are highlighted 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.

The methodology recommended for use in developing the baseline risk assessment is described in the *Risk Assessment Guidance For Superfund, Volume I: Human Health Evaluation Manual, Part A* (RAGS HHEM) (EPA 1989d) and *Volume II, Environmental Evaluation Manual* (EPA 1989c). Parts B (EPA 1991c) and C (EPA 1991d) of the Human Health Evaluation Manual (HHEM) provide guidance on the use of risk assessment in the Feasibility Study. Additional ecological risk assessment guidance can be found in the *Framework for Ecological Risk Assessments* (EPA 1992a), the draft *Ecological Risk Assessment for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (EPA 1994a) and the upcoming EPA Risk Assessment Forum's *Ecological Risk Assessment Guidelines* (not yet available at time of publication).

Text Box 1-1 Highlights of Revised Region 10 Guidance

- Ecological Risk Assessment Guidance (Sections 3.4 and 5.0)
- Revised Radionuclide PRG Equations (Appendix A)
- Use of Region 3 Risk-Based Screening Concentrations (Attachment 1)
- Updated Resources and References (Section 7.0 and 8.0)
- [Mapping in Risk Assessments (Section 4.4)]
- Technical Issue Papers Section (Appendix C)
- Case Studies Section (Appendix D)

1.1 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 X 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 1-2), or may be submitted as separate technical memos, according to the needs of the particular project. The EPA Remedial Project Manager (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 submitted, as outlined in text box 1-2. Further discussion of scheduling of risk assessment deliverables is provided in sections 2.1, 3.1, 4.1, 5.0 and 6.1. Headquarters guidance (EPA 1991f) also addresses 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 1-2 Integration of Risk Assessment Deliverables in RI/FS Process

Phase I. RI/FS Project Planning

Scoping

Conceptual Site Model (2.1)
Preliminary Remediation Goals (2.2)

RI/FS Work Plan

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Phase II. Preliminary Data Analysis / Site Characterization Summary

Evaluation of Lab Contaminants and Natural Background (3.2)
Risk-Based Screening of Contaminants (3.3 & 3.4)
Revised Conceptual Site Model/ Exposure Pathways (as needed) (3.5)
Revisions to Work Plan
Ecological Screening Level Results (5.1 & 5.2)
Ecological Endpoint Selection (5.3 & 5.4)

Phase III. Remedial Investigation and Feasibility Study Reports

Remedial Investigation Report

Baseline Risk Assessment (4.0 and 5.0)

Feasibility Study

Risk Evaluation of Remedial Alternatives (6.0)

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

1.2 Focus of Risk Assessment

Detailed EPA guidance is available on the subject of risk assessment in general as well as Superfund risk assessment in particular. (See section 8.0, Resources.) We hope that this regional guidance will be useful in pointing out relevant guidance for specific issues. However, guidance does not serve as a "cookbook" or establish an invariable pattern, but is subject to interpretation.

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 any two sites. The process will be modified as appropriate to each project. The professional judgement 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. See RAGS HHEM (EPA 1989d), chapter 3, for additional discussion regarding goals and focus of the human health 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. 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 Regional Technical Guidance

To avoid overly frequent update releases of this guidance the region will issue an update publication to address evolving risk assessment technical issues. The *Region 10 Risk Review* will be released intermittently in response to selected human health and 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* should 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 human health/ecological risk assessments.

2.0 RI/FS PROJECT PLANNING

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

- Conceptual Site Model (2.1)
- Preliminary Remediation Goals (2.2)

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. 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)).

2.2 Conceptual Site Model

The Site Characterization Document, or another document used at 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 and 2-3. 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. More in depth discussion of the ecological components of the conceptual site model is presented in section 5-4.

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 threats in to perspective as well as to avoid redundancy in evaluation of components connected with both human and ecological health (e.g., contaminant uptake by fish which may be ingested by humans). RAGS HHEM (EPA 1989d) chapter 6 and *Standard Default Exposure Factors* (EPA 1991h) provide guidance on human exposure scenarios and pathways, as does section 4.2 of this regional guidance. Ecological exposure scenarios are discussed in the *Wildlife Exposure Factors Handbook* (EPA 1993a).

A written presentation of human and 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.

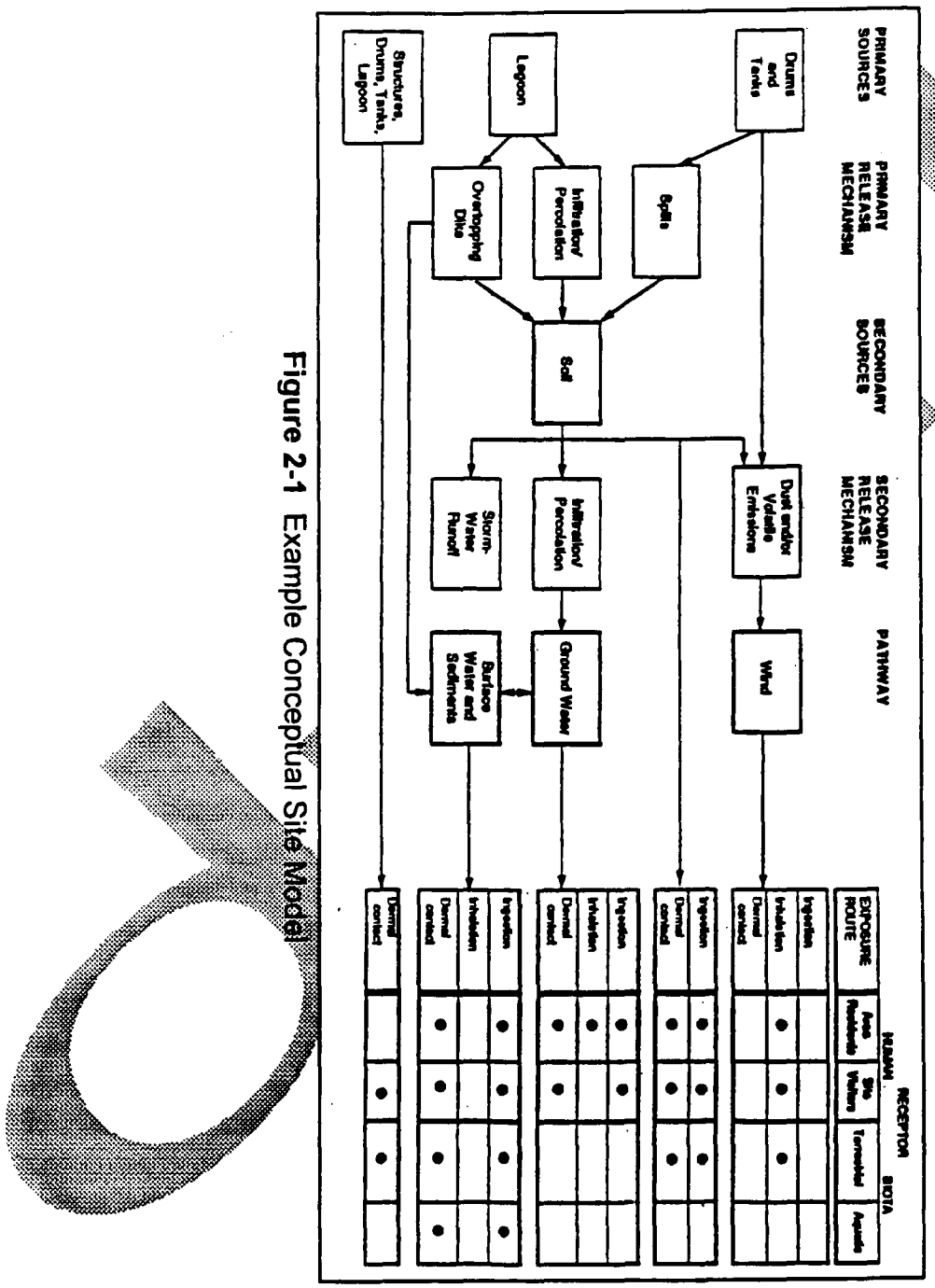


Figure 2-1 Example Conceptual Site Model

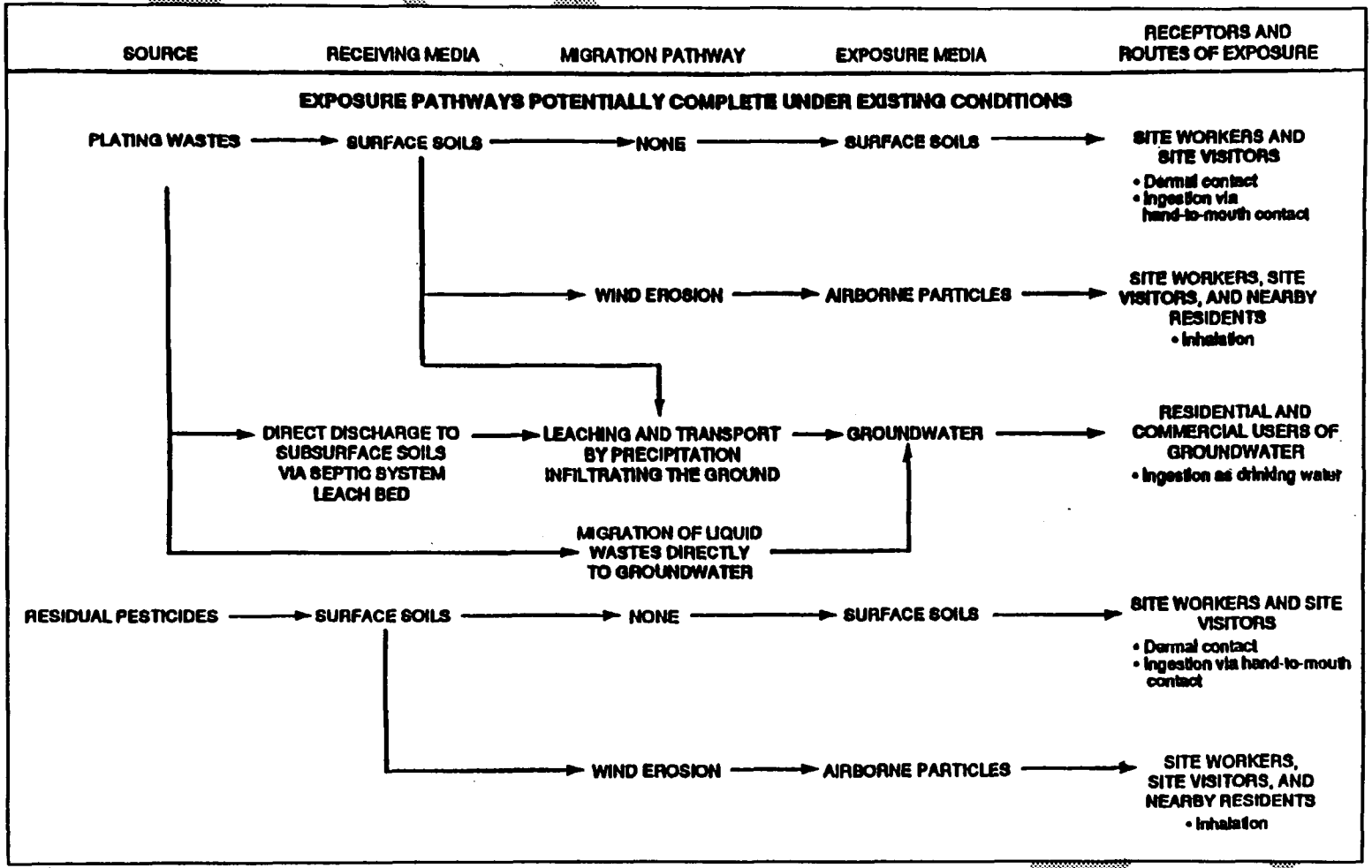
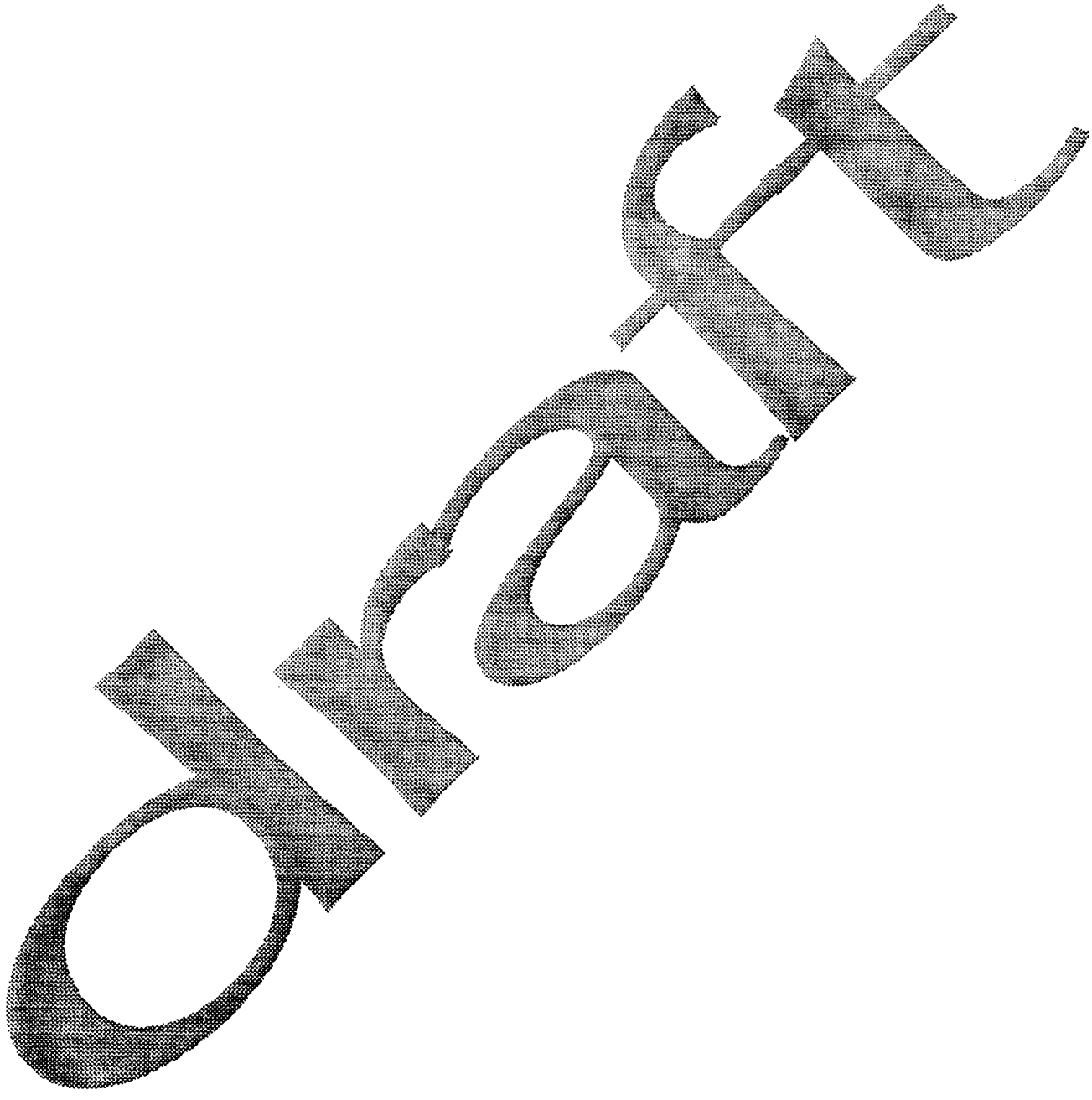


Figure 2-2 Example Graphical Conceptual Site Model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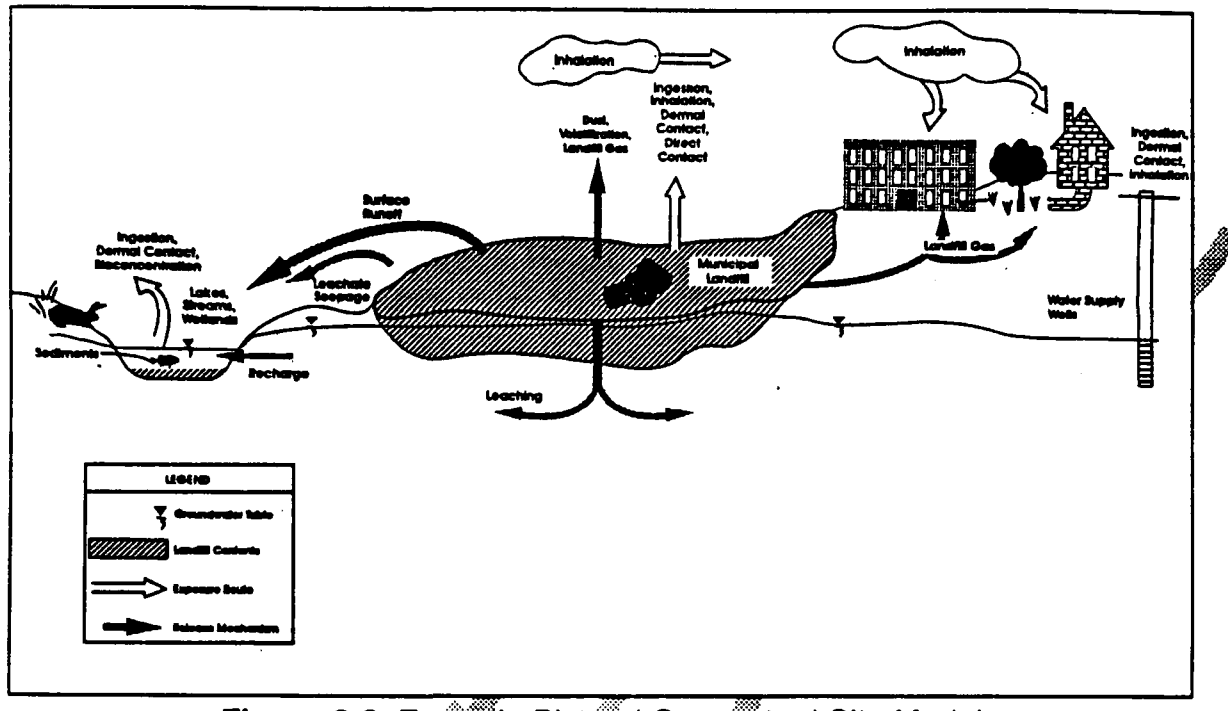


Figure 2-3 Example Pictoral Conceptual Site Model

2.2 Preliminary Remediation Goals

Preliminary remediation goals (PRGs) are categorized in two ways: (1) ecological vs. human health, and (2) risk-based (e.g. RBCs) vs. 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 much information available for both ecological and human heath threats be presented in this context. The Regional *Policy on Conduct of RI/FS* (EPA X 1990) emphasizes that preliminary remedial action objectives be developed at the initial scoping group meeting.

Steps involved in developing PRGs are presented in text box 2-2. Part B of the RAGS HHEM, *Development of Risk-Based Remediation Goals*, (EPA 1991c) addresses the need for early consideration of risk-based clean-up numbers. It presents simplified equations for calculating risk-based PRGs. However, the radionuclide equations in section four of RAGS HHEM Part B have been updated; new equations are given in Appendix A of this document. Human health screening level risk-based concentrations for a large number of chemicals are calculated and released semiannually by EPA Region 3; a compilation of these values at the time of this document's release can be found in attachment 1 of this document. Values for a limited number of contaminants, which take into account the additional transport pathway of migration of contaminants in soil to groundwater, may also 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 2-3, so it is essential to clearly site sources. Other references for ecological values may be found in section 7.3.

Text Box 2-2 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

The risk assessor should gather information, perform necessary calculations and present information, separated by media, in tabular form noting the following:

- contaminant,
- regulatory PRG(s) (ARARs) for each exposure pathway of concern,
- risk at ARAR(s) (primarily for human health values), and
- risk-based PRG(s) (RBCs) for each exposure pathway of concern.

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.

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. (See also section 2.3.) Also, as RI data becomes 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. (See also chapter 3.)

Project managers and other staff should be aware that the risk-based concentrations presented at this stage are preliminary. Changes may occur if new or revised toxicity information is obtained, and/or if site-specific modifications in exposure assumptions are appropriate. Consideration of cumulative exposures to multiple pathways and contaminants may affect risk-based numbers. Note that risk-based concentrations provided in Attachment 1 do not protect for ecological effects, migration of contaminants to groundwater or inhalation exposure pathways. To adequately confront human health concerns, volatile compounds may need to be addressed from a different perspective. Risk-based concentrations for soil are particularly susceptible to change, because assumptions about human exposure to contaminants in soil depend on several site-specific factors. 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.

2.2.1 List Expected Contaminants

The first step in developing PRGs is to assemble a list of potential site-related contaminants. Based on information about 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 in compiling the list of expected contaminants should be provided somewhere; the discussion may be part of the scoping document or conceptual site model,

or may accompany the table of PRGs. The list of expected contaminants may be lengthy for sites with complex sources. Chemicals may be added to or deleted from the list as more information becomes available during the RI.

2.2.2 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.

Human health risk at ARARs is calculated by treating ARAR concentrations as exposure point concentrations in risk equations, using standard default exposure factors. Risk-based concentrations for each contaminant are calculated by rearranging the same equations. For this step, the concentration corresponding to a target risk of 10^{-6} and 10^{-4} for carcinogens, and hazard quotient of 1 for non-cancer effects, is calculated. Relevant equations can be found in RAGS HHEM part B and, for radionuclides, in Appendix A. No calculation of ecological risk at ARARs is required; however, should such an analysis be deemed useful in decision making for the risk assessment, an analogue type of approach may be used. The use of analogues to estimate toxicity to aquatic organisms is described by EPA's Office of Toxic Substances (EPA 1988f).

2.3.3 Identify Risk-based Concentrations

Risk-based screening values for both ecological and human health have been calculated and are available for many contaminants. As noted above, Region 3 RBC tables are a good source of human health protective values, and are generally adequately conservative screening concentrations for most sites. Ecotox threshold values are listed in a recent *EcoUpdate* (EPA 1996), but when using these values, care should be taken to insure that they are adequately conservative for site-specific conditions. Other sources of potential screening values are listed in chapter 7.

Text Box 2-3 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
- NOAA Screening Guidelines
- AQUIRE database
- *Wildlife Exposure Factors Handbook* (EPA 1993a)
- current *ECO Updates*
- *Summary of Guidelines for Contaminated Sediments* (WDOE, Publication #95-308)
- *Screening Benchmarks for Ecological Risk Assessment* (Oak Ridge National Laboratory)

For some contaminants, and some media, pre-calculated values will not be available. In such instances toxicity data must be gathered, and risk-based concentrations calculated. Human health toxicity data can be found in IRIS (EPA 1995d) and HEAST (EPA 1995c). (See also section 4.3.1.) Toxicity reference values (TRVs) for ecological risks will also be needed to calculate PRGs. Such values may be found in the literature as well as many of the resources listed in text box 2-3. (See also sections 3.4 and 5.2.)

2.2.4 Present PRG Information in a Table

As noted above, results of the development of PRGs should be summarized in a tabular format. Separate tables for each medium (soil, groundwater, surface water, and sediment) are encouraged. Information pertaining to human health and ecological risk can be incorporated in the same presentations, if appropriate. However, ecologically-derived and human health-derived values should be clearly identified as such. Sources of data must be cited.

2.3 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 appropriate exposure pathways and chosen ecological endpoints for the risk assessment. The sampling plan should be designed with all data uses, including risk assessment, in mind. Hence, risk assessors must be involved in the development of data quality objectives related to the risk assessment. Development of data quality objectives is not limited to concern for the precision, accuracy, representativeness, completeness and comparability of the data. Data quality objectives also relate to determination of:

- types of laboratory analysis used,
- sensitivity of the analytical technique,
- detection limits,
- confidence limits, and
- the resulting data quality (ATSDR, 1994).

Specific risk assessment aspects of data quality objectives are discussed in the following subsections.

2.3.1 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 purposive design? 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 that have been selected for use at the site should be identified in the work plan. The *Superfund Exposure Assessment Manual* (SEAM) (EPA 1988e), *AirSuperfund National Technical Guidance* (EPA 1990a), *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 characteristics of soils, should be identified, and appropriate data collection activities included in the sampling plan.

2.3.2 Analytes and Detection Limits

Selection of analytical methods involves consideration of many site-specific factors, including

site use history and expected contaminants. Judgement of the RPM, chemist and risk assessor will be used to evaluate advantages and disadvantages of available methods. Appendix III of the *Data Useability Guidance* (EPA 1990b) compiles information on various analytical methods and associated detection limits, listed by chemical. Information developed during the scoping process, particularly RBCs and PRGs for expected site contaminants, will 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. Issues of cost and other data uses will affect the method selected. 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 chapter 5 of RAGS HHEM (EPA 1989d) and in the *Data Useability Guidance* (EPA 1990b). Judgement regarding the needs of a particular project should be used in interpreting this guidance. The discussion below highlights some important issues.

For many Superfund sites, a large number of chemicals is detected in site media. The ecological and human health threats posed by these the many contaminants present will vary in degree and distribution. Some contaminants, often referred to as the "drivers" will pose greater and/or more encompassing 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 presenting little risk should be conducted in a systematic manner, as presented in 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

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

- Evaluation of Laboratory Contaminants and Natural Background (3.2)
- Risk-based Screening of Contaminants (3.3 & 3.4)
- Revised Conceptual Site Model/Exposure Pathways (3.5)
- Revisions to Work Plan
- Ecological Screening Level Results (5.1 & 5.2)
- Ecological Endpoint Selection (5.3 & 5.4)

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 exposure 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, errors or gaps will be carried through the baseline risk assessment.

For PRP-lead sites, again the specifics of the schedule may be different. RI sampling results will need to be provided as a deliverable to the risk assessor before he or she can proceed with the risk assessment data analysis tasks.

3.2 Evaluation of Laboratory Contaminants and Natural Background

3.2.1 Laboratory Contaminants

Contaminants introduced into samples during laboratory analysis should not be considered among site risks. As discussed in RAGS HHEM section 5.5, common laboratory contaminants include acetone, 2-butanone, methylene chloride and phthalate esters. These may be eliminated from the risk assessment as indicated in RAGS HHEM page 5-16:

> ...if the blank contains detectable levels of common laboratory contaminants, then the sample results should be considered as positive results only if the concentrations in the sample exceed ten times the maximum amount detected in any blank.

3.2.2 Natural Background

RAGS HHEM page 5-19 states:

If inorganic chemicals are present at the site at naturally occurring levels, they may

be eliminated from the quantitative risk assessment...comparison with naturally ocurring levels is applicable only to inorganic chemicals...

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. Interpretating 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 section 7.

3.3 Risk-based Screening of Contaminants: Human Health

The number of contaminants considered in the baseline risk assessment may be further reduced using a conservative risk-based screening. For risk assessments submitted to Region 10, a screening process comparing concentrations to risk-based concentrations as outlined below is suggested (instead of "concentration/toxicity screen" as in RAGS HHEM section 5.9.5). Site-specific screening criteria different from below may be used if approval of the RPM and risk assessment reviewer are obtained.

3.3.1 Risk-Based Screening: Suggested Approach

The screening of contaminants should compare the maximum concentration of each contaminant

Text Box 3-2 Human Health
Risk-based Screening of Contaminants

- List maximum concentration of each chemical in each medium.
- Compare to risk-based concentration
- Eliminate chemicals if maximum detection of contaminant, in given medium:
  - $< 10^{-6}$ cancer risk screening value, or
  - < 0.1 hazard quotient screening value.
- Carry remaining chemicals through baseline risk assessment.

detected at the site to a risk-based concentration calculated using a conservative target risk, based on calculations utilizing standard default exposure factors. The target risks specified here were chosen based on lower end of the 10^{-4} to 10^{-6} "risk range" specified in the NCP (EPA 1990d). The assumption used is that if no single sample exceeds a concentration representing a human health risk concern, total exposure to the contaminant from the site will not be of concern. The "screening risk" deliverable should include tables clearly showing comparisons used, with columns showing risk-based screening concentration and maximum concentration on site in each medium for each contaminant eliminated from the risk assessment. The risk assessor may also want to list toxic endpoints for each contaminant eliminated, to insure that cumulative hazard is not overlooked. Basic steps of this process are outlined in text box 3-2.

The default screening level at which carcinogenic contaminants can be eliminated is 10^{-6} risk, calculated as in RAGS HHEM Part B. For non-carcinogens, because multiple pathways and multiple contaminants may result in cumulative effects, the screening concentration should be 0.1 hazard quotient. Chemicals exceeding these screening concentrations should be carried through the baseline human health risk assessment. Note that the risk-based screening criteria for carcinogens in water would be the same risk-based concentrations shown in the Region 3 RBC tables (Attachment 1). The more conservative screening criterion of a 0.1 hazard quotient for non-carcinogens differs from numbers presented in Attachment 1 by a factor of 10, in other words the decimal point is moved one place to the left.

If contaminants are detected that were not part of the list compiled at the project planning stage, toxicity data will have to be sought and risk-based concentrations calculated as in 2.2.3 and 2.2.4 above, RAGS HHEM part B and Appendix A. For chemicals for which no toxicity values are available that are detected in site samples, and therefore no risk-based concentrations can be calculated, Region 10 and NCEA should be contacted if this has not already been done.

3.3.2 Chemical-Specific Screening Criteria

Bear in mind that for contaminants in soil, additional pathways (e.g. dermal or inhalation) not accounted for in risk-based screening concentrations could resut in significantly higher exposures to some chemicals. If chromium, cadmium, elemental mercury, or carcinogenic forms of nickel are present as contaminants in soil, they should not be eliminated based on the soil ingestion screening criteria. This is due to the special issue of their inhalation toxicity being more of concern than ingestion, according to the current EPA toxicity assessment. The same concept would apply to other contaminants having disproportionately high inhalation or dermal toxicity. Also, soil ingestion risk-based screening concentrations do not take into account potential ecological effects or migration to

groundwater; these pathways are addressed in the EPA *Soil Screening Level Guidance* (EPA 1994b).

Five inorganic constituents which are often analyzed for but which are not associated with toxicity to humans under normal circumstances are calcium, magnesium, potassium, iron and sodium. No quantitative toxicity information is available for these elements from EPA sources. These five elements can generally be eliminated from the human health risk assessment at the screening stage based on qualitative judgement.

3.4 Risk-based Screening: Ecological

Like the human health screening, the ecological screening process includes the identification of contaminants of potential concern. However, unlike in 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 preliminary identification of both contaminants and receptors. Text box 3-3 outlines the

Text Box 3-3 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 contamiants and receptors must be presented along with rationale for eliminations made during screening.*

ecological screening process.

This step should focus the risk assessment on those contaminants that may pose significant threats to the ecosystem. Figure 5-1 depicts where this step fits into the greater ecological risk assessment process. The risk-based screening will indicate whether or not there exist any potential threats to ecological components at the site. Contaminants found at concentrations not indicative of significant threat to the ecosystem should be dropped from the subsequent ecological risk assessment process, but should be retained for risk characterization. In the risk characterization the [lack of] risk such contaminants present and the uncertainties related to these conclusions should be documented.

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 2-3. For the many contaminants for which ecological risk-based concentrations are not available, toxicity reference values must be determined and subsequent hazard calculations executed.

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 5.7.1.3 outlines toxicity calculations to be used in risk-based screening of site-related contaminants.

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. Additional site maps presenting spatial distribution of particular contaminants on the site should be provided only if they further elucidate site conditions.

At the conclusion of the screening stage of the risk assessment, the results should be submitted to the remedial project manager. A summary of decision points and corresponding deliverables is located in table 3-1. 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:

- the contaminant,
- the maximum concentration found in each medium,
- whether there are any ecological receptors with a complete exposure pathway to this contaminant in each environmental medium (This may also be covered within the text.),
- the screening value used to evaluate the potential hazard(s) associated with the contaminant*,
- the hazard quotient,
- the contaminant background level in each medium in which it occurs, and
- whether or not the contaminants of concern should be carried through the baseline ecological risk assessment, or at least the frequency of exceedences.

An example is presented as table 3-1. A site map indicating sampling sites 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. Figure 3-1, shows a sample distribution map.

*The screening level may be a TRV derived from a NOAEL or related value or it may be an RBC from a source approved by the RPM during Phase I of the RI/FS process. At this time very few RBCs exist for ecological risk comparisons; it is important to consult the RPM before choosing to use any values encountered.

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 Values
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
Dibromochloromethane	0.6	0.13	1/101	NA	NA
Pesticides/PCBs					
Aldrin	0.08	0.004	3/82	NA	NA
Aroclor 1254	1.18	0.0087	3/101	NA	NA
Dieldrin	0.01	0.0042	2/101	NA	NA
DDT	0.4	0.2	1/101	NA	NA

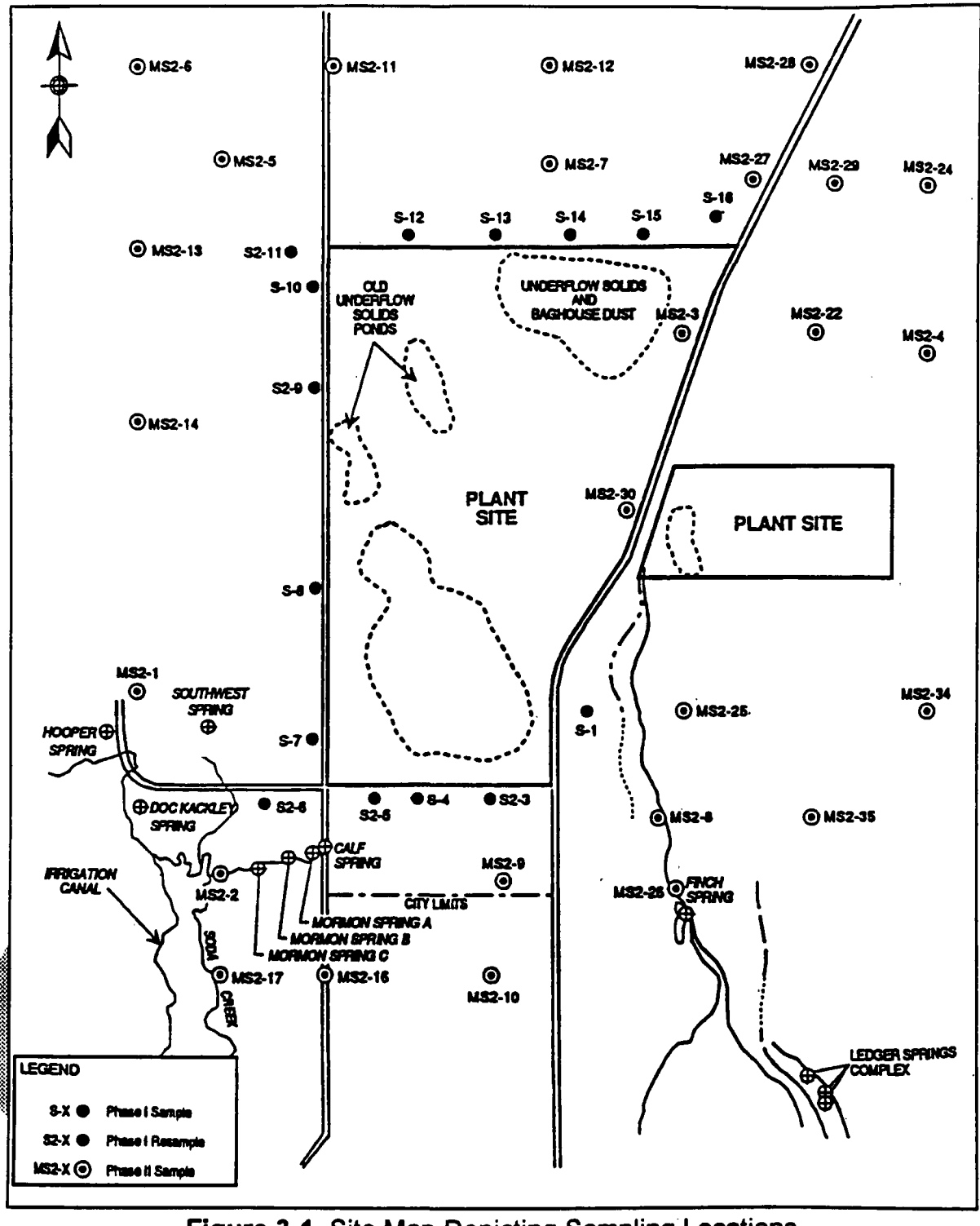


Figure 3-1 Site Map Depicting Sampling Locations

Background data may be employed in the screening process to determine which site-related contaminants, particularly inorganics, exist on site at concentrations elevated above surrounding natural background levels. Planning for background sampling should have occurred at early in the RI so that time is not wasted waiting for background data to be collected. The collection and use of soil background data for ecological risk assessments is discussed in further detail in an issue paper in Appendix C; other relevant references are listed with that paper and in section 7.

As can be seen from the discussion above, the contaminant portion of the screening process is somewhat prescribed; the screening process for receptors, although it can become somewhat complex, is not so established. Receptor screening should simply identify potential receptors and 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), from the site.

Such a screening may be organized by species or functional groups or even by specific populations. It should be through and 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 judged not to be potential receptors and justification for each determination. This may be presented in the following described interim deliverable; it will aid in development of the conceptual site model as well as in the risk characterization summary justifying inclusion or exclusion of particular organisms in the more detailed analyses of the risk assessment.

At the conclusion of the ecological risk-based screening, an interim deliverable should be submitted to the remedial project manager (RPM). Such a 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 included. A list of potential receptors and identifying those with complete exposure pathways to contaminants should also be presented. Relevant concentration-based distributional maps which illustrate fate and transport and/or exposure pathways for selected contaminants may also be included.

3.5 Revised Conceptual Site Model/Exposure Pathways

The conceptual site model and exposure scenarios and pathways planned for the risk assessment should be revisited at this stage. Depending on the amount of information previously available and new information obtained from sampling data, a revised conceptual site model and presentation of exposure scenarios may be needed. If only general ideas were presented at the scoping stage, more specifics should be presented. If new information causes significant changes, revisions should be submitted. If additional phases of sampling are planned, revised information on exposure should be considered in the new work plans.

4.0 BASELINE HUMAN HEALTH RISK ASSESSMENT

4.1 Scheduling of the Baseline Risk Assessment

The baseline human health and ecological risk assessments (section 4 and 5) may be submitted as part of the RI report, or as separate documents.

4.2 Exposure Assessment

The degree of "protectiveness" or "conservatism" that will be used in exposure assessment for Superfund risk assessments has been the subject of considerable discussion. In order to have consistency in risk assessments nationwide, Superfund program guidance descibes in some detail the approach that will be used. RAGS HHEM Part A (EPA 1989d), Chapter 6, provides guidance on development of reasonable maximum exposure (RME) scenarios, and *Standard Default Exposure Factors* (EPA 1991h) gives specific exposure factors, for example drinking water ingestion rate, that should be used as defaults for all sites. These factors will seldom be subject to modification. However, certain aspects of the exposure assessment, particularly quantification of absorption of chemicals from soil and estimation of exposure point concentrations using modeling or other predictive approaches, have not been "standardized" and will require site-specific data and judgement. The use of simplified conservative (protective) assumptions is a tool of an iterative risk assessment approach. Where this or other EPA guidance proposes simplified or screening calculations to evaluate a particular pathway of release or exposure, subsequent calculations are often subject to refinement in the next iteration, if necessary. For example, if conservative "worst-case" assumptions about release of contaminants from soil to air are used in human exposure calculations, and results show that risks are well below risk-based goals and levels of regulatory concern, more complex or detailed models would not be necessary. If results of the same calculations show risks of concern, additional effort and collection of site-specific data is justified.

4.2.1 Selection of Exposure Scenarios

To insure that appropriate data collection is planned, the conceptual site model and the exposure scenarios and pathways should be presented as early in the RI/FS process as possible. Exposure scenarios are revised as necessary as more information becomes available. Issues affecting selection of exposure scenarios and pathways are discussed below.

The baseline risk assessment will consider risks under both current and future land uses.

The land use scenarios most commonly evaluated in Superfund risk assessments are residential and industrial land use. However, scenarios in addition to residential and industrial use can be developed in consideration of the location, size, and current and potential uses of the affected area. Scenarios may include fishing, agriculture, recreational or other occasional activities, as appropriate. Evaluation of multiple scenarios (including residential, industrial, and recreational land use) will be appropriate for many sites.

Region 10 recommends that a residential land use scenario be evaluated as a potential future use in the baseline risk assessment for most Superfund sites. The reasons for making the general recommendation that residential land use should be evaluated include the following:

1) Predicting the likelihood of future changes in land use can be uncertain. For example, anticipating which military bases may face closure in the future is beyond the scope of a Superfund risk assessment; the residential scenario should be evaluated as a "what if" question.

2) For sites where institutional controls or access restrictions will be implemented to prevent future residential land use, evaluation of the residential scenario in the baseline risk assessment provides justification for this type of action.

3) The residential scenario usually provides the most conservative estimate of exposures at a site, in other words the highest estimate of risk. If results were low risks, this would provide the most comfortable basis for a no-action decision, and confidence that Superfund could "walk away" from the site.

Including residential land use in the risk assessment does not dictate that the site will be cleaned up for residential use. Presentation of results of quantitative evaluation for more than one scenario in the baseline risk assessment for a site gives decision-makers more information when considering various risk management options. During the FS process, managers will determine which land use assumptions will be the basis for deciding whether remedial action is warranted, and the basis for selection of final remediation goals.

However, at some sites or operable units the RPM may determine that it is not appropriate to evaluate residential land use in the risk assessment. For specific sites where the RPM believes that future residential use is highly unlikely, this scenario may be given less effort in the risk assessment, or may be eliminated. If evaluation of a residential scenario for such a site would necessitate additional sample collection, the benefits of the information should be weighed against the costs of collecting it before proceeding. The level of effort devoted to evaluating residential land use may be limited through the use of pre-existing sample data, standard exposure assumptions, and "screening" pathways.

4.2.2 Select Exposure Pathways

Within each exposure scenario, specific pathways that will be evaluated will be selected based on site-specific characteristics and on general considerations outlined below and in table 4-1. Soil and water ingestion pathways should always be considered. After comparing contaminant concentrations to screening concentrations based on these pathways, as discussed in section 3 above, multiple pathway exposures should be evaluated, as outlined in table 4-1, for each "contaminant of concern" remaining to be carried through the baseline risk assessment.

Contaminated Medium	Exposure Scenario	Potential Exposure Pathway	Evaluate in Risk Screening?	Evaluate in Baseline Risk Assessment?
Groundwater	Residential use as potable water	Ingestion of water	Yes	Yes
		Inhalation of volatiles	Yes, if volatiles present	Yes, if volatiles present
		Dermal contact with water	*	Yes, for organic contaminants of concern
	Industrial use as potable water	Ingestion of water	*	Yes
		Inhalation of volatiles	*	Site-specific decision
		Dermal contact with water	*	Site-specific decision
Surface water and sediment	Residential or industrial use as potable water	See Groundwater	Site-specific decision	Site-specific decision
	Recreational or subsistence fishing	Consumption of fish/seafood	*	*
	Recreational or trespasser	Ingestion of water	*	*
		Dermal contact with water	*	*
		Ingestion of sediment	*	*
		Dermal contact with sediment	*	*
Soil	Residential	Soil ingestion	Yes	Yes
		Dermal contact with soil	*	Yes, for contaminants of concern
		Inhalation of particulate/volatiles from soil	*	Yes, for contaminants of concern
	Residential or agricultural	Consumption of produce, meat, milk	*	Site-specific decision
	Industrial	Soil ingestion	*	Yes
		Dermal contact with soil	*	Yes, for organic contaminants of concern
		Inhalation of particulate/volatiles from soil	*	Yes, for contaminants of concern

* In general, these pathways will not be included in a simplified screening, but they may be considered if site-specific screening criteria are developed.

Figure 4-1 General Approach for Selection of Exposure Pathways

4.2.2.1 Pathways of Exposure to Soil

For contaminated soil, incidental ingestion should always be evaluated. Assessment of exposure through dermal contact with soil requires chemical-specific absorption information. Absorption data for organics should be sought in the *Guidance for Dermal Exposure Assessment* (EPA 1991b). If no absorption data for contaminants of concern (or analogous compounds) is available, dermal exposure should be addressed qualitatively. Quantitative information on dermal absorption of inorganics from soil is not available. Dermal contact with contaminants that have toxic effects at the skin surface, for example certain metals, can be evaluated quantitatively if information can be obtained. Inhalation of volatile and particulate contaminants released from soil to air should be evaluated, again usually limiting the evaluation to contaminants of concern identified at the screening stage. Evaluation of air pathways can be particularly important for sites where waste or contaminated soil is left in place, with direct contact prevented through access restrictions. Other pathways of exposure to contaminants in soil, such as uptake into plant or animal food products, will be evaluated less frequently. Site charactistics which would make consideration of food chain pathways important would be:

- current residential site use
- large areas of contaminated soil located in agricultural area
- contaminants known to be taken up into plants or animals at potentially significant levels, for example cadmium and PCBs.

Decisions to include food chain pathways in should be made in consultation with the RPM and the Region 10 risk assessment contact.

4.2.2.2 Pathways of Exposure to Groundwater

If contaminated potable water is present, or contaminants may potentially affect potable water, exposure through ingestion of water, and through inhalation of volatiles released from household water use, should be evaluated. Dermal contact during bathing should be evaluated for organic contaminants of concern using permeability coefficient data available in the *Dermal Exposure Guidlines* (EPA 1991b).

4.2.2.3 Pathways of Exposure to Surface Water and Sediment

For contaminated surface water and sediment, potential for human exposure varies greatly depending on the size and location of the water bodies. For sites that have small water bodies or that are in remote locations, exposure pathways can be limited to incidental ingestion for a child playing or a "trespasser." If these exposures appear to be of concern, however, or for some sites with potential for recreational use, dermal contact should also be included. Fish or seafood consumption pathways will be an important consideration at sites where large water bodies are affected by contamination.

4.2.3 Calculating Exposure Point Concentration from Sampling Data

4.2.3.1 Calculating the "RME" Concentration

HHEM Section 6.4.1 states that where results from several samples will be combined to estimate exposure point concentration, the appropriate calculation is the ninety-five percent upper confidence limit (95% UCL) on the arithmetic average (except when the 95% UCL exceeds the maximum) of concentrations that would be contacted by the "RME" individual. Averaging and statistical treatment of data is correct only for samples that were collected with an appropriate random or systematic sampling design. Further guidance on developing the "RME" exposure concentration is available in EPA guidance (EPA X 199_).

4.2.3.2 Grouping Samples

Combining data to evaluate exposures must take into account spatial distribution of contaminants, human activity patterns, and potential fate and transport. Section 6.5.1 of RAGS HHEM summarizes some exposure pathways issues and includes the following guidance:

> The manner in which the data are summarized depends upon the site characteristics and the pathways being evaluated. It may be necessary to divide chemical data from a particular medium into subgroups based on the location of sample points and the potential exposure pathways. In other instances, as when the sampling point is an exposure point (e.g., when the sample is from an existing drinking water well) it may not be appropriate to group samples at all, but may be most appropriate to treat the sample data separately when estimating intakes.

If more than one source exists at a site, it may be appropriate to evaluate exposures for a separate "RME" individual for each source area, because the soil or water at one source area may present distinct exposures and risks that are not present elsewhere on site. However, for a site with multiple source areas it is also possible that release of contaminants to air or water from various sources will

affect the same down-wind or down-gradient receptor, so the cumulative exposure should also be evaluated. It is useful to identify the location of contaminant concentrations of each contaminant in soil and water on a map to evaluate whether risks from different contaminants do or do not coincide in location. Needs of decision-makers will be a factor in determining whether to evaluate source areas together or separately.

Groundwater samples from a single well location over time should generally be used to represent the 95% UCL average concentration that would be contacted by the RME individual at that location. In practice, a single well point usually does not yield enough data to permit calculation of the 95% UCL. A simple average has been used in some risk assessments. Future exposure point concentrations estimated by modeling may be used in the risk assessment if the RPM and technical staff determine that modeling is appropriate.

Surface soil sample data should be used to represent the 95% UCL average concentration for an area the size of a yard for residential use scenarios. The risk assessment should identify whether the concentrations used for calculations are typical of large areas of the site, or represent a "hot spot." If contaminant concentrations vary significantly over the site area, it may be appropriate to calculate several different exposure point concentrations, using a subset of samples for each. For sites where future construction of residences is possible, the exposure assessment should consider concentration at the current surface, and also that construction activities could result in excavation of soil, and distribution of this soil at the surface. Exposure calculations would use the 95% UCL average of samples to an appropriate depth for this case.

4.2.3.3. Risk Maps

The entire issue of grouping samples can be avoided by using "risk maps" to present reults... [To be filled in following consultation to OEA HH risk assessors.]

4.2.3.4 Background

The RPM may request that exposures and risks from on-site sources be summed separately from natural and anthropogenic background in the risk assessment. Treatment of "background" in the risk assessment will depend on ability to distinguish site-related contaminants from other chemicals detected, and risk management issues.

4.2.3.5 Non-Detects

Where a specific contaminant has been detected at some locations on a site, but not others, or has been detected in past sampling events but not in current samples, the contaminant should be assumed to be present in the "non-detect" sample at one-half the sample detection limit. This approach is specified in section 5.3.3 of HHEM. However, judgement should also be used in evaluating of non-detects. First, it is important to consider spatial distribution of contaminants at the site as well as past sampling events. Second, if high detection limits for certain samples would result in bias using the "half detection limit" assumption, other interpretations may be appropriate, for example:

- Calculate RME concentration using one-half the detection limit for non-detects.
- Compare the result with the maximum detected concentration. Use the lower of the two values as the exposure point concentration for the risk assessment.

4.2.4 Predicting Exposure Point Concentration Using Modeling/Estimates

Appropriate publications (SEAM (EPA 1988e), NTGS (EPA 1990a), etc.) should be consulted for guidance on use of fate and transport modeling for risk assessment. The *Standard Default Exposure Factors* directive (EPA 1991h) does not comprehensively review methods of evaluating contaminant fate and transport or uptake into the food chain. Although some examples of approaches or models for development of predicted exposure point concentrations are mentioned in the directive, their use is not being mandated. In addition to the cited references, continue to consult national guidance and the published literature for the most appropriate methods for predicting contaminant concentrations in air, in agricultural products, and in fish. Examples of approaches to predicting uptake of chemicals into agricultural products and fish can be found in documents from EPA Office of Research and Development (EPA 1988c, EPA 1989a, EPA 1990c).

An acceptable default approach for estimation of indoor inhalation exposure to volatiles released from contaminated water is to:

- Include as "volatiles" all organic contaminants with Henry's constant (unitless) > 10^{-4} and molecular weight <200.
- Estimate indoor air concentrations by assuming that they will be related to concentration in the water supply according to a coefficient of 0.5 l/m^3 (EPA 1991c).

4.2.5 Contact Rate, Exposure Frequency and Duration

Table 4-1 Sources of Exposure Factors for Superfund Risk Assessments

Exposure Pathway	Exposure Factors[†] RME	Average
Ingestion of Water	SDEF	Region 10
Indoor Inhalation of Volatiles	SDEF	Region 10
Dermal Contact with Water	Region 10	Region 10
Soil Ingestion	SDEF	Region 10
Dermal Contact with Soil	Region 10	Region 10
Inhalation of Particulate/Volatiles from Soil	SDEF	Region 10
Consumption of Produce, Meat, Milk	Site-specific	
Consumption of Fish/Seafood	Site specific	

4.2.5.1 Use of Standard Default Exposure Factors

The supplemental guidance document entitled *Standard Default Exposure Factors*, (EPA 1991h) provides specific exposure factors which are to be used for Superfund Human Health Risk Assessments. A draft update of the *Exposure Factors Handbook* has also been released (EPA 1995). The standard default exposure factors (SDEF) are summarized on page 15 of the directive and in Appendix B, table B-2, here. The values in the directive supercede the RME values presented in the January, 1990, Region 10 *Statement of Work RI/FS Risk Assessment.*

As stated on page one of the SDEF supplemental guidance,

> ...the exposure factors presented in this document are generally considered most appropriate and should be used in baseline risk assessments unless alternate or site-specific values can be clearly justified by supporting data.

Drinking water ingestion, soil ingestion, and inhalation defaults will apply to virtually all sites. The

[†]The *Standard Default Exposure Factors*, (EPA 1991h) compiled by the Superfund program, is the source for RME exposure factors for Superfund risk assessments. For "average" exposure factors, and for pathways not addressed in the SDEF guidance, Region 10 has provided recommended values, mostly selected from the *Exposure Factors Handbook* (EPA 1995b) or *Dermal Exposure Guidelines* (EPA 1991b). For convenient reference, exposure factors from both SDEF and Region 10 are presented together in Appendix III.

need to evaluate consumption of homegrown produce, meat and milk, and consumption of locally caught fish will be determined according to characteristics of each site. For these food chain pathways, it is also expected that site-specific exposure values will usually be preferable to defaults. Assessment of dermal exposures is not discussed in the directive. The "Guidance on Dermal Exposure Assessment" being developed by ORD Exposure Assessment Group will address this pathway.

4.2.5.2 Region 10 Default Exposure Factors

Exposure factors for the dermal pathway, which is not addressed in the SDEF, for the RME, and for all pathways for average exposures, are presented in Appendix B, table B-1. Although regulatory decisions for Superfund sites will be based on risks at RME exposures, average exposure factors are presented here for two purposes. Average exposure factors will be used for comparison in uncertainty analysis. Also, average exposures will be included in some RME scenarios, as stated in RAGS HHEM on page 6-47:

> To calculate an exposure that is a reasonable maximum across pathways, it may be necessary to combine the RME for one pathway with an estimate of more typical exposure for another pathway.

When subchronic or acute exposures are evaluated, age-specific intake factors and body weights for children should be used. Age-specific factors are presented in the *Exposure Factors Handbook* (EPA 1995b). RME exposure factors for the dermal pathway presented in Appendix B are recommended by Region 10 based on the *Dermal Exposure Guidelines* (EPA 1991b).

4.3 Toxicity Assessment

Toxicity assessment should be conducted as described in chapter 7 of RAGS HHEM.

4.3.1 Toxicity Reference Values

The heirarchy of sources for toxicity information is as follows:

1. Integrated Risk Information System (IRIS; EPA 1995d). On-line database. IRIS is the preferred EPA source for toxicity information. It provides RfD's and carcinogen slope factors that have been reviewed and verified by agency-wide work groups. Supporting discussion and references also appear in each chemical file. IRIS User Support (513-569-7254) can provide information about how to access IRIS. IRIS is also available on PC-compatible diskettes from NTIS.

2 Health Effects Assessment Summary Tables (HEAST; EPA 1995c). (OSWER Directive No. 9200.6-303. NTIS No. P890-921100.) Prepared by the Environmental Criteria and Assessment Office for the Office of Emergency and Remedial Response. The HEAST tables provide a summary of all currently available toxicity factors developed by NCEA, and a bibliography of Health Effects Assessments and related documents. These documents contain supporting information for toxicity values developed by EPA NCEA. Additional chemicals that do not appear in IRIS are included in HEAST. The HEAST tables are revised quarterly. Effective in the second quarter, 1991 edition, toxicity factors that appear in IRIS will no longer appear in HEAST.

3 Toxicity reference values developed by, or in consultation with, the EPA Superfund Technical Support Center at the National Center for Environmental Assessment (NCEA) in Cincinnatti, (513) 569-7300. Region 10 risk assessment staff should always be contacted before calling NCEA.

4 ATSDR minimal risk levels (MRLs). These values are developed using an approach that is consistant with reference dose methodology. These are available for acute, intermediate, and chronic exposure durations, and are potentially useful for situations of short-term exposure, for which verified RfDs seldom available. These numbers can be found in the ATSDR Toxicity Profile documents, in the Health Effects Summary section, in the text and/or on the "thermometer" chart. Concurrance with use of MRLs for a specific situation should be sought from Region 10 and NCEA.

4.3.2 Toxicity Profiles

The baseline risk assessment (or an appendix) should include a short toxicity profile for each contaminant of concern identified in screening. See RAGS HHEM section 7.7 regarding the type of discussion of toxicity information for each chemical. These profiles should provide two types of information:

- General toxicity information, intended for the non-specialist reader. This discussion should be concise and "non-technical," or at least not too technical. ATSDR Toxicity Profiles are good sources of general toxicity information for many hazardous waste chemicals, and the introductory sections are good models of informative yet readable discussions of toxicity.

- Summary of information used in developing slope factor or RfD. This can be very brief, referring the reader to IRIS or other original source for details; however, it should identify target organs for carcinogens and describe critical effects, LOAEL and uncertainty factors for noncarcinogens.

In some situations, more detailed toxicity profiles will be needed. At sites where potential exposures resulting in hazard quotients around one pose an issue, additional discussion of the database

supporting the RfDs will be important. In addition to sources listed in 4.2.1 above, the published literature can also be consulted and referenced for toxicity profile information.

4.4 Risk Characterization and Uncertainty Analysis

Combining exposure and toxicity data to characterize risks is described in RAGS HHEM chapter 8. Uncertainty analysis is discussed in RAGS HHEM sections 6.8, 7.6, and 8.4.1. Some frequently occurring questions/issues are addressed below.

4.4.1 Exposure Duration for Noncarcinogenic Soil Contaminants

[To be discussed with Region 10 OEA HH risk assessors.]

4.4.2 Risk Characterization Using RfCs and Units Risks

Toxicity reference values for inhalation pathways are now provided by EPA as reference concentrations (RfCs). RfC units are concentration in air, (mg/m^3). The RfC can be used in risk characterization using a simple comparison; the most straight-forward approach is to evaluate a hazard quotient by dividing the exposure point concentration by the RfC. The RfC or unit risk will not fit into the equations on page 8-6 and 8-11 of RAGS. The RfC can be compared to the exposure point concnetration in air (Exposure Point Concentration/RfC = HI) or the unit risk can be multiplied by the concentration. For Superfund risk assessments, an alternate approach is to convert RfCs and Unit Risks to inhalation RfDs and slope factors using $20m^3$/day breathing rate and 70 kg body weight. The mathematical conversion to mg/kg-day should not be used to inappropriately adjust chronic RfCs to subchronic or acute exposure periods.

4.4.3 Summary Tables

Summary tables of results should be prepared in which each risk or HI number is associated with a specific scenario, exposure pathway and chemical. One or a few numbers do not characterize a site; multiple scenarios are presented. See exhibits 8-2 and 8-3 in RAGS for sample format. Although additional decimal places should be carried through calculations, when final risk and HI estimates are presented they should be rounded to one significant figure.

4.4.3 Uncertainty Analysis

4.4.3.1 Qualitative Uncertainty Analysis

Qualitative discussion of uncertainties is expected for all risk assessments submitted to Region 10. Uncertainties in the quantitative risk assessment process should be recognized, as discussed in the agency guidelines. The RfD Background Document (EPA 1988d) provides perspective on interpreting reference doses, including the following:

> ...the RfD is an estimate (with uncertainty spanning perhaps an order-of-magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime...However, it should not be categorically concluded that all doses below the RfD are "acceptable" (or will be risk-free) and that all doses in excess of the RfD are "unacceptable" (or will result in adverse effects) (EPA 1988d).

Slope factors for carcinogens are derived by the EPA usually using the "linearized multistage procedure." The Guidelines for Carcinogen Risk Assessment (EPA 1986) acknowledge that:

> ...the linearized multistage procedure leads to a plausible upper limit to the risk that is consistent with some proposed mechanisms of carcinogenesis... The true value of the risk is unknown, and may be as low as zero.

However, because the risk assessment for a Superfund site is intended to support decision making within a defined regulatory context, the risk assessor should clearly distinguish uncertainties inherent in the risk assessment process (i.e. toxicity values based on low-dose extrapolation from high-dose experiments), or common to Superfund risk assessments (i.e. assumptions in standard default exposure parameters, lack of data on dermal absorption from soil) from uncertainties specific to the particular project. Discussion should focus on site-specific uncertainties. These might include data gaps in site sampling, uncertainty in modeling for fate and transport, uncertainty in assumptions about future land use, and data gaps for toxicity or absorption information. After risks at RME are calculated for each pathway, it is possible to identify which chemicals, scenarios and exposure routes present risks of larger magnitude. Discussion of uncertainty should focus on the more significant pathways and chemicals.

4.4.3.2 Quantitative Uncertainty Analysis

Semi-quantitative analysis of uncertainty in exposure assessment should be presented. The format suggested by Region 10 is evaluation of impact of average compared to RME values for exposure factors and exposure point concentrations for pathways contributing most of the risk. If modeling has been used to develop exposure point concentrations, sensitivity analysis for model input assumptions is also appropriate. Because decisions at Superfund sites are based on risks to the reasonably maximally exposed individual, as specified in the NCP (EPA 1990d) and as defined

by the associated guidance (RAGS HHEM, SDEF), more sophisticated approaches to quantitative uncertainty analysis will usually not be used.

4.4.4 Summary and Conclusions

The risk assessor and reviewer should devote some care to providing an effective and concise summary of site risks, because this section will "stand alone" for some persons interested in the site who may read the summary but not the rest of the risk assessment.

Risk assessments containing unqualified statements such as: "Risk from chemical XYZ in drinking water are unacceptable..." and "Risks from exposure to soil are insignificant..." have sometimes been submitted to Region 10. Writers of Superfund risk assessments should avoid the use of terms such as "significant," "unacceptable," or "not of concern" in interpreting results, particularly if the criteria for significance or concern are not clearly defined in the report. These terms imply conclusions about whether remediation will be undertaken at the site; risk management should be discussed in the Feasibility Study, not in the baseline risk assessment. Preferred language would be something like, "Risk from chemical XYZ in drinking water was calculated to be 9×10^{-4}. For soil, total risk from all contaminants was less than 10^{-6}." The risk assessment may cite the NCP (EPA 1990d; see page 8848) or *Role of the Baseline Risk* memo (EPA 1991e), and quote the language on the "risk range" used in Superfund, if this is acceptable to the RPM.

5.0 BASELINE ECOLOGICAL RISK ASSESSMENT

5.1 Introduction

The purpose of this ecological risk assessment chapter is to provide guidance to regional ecological risk assessors on how to conduct an effective risk assessment. This chapter also serves as a supplement to the national guidance to clarify and streamline the ecological risk assessment process for Region 10 Superfund sites.

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. This chapter focuses on the former.

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.

EPA 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 national *Ecological Risk Assessment Guidance for Superfund* (EPA 1994a), 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. Figure 5-1 outlines the major steps of the ecological risk assessment process. Text Box 5-1 summarizes the pertinent decision points and associated steps; table 5-1 shows these decision points in relation to corresponding deliverables.

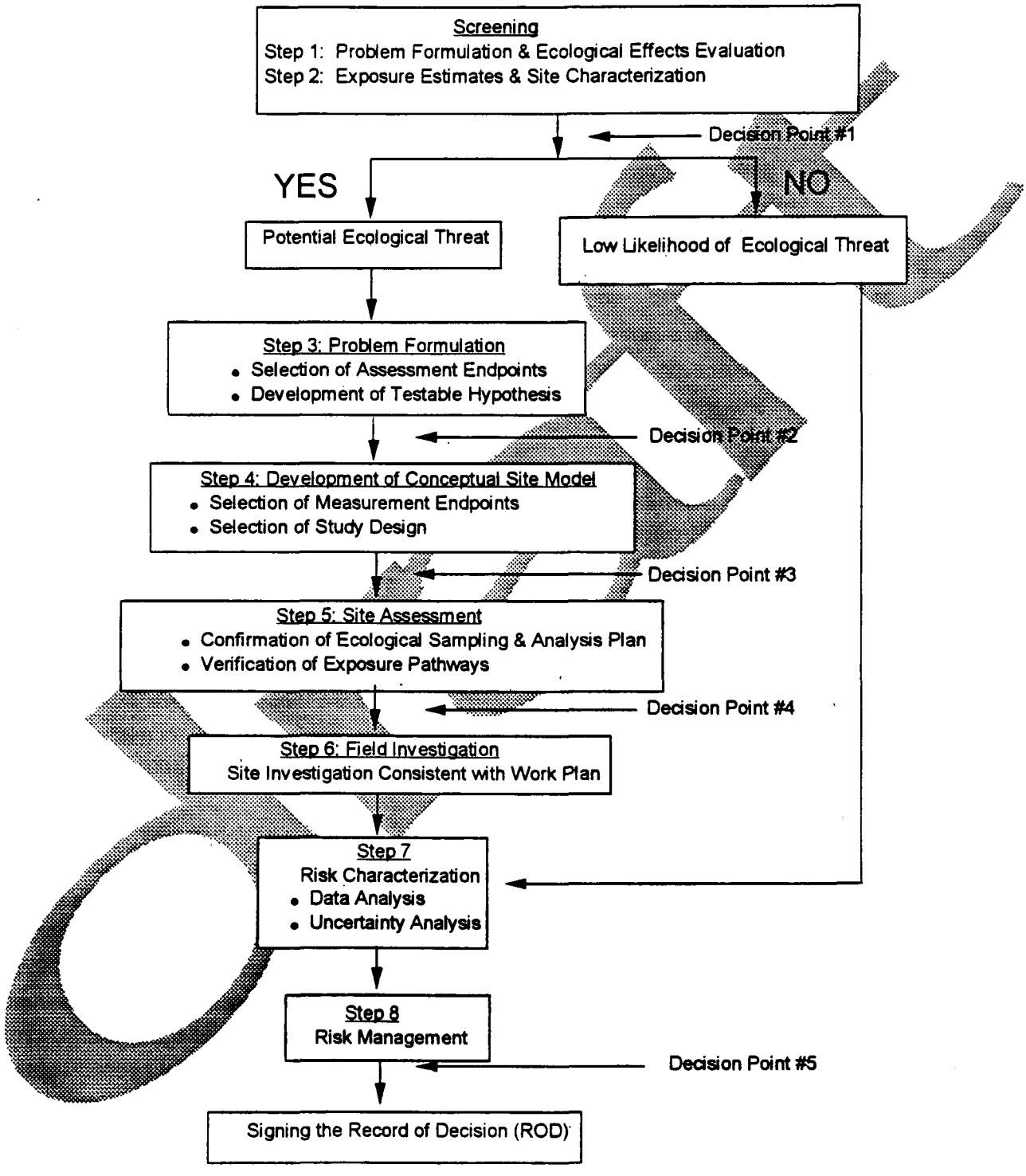


Figure 5-1 The Ecological Risk Assessment Process

This chapter is intended as a supplement to the upcoming EPA headquarters *Ecological Risk Assessment Guidance* for regional site managers, risk assessors and others involved in ecological risk assessments. 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.

5.1.1 Chapter Objective

This chapter is organized according to the EPA headquarters' outline of major steps in the Superfund ecological risk assessment (EPA 1994a). 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 had existed.

5.1.2 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 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 related organizations such as the U.S. Fish and Wildlife Service, the National Oceanic and Atmospheric Administration and related state agencies (e.g., DOE). These members function in an advisory and review capacity to assist the RPM with the risk asessment 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 the BTAG will facilitate the ecological risk assessment process and will help generate some consistency among all parties involved.

5.1.3 Technical Issues

5.1.3.1 The "Tool Box"

The "Tool Box," Appendix C, delineates specific technical issues relevant to the risk assessment process. One of the ecological issues addressed in the "Tool Box" is the determination and application of background concentrations of contaminants in soil at Superfund sites. Appendix C will be an evolving section of the guidance which will address various risk assessment technical issues as the need arises and information becomes available. Additions to this section will be released intermittently in the form of the new *Region 10 Risk Report* newsletter. Since issues described in the "Tool Box" are not the only ones encountered in the ecological risk assessment process. Please refer to the following EPA publications for a more comprehensive list of issues and additional information: *Eco Updates*, BTAG Forum and Risk Assessment Forum Newsletters.

5.1.3.2 Site-Specific Case Studies

Site-Specific Case Studies provide "real world" examples of how ecological risk assessments have been conducted. These case-studies are examples taken from risk assessments that have been completed. The following are some examples: *Effects of Radionuclides in the Columbia River System - A Historic Assessment* (EPA/630/R-94/003); *Commencement Bay Tidelands Assessment* (EPA/630/R-94/003); and *The Effects of Acid Deposition on Aquatic Ecosystems: A Regional Problem* (EPA/630/R-94/003). For additional Case Studies examples, please refer to Appendix D, and to the EPA publication: *A Review of Ecological Assessment case studies from a Risk Assessment Perspective*, Volume II (EPA/630/R-94/003). Similar to Appendix C, Appendix D will be expanded on an intermittent basis via special releases of the *Region 10 Risk Report*.

Text Box 5-1 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 and Verification of Exposure Pathways (DECISION POINT # 4).
- Field Investigations: Site Investigation Consistent with Workplan.
- Risk Characterization.
- Risk Management (DECISION POINT # 5).

5.1.4 Scheduling the Baseline Risk Assessment

As indicated in section 4.1 of this document, the baseline human health and ecological risk assessments may be submitted as part of the RI report or as separate documents. This will be determined by the RPM with input from the contractor conducting the assessment, as well as advice from the BTAG team. A time line which addresses the deliverables associated with each decision point should be established with the RPM at the beginning of the risk assessment. The first three of these interim deliverables will be related to Phase II of the RI/FS process; and the baseline risk assessment itself occurs within Phase III of the risk assessment. These phases are further explained within section 1.1 of this document.

Table 5-1 Decisions Points and Corresponding Deliverables

Section which concludes with Decision Points	Decision to be Made	Deliverables
Screening	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 workplan, 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 workplan and/or SAP
Risk Management	Determine and initiate remedial actions for the site and the development of the Record of Decision (ROD).	• Baseline Ecological Risk Assessment with: Remedial Action Objectives (RAOs) and Risk Characterization

5.1.5 Chapter Organization

This chapter (chapter 5) is organized in accordance with the EPA *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (EPA 1994a) and with an ecological assessment overview presented in the EPA's ecological risk intermittent bulletin, *ECO Update* (EPA 1989b). The former document is based on the EPA's *Framework for Ecological Risk Assessment* (EPA 1992a).

5.2 Screening

Ecological risk assessment is an iterative process which mandates increasingly specific levels of investigations as data are acquired. The screening process must be thorough in its scope, but not overly detailed. Overly detailed screening can encourage limited areas of focus; and this step must 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.

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. The components addressed within these two initial steps are listed in text box 5-2. These components are described in chapters 2 and 3 and they are often begun before work on the baseline risk assessment is formally initiated.

Text Box 5-2 Steps Involved in Ecological Risk Assessment Screening

- Preliminary Problem Formulation
- Ecological Effects Evaluation
- Exposure Estimation and Risk Calculation
- Preliminary Site Characterization

5.3 Step 3: Problem Formulation

The problem formulation step identifies environmental attributes to be protected and the types of data and analyses needed to accomplish this. These characteristics will be identified through the development of a conceptual site model.

The steps involved in problem formulation are interactive, depending on iterative feedback loops, particularly in the development of the conceptual site model. Information from the screening stage of the risk assessment is important for this next step. Although the data from the screening stage usually cannot be used in making remedial decisions, these data can be used as a starting point that will eventually lead to the compilation of data for the risk assessment.

Problem formulation directs the gathering of data connected with the following: contaminants of concern, potential receptors, exposure pathways, assessment and measurement endpoints, ecological effects, and the formulation of a testable hypothesis. The overall objectives of the risk assessment will be determined at this step of the study. In order to best accomplish this, a conceptual model for the site should be developed. The development of a conceptual model should be interactive with all of the other steps in the problem formulation and may not be complete until

all data for the other sections have been gathered.

5.3.1 Site Characterization

The aim of the preliminary site characterization is to compile as much general and specific data about the site as possible. A physical and ecological description of the site, as well contaminant distribution and related information should be gathered. The following information should be presented by the conclusion of this step, much of it having been included in screening stage interim deliverables:

- Contaminants known at the site and the maximum concentration of each present in each medium;
- Contaminant fate and transport at the site;
- Complete exposure pathways that *may* exist at the site;
- Ecotoxicity associated with contaminant exposure pathways (EPA 1994a),
- Physical description of site, and
- Ecological description of site, including all potential receptors or receptor groups.

As noted earlier, worst-case assumptions should be used in the screening stage of the risk assessment unless otherwise agreed upon in advance with the remedial project manager. Table 5-3 lists parameters to be measured for ecological site characterization.

Toxicity profiles for contaminants should be assembled with emphasis on information pertinent to the specific risk assessment and site needs. Any data provided which are specific to a particular exposure route should be accompanied by a description of the exposure route and any other relevant information. Data presented in a toxicity profile should include: solubility, bioconcentration, bioavailability/persistence and information regarding plant uptake, if relevant. A preliminary identification of receptors present at the site should be made by an ecologist or using information provided by local wildlife agencies.

Identification of fate and transport at the site is essential for determining the completeness of exposure pathways, the extent of contamination and the course of the remedial action. Fate and transport information should be thorough and detailed. Table 3.4.1 lists the minimum information

which should be assembled to characterize the system(s) present. Additional information should be provided depending on the needs at the site. Also include a description of all possible transport routes for all media, including surface water, ground water, air currents and soil. Include diagrams when additional clarification of a pathway is required.

Table 5-3‡: Basic Parameters for Characterization of System(s) Present

	Surface Water	Sediment	Soil
Field Parameters	Temperature Dissolved Oxygen pH Conductivity Salinity (marine only) Flow (width & depth)	Temperature Eh pH Conductivity Color	Layer composition pH Conductivity
Laboratory Parameters	Total suspended solids Alkalinity Hardness BOD COD TDS (Non-settleable solids)	TOC Grain size/hydrometer Moisture Solids (%)	Moisture TOC CEC/AEC

5.3.2 Qualitative Evaluation of Contaminant Release, Migration and Fate

Information identified in the qualitative evaluation will address two questions: What aspects of the ecosystem at the site are at risk? What are the potential adverse ecological responses associated with these risks? (EPA 1994a) This information may also serve as the basis for establishing the conceptual site model. This evaluation should identify all available data on the contaminated media, contaminant movement and the potential receptors. It might also be necessary to consider the following pathways: potential groundwater contamination, groundwater to surface water/wetlands, sediment-related transport, runoff and erosion from contaminated soils, bioaccumulation and bioconcentration (EPA 1989b).

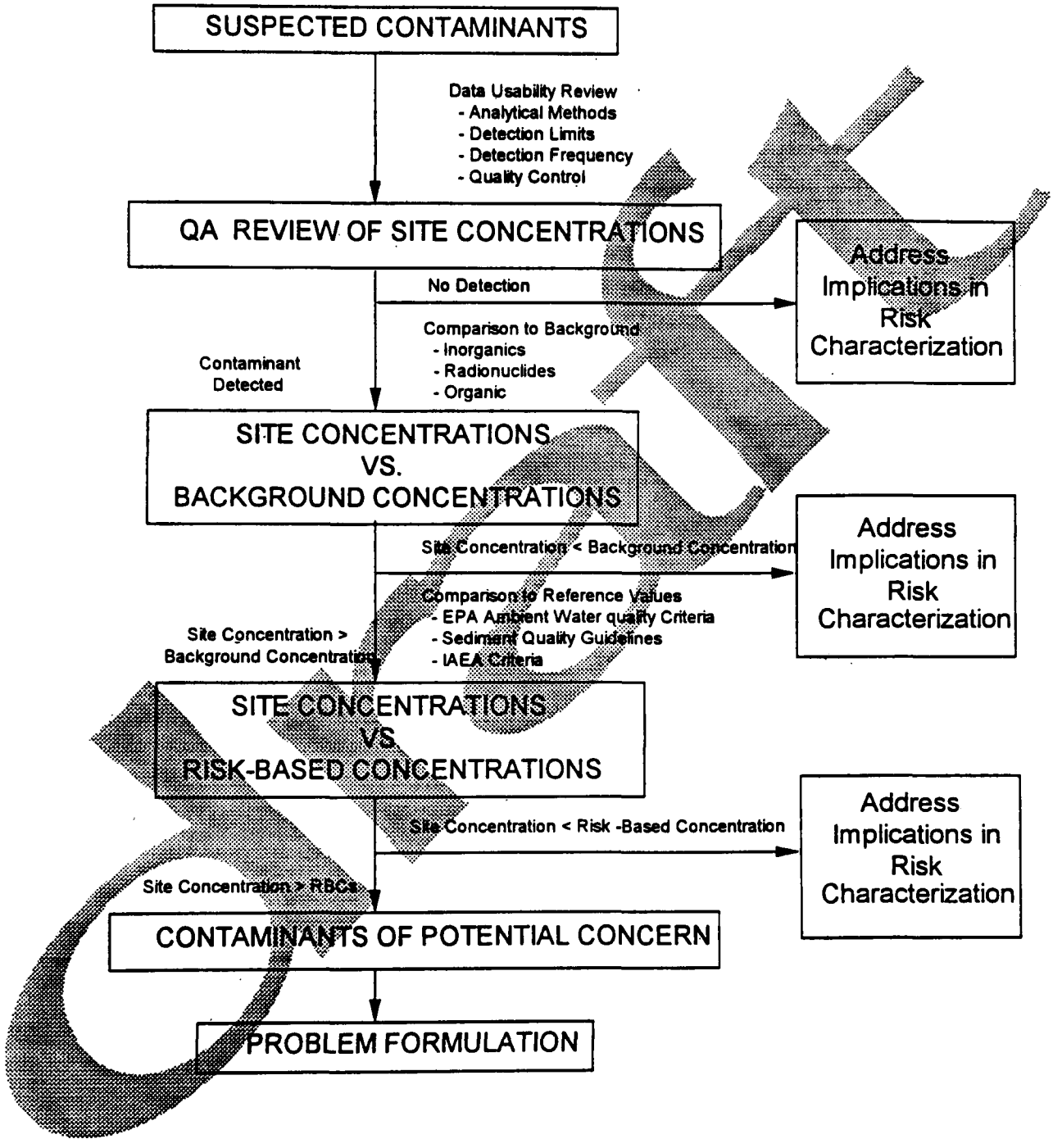
5.3.3 Parameters of Concern

‡Information provided under the "Surface Water" and "Sediment" columns was taken from Region 3 interim ecological risk assessment guidance (EPA III, 1994).

In any ecological risk assessment there are three basic parameters of concern that should be considered. These parameters are contaminants, receptors and exposure pathways which link contaminants to receptors. The cohesive identification of anticipated ecological effects of contaminants on receptors through a particular exposure pathway is essential in determining the potential for adverse effects.

5.3.3.1 Identification of Contaminants of Concern

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. A flow chart to help discern contaminants of concern is presented in Figure 5-3. (Appendix C includes a detailed discussion of soil background concentrations.)



Adapted from INEL (1994)

Figure 5-3 Selection of Contaminants of Concern

5.3.3.2 Identification of Ecological Receptors

The identification of potentially exposed receptors and habitats on or near the site is an extensive task. This activity can be accomplished by utilizing data from a variety of sources including field reconnaissance, aerial photography and satellite imagery as well as information assembled from other relevant investigations at the site. Once habitats have been determined, species associated with those habitats can be identified. All potential receptors should be identified, including species essential to or indicative of the area's ecological health, species which are rare, endangered or threatened and any species protected under federal or state law (EPA 1989b). The Department of Natural Resources, the United States Fish and Wildlife Services, and the National Oceanic and Atmospheric Administration (NOAA), along with other State and local agencies, have data or information which may help the risk assessor in identifying these potential receptors and habitats at or near the site.

5.3.3.3 Identification and Verification of Exposure Pathways

All potential exposure pathways must be identified. The sampling and analysis steps of the risk assessment may reveal some incomplete exposure pathways; however, if there is evidence that indicates a high probability that a pathway exists, then it should be submitted for further scrutiny. After receptors have been identified, exposure routes for each receptor to each contaminant in each corresponding medium (air, ground/surface water, soil, sediment, and biota) on the site can be evaluated.

5.3.3.4 Identification of Known Effects

Once the previous three characteristics (contaminants of concern, potential receptors and exposure pathways) have been identified, a linkage between stressors and effects on receptors must be established. Which contaminants of concern produces adverse effects on which receptors via which exposure pathway(s)? Furthermore, what are the adverse effects of the exposures? This information should be both qualitative and quantitative and may even be gathered from the peer reviewed journal publications. The documentation of all known or suspected effects of the contaminants will assist in the selection of assessment and measurement endpoints.

5.3.4 Definition of Objectives and Scope

The scope and objective(s) of the risk assessment should be established early in the process

to insure that a consistent and relevant assessment is performed. They cannot be establishedbefore the screening stage because they are based on some knowledge of the general state of the site. Once those data become available, the objective(s) of the risk assessment must be set. This step is an iterative part of the problem formulation process. Defining the scope of the risk assessment may reveal some data gaps in the current data set; collection of more data may further influence the objective(s) of the risk assessment. The objective(s) of the study at the end of the problem formulation step should be included in the deliverable for the decision point. The objective(s) should also be used to determine appropriate assessment endpoints for the site.

5.3.5 Selection of Endpoints

The selection of appropriate endpoints is critical to the risk assessment process. Assessment endpoints will be used to determine the status of the site's ecological health not only by the scientists involved in the risk assessment and subsequent remediation, but also by other federal and local trustees and the general public. Selection of endpoints is therefore part of a decision point and will be addressed in the deliverable to be submitted at the conclusion of the problem formulation.

To facilitate the decision-making process, a clear and concise summary of all endpoints should be provided. A three-column table will help to insure that a clear relationship exists between the proposed measurement and assessment endpoints. The first column should indicate the assessment endpoints chosen. The second column should list the measurement endpoint(s) which directly correspond to each of the assessment endpoints. The third column should list alternate measurement endpoints which will serve as a sort of contingency plan should any difficulties arise when site monitoring/measurements are scheduled. A sample is shown in table 5-4. This table should be accompanied by a brief description of the objective(s) of the risk assessment (as described in section 5.3.4), any hypotheses which the risk assessment will be testing and an explanation of how the chosen assessment endpoints relate to the objective(s) and hypotheses. The written portion may also include a brief explanation of how the selected measurement endpoints relate to the assessment endpoints, and also, why particular measurement endpoints were chosen if more obvious choices appear to exist. The relationship between the measurement endpoints and the assessment endpoints should be fairly straightforward and should not require a lengthy explanation.

Table 5-4 Sample Summary of Endpoints

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

The examples in table 5-4 represent clear relationships and straightforward measurements. For example, to assess for the stability of the raptor population at a site in Kitsap County Washington, measurement endpoints must aid in assessing both current and potential future effects. Changes in seasonal reproductive fecundity, as measured via number of the peregrine falcon eggs, will indicate whether any impacts are currently being experienced by the raptor population, while peregrine falcon egg-shell thinning will serve as an indicator of potential future raptor population decline. Alternate measurement endpoints should be provided to help assess the same impacts should the other measurements not be possible. For example, a decrease in the number of peregrine falcon nests at the site will indicate current impairments, while the levels of DDT (a contaminant of concern for the site) in the food source for the falcons will indicate the potential for future adverse effects. A similar example is presented for coho salmon populations. (See table 5-4.)

5.3.6 Selection of Assessment Endpoints

Text Box 5-3 Suggested Assessment Endpoints

Population	*Community*	*Ecosystem*
Extinction	Market/sport value	Productive capability
Abundance	Recreational Quality	
Yield/Production	Change to less useful/desired type	
Age/size class structure		

SOURCE: EPA 1989e

Selection of assessment endpoints can be a very complex task. Assessment endpoints are used by various organizations/agencies and trustees to determine the importance of site remediation in a broad range of contexts (scientific, political, economic and social). Therefore, assessment endpoints must be easily understood and must possess clear social *and* biological relevance (EPA 1989e). A more in depth discussion of the characteristics of good assessment endpoints may be found in Chapter 2 of *Ecological Assessment of Hazardous Waste Sites* (EPA 1989e). Text Box 5-3 presents a list of potential assessment endpoints.

5.4 Step 4: Development of Conceptual Site Model

The conceptual site model is the central component on which most of the risk assessment is based. Its development assists with and parallels the entire problem formulation; and it is the basis for evaluating the information which will be uncovered during the course of the risk assessment. The purpose of the conceptual site model is to identify:

- known or potential sources of contaminants;
- individual contaminants known from preliminary sampling to be present at the site, or believed to exist based on known types of current and historical site activities;
- environmental media that may potentially be affected by the contaminants, including surface and groundwater, soil, sediment, air, and biota;
- potential contaminant exposure pathways for ecological receptors living on or near the site, based on collected data or expected pathways;
- potential terrestrial and aquatic receptors at or in the vicinity of the site (EPA 1989b).

While the conceptual site model for the overall RI/FS process is included in Phase I along with the scoping reports (section 1.1 of this document), a more detailed model is necessary for a thorough risk assessment. The conceptual site model developed in Phase I of the RI/FS process will provide a general model to initiate the investigation. The risk assessment conceptual site model must now identify true and complete exposure routes, actual receptors and contaminated media and transport mechanisms. It should be a separate model and be specific to the ecological concerns of the site. It should also take into account the selected endpoints for the risk assessment. An example of a schematic conceptual model is presented in figure 5-4. It includes the primary and secondary release mechanisms potentially associated with each affected matrix. As shown in figure 5-5, a graphic can also be used to convey this information. It is important to clearly identify all potential pathways by which contaminants of concern may be transported as well as ecological receptors associated with each form of exposure.

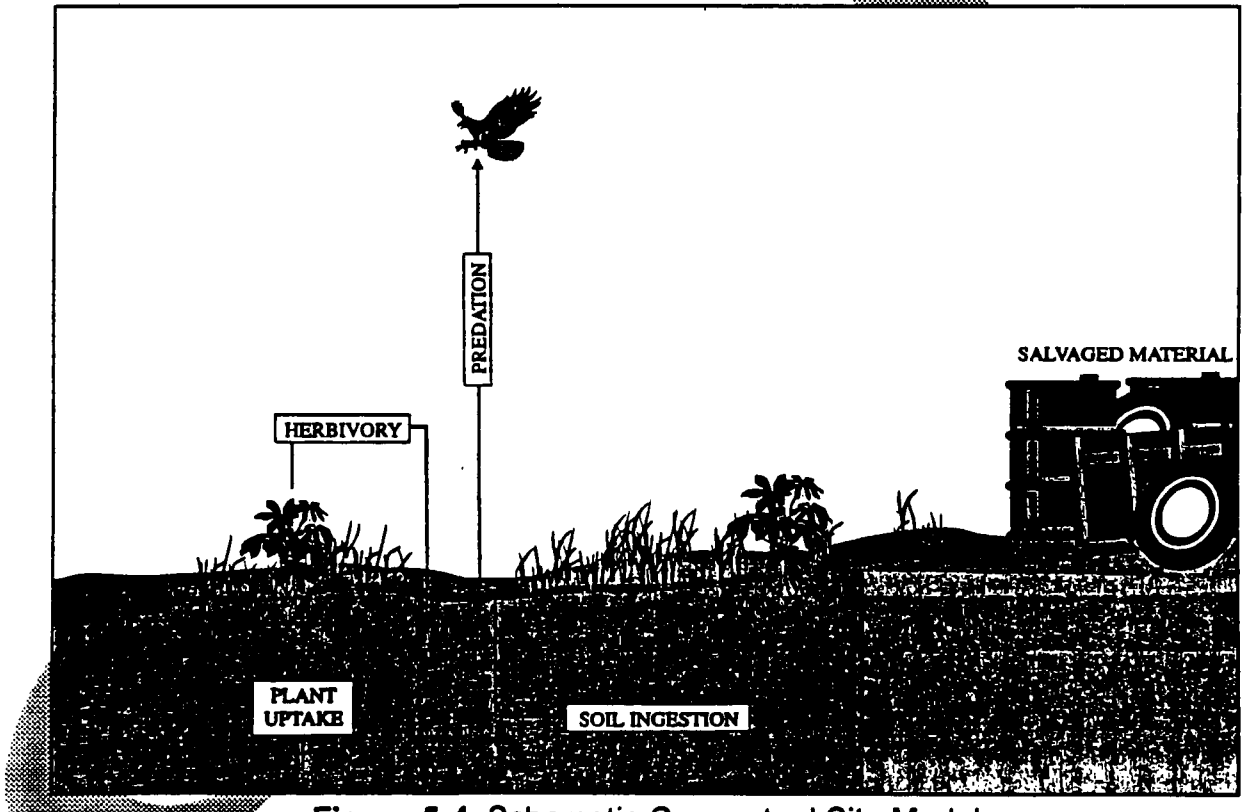


Figure 5-4 Schematic Conceptual Site Model

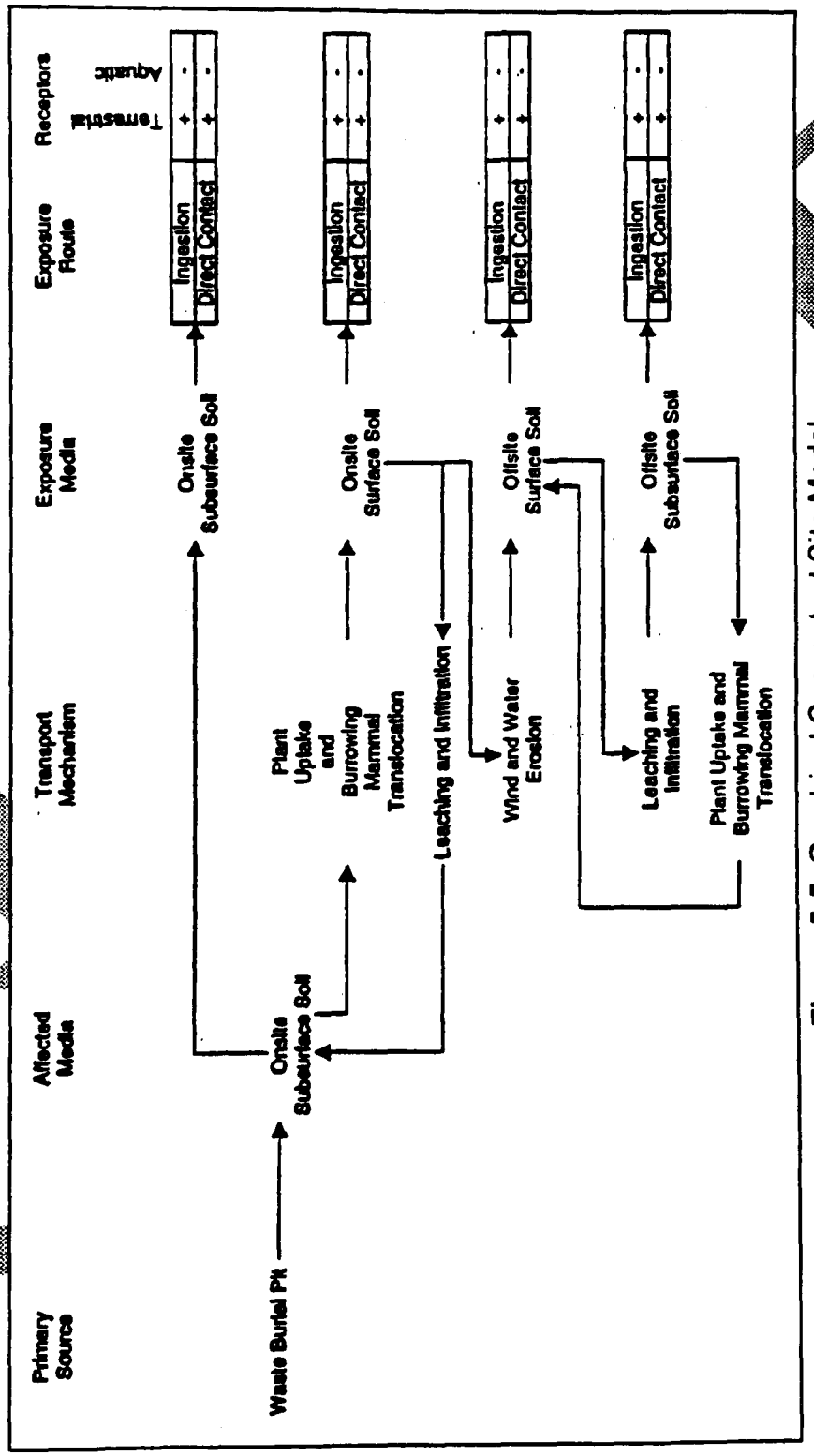


Figure 5-5 Graphical Conceptual Site Model

Definition 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, as marked by standard indices, when due to exposure, may indicate a potential receptor. Third, if a prey organism serves as a source of exposure to predators (based on body burden and sample model), it may also be a potential receptor 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.

5.4.1 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 5-4 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".

Text Box 5-4 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

5.4.2 The Relationship Between Measurement Endpoints and Assessment Endpoints

The relationtionship between measurement and assessment endpoints can be complex. Assessment endpoints can sometimes also serve as measurement endpoints. Endpoints are identifiable environmental characteristics designed to help assess ecological integrity in an objective and straightforward 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, as presented in table 5-4, 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 more concrete and directly

able to be evaluated).

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*.

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.

Text Box 5-5 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

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 5-5 presents characteristics of good assessment and measurement endpoints.

5.4.3 Selection of Study Design

At this juncture of the risk assessment, the conclusion of the problem formulation, including the conceptual assessment site model, the two associated sets of deliverables should be submitted to the project manager and the corresponding decisions made. The following questions should be addressed: Are the stated objective(s) appropriate? Do the endpoints support a focussed, efficient and effective ecological risk assessment? Have the exposure pathways been adequately identified? Is the workplan clear and thorough? Any additions or changes necessary for conducting the specialized tasks indicated in the workplan should be determined. Once these questions have been addressed, the risk assessment should continue in accordance with the workplan.

5.4.4 Literature Search

Text Box 5-6 Possible Sources of Ecological Effects/Toxicity Data

- *primary literature*
- Registry of Toxic Effects of Chemical Substances
- Hazardous Substances Database
- IRIS
- Agency for Toxic Substances and Diseases Registry
- Phytotox Database
- Aquatic Information Retrieval
- Chemical Evaluation Search and Retrieval System
- Fish and Wildlife Service Contaminant Hazard Reviews
- Fish and Wildlife Service Contaminant Data Source

Literature search should be conducted as soon as the problem formulation phase is completed. In fact, it should be initiated during the screening phase of the risk assessment. Inadequate literature searches can result in unnecessary toxicity testing as well as delays in the overall process due to a lack of data. The literature search may provide ecological effects data for particular contaminants and species. The data obtained from the literature search can be compared with site-specific data on contaminant concentration and adverse effects, which will be used to characterize associated risks (EPA 1989b). At the conclusion of the literature search, data gaps can be identified. It should then be decided whether contingent toxicity tests and field studies are needed. Text Box 5-6 presents a list of possible sources of relevant ecological risk-based values such as LD50s, LC50s, NOAELs and LOAELs.

5.5 Step 5: Site Assessments

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 determinedat the decision point following the problem formulation.

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

Sampling design should be clearly laid out in the workplan as influenced by the decisions made and the associated deliverables at the problem formulation step. Sampling should be thorough and based on sound judgement taking into consideration all available and relevant data about the site. Direct sampling of media is obviously 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. Any sampling of background areas should be included in the Sampling and Analysis Plan.

5.5.2 Verification of Exposure Pathways: Characterization of Receptors

Characterization of receptors should be limited to site receptors (not *all* organisms present at the site), 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.

5.5.3 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 5-5 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 5-5 Sample Intake Calculation 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	28.7

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/kg-day

Daily Intake Invertebrates = ($Concentration_{soil}$ x $bioconcentration\ factor_{invertebrate}$ x %invertebrates in diet x food/day)body weight
= (150 mg/kg x 0.65 x 0.38 x 0.007 kg/day)/0.02
= 12.97 mg/kg-day

Note: Bioconcentration factor for invertebrates 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/kg x 0.40) + (16.3 x 0.14)) x 0.007)/0.02
= 2.00 mg/kg-day

Note: Concentration of seed and leaf tissue measured at site (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/kg-day

Table 5-5 Sample Intake Calculation 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
Concentration of Pb in Seed	=	8.6 mg/kg (Hypothetical)
Percent Seed in Diet	=	40%
Daily Intake$_{plant}$	=	2 mg/kg-day
Concentration of Pb in Leaf	=	16.3 mg/kg
Percent of leaf in Diet	=	14%

5.5.4 Toxicity Tests

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. 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 5-7 lists recommended toxicity tests for different media.

Text Box 5-7 Possible Toxicity Tests

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

5.5.5 Toxicity Bioassays

Toxicity bioassays can be performed for each matrix (water, sediment, and soil). 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 toconclude 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 a potential stressor in the media and 2) to validate chemical analyses corresponding to each

medium.

5.6 Step 6: Field Investigation

5.6.1 Site Investigation and Ecological Effects Assessment

This step provides a link between exposure to contaminants and observed effects on receptors at the site. It focusses 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.

5.6.2 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 other 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.

Literature can also provide an expedient and available means of referencing pertinent toxicity information. However, often the literature does not contain the species-specific or surrogate information required for the assessment. Although field studies involve additional time and cost, they also provide site-specific and species-specific exposure and toxicity data which can reduce the uncertainty in the risk assessment and contribute to a stronger ecological risk characterization of the site.

5.7 Step 7: Risk Estimation and Characterization

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).

5.7.1 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.

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 5-1 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 consideration of effects distributions. In situations in which such data are available, a distribution of risk can help to provide a better representation of the conditions present at the site than a single value (personal communication with Pat Cirone, January 1996).

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 more representative understanding of risks present at the site. Such combining 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. The more angles considered, the more accurate a representation the risk estimate can provide. Yet the more

angles considered, the more data presented and the greater the potential confusion.

To avoid clouding the risk characterization with unclear or inapplicable data, all data should be presented clearly, and in the context of the associated endpoints within the illustration of the conceptual site model. 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 to the conceptual site model was discovered, it should be clearly stated before related data is discussed; if an extrapolation from toxicity data based on a related, but different species, it should be noted. Essentially, the "line of evidence" leading to the risk estimates should be presented. Such an analysis is necessary in both quantitative and qualitative risk estimation. Describe the source of toxicity and exposure parameters, the reasoning behind professional judgements and any inferences applied to the data.

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.

5.7.1.1 Current Adverse Effects

Information presented must be clear. 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 the 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 site 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.

5.7.1.2 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.

5.7.1.3 Risk Calculation

Risk calculations may be used during screening as well as later stages of the risk assesment 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 deciding which contaminants will be carried through the risk assessment.

Ecological risk calculations primarily involve the hazard quotient (HQ), which is sometimes referred to as the toxicity quotient (TQ). Equation 5-1 shows how to calculate the HQ.

$$HQ = Dose/TRV$$

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 5-1 The Hazard Quotient

(a) NOAEL = Acute or Subchronic LOAEL/10

(b) NOAEL = Chronic LOAEL/5

(c) NOAEL = $(LD_{50}/5)/10$

(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)

SOURCE: Sigal & Suter, 1989.

Equation 5.2 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 5-2 (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. 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 5-3.

$$HI = \sum HQ$$

$\sum_{HQ}^{HI}$ = Hazard index
$\sum HQ$ = The summation of all hazard quotients of related contaminants of concern

Equation 5-3: The Hazard Index

Hazard Quotient (HQ) values greater than or equal to one indicate a likelihood of risk. Contaminants with an HQ $\geq$ 1 should continue to be evaluated throughout the following stages of the ecological risk assessment. 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 $\geq$ 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.

5.7.1.4 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. When possible, uncertainty documentation should include a quantitative component.

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.

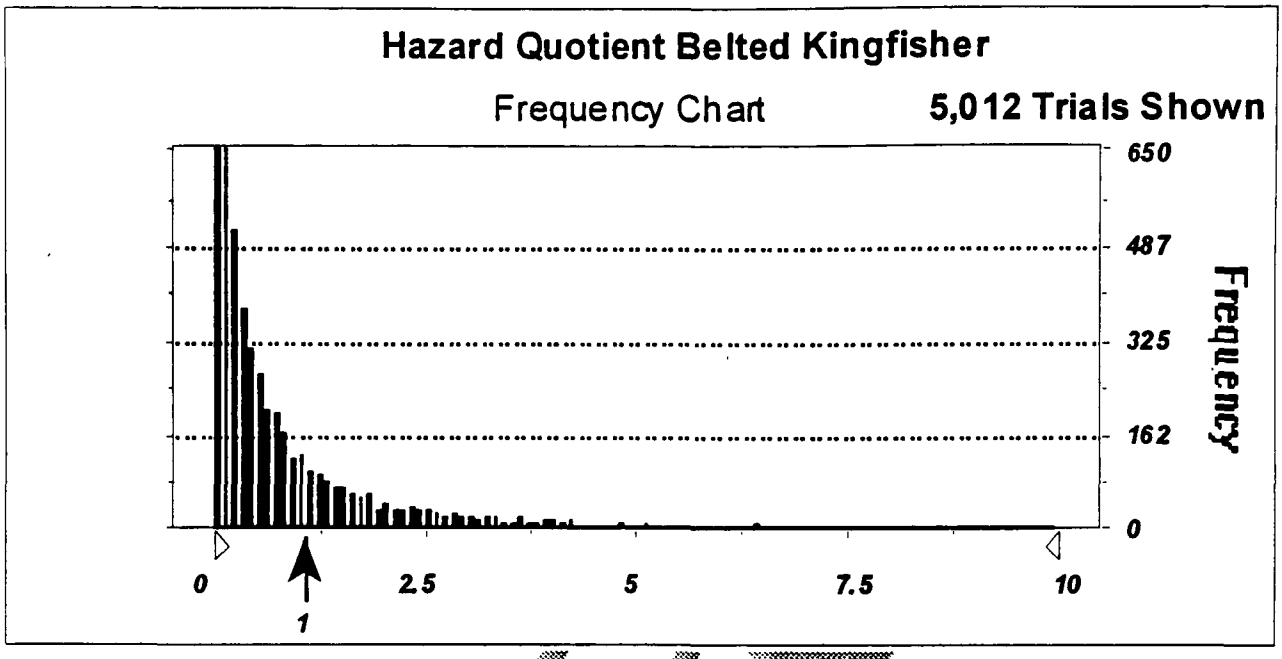


Figure 5-6. Frequency Chart of the Hazard Quotient for the Belted Kingfisher.

Figure 5-6 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.

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.

5.7.2 Risk Description and Interpretation of Uncertainty

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.

5.7.2.1 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.

5.7.2.2 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 line 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.

5.8 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 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.

6.0 RISK ASSESSMENT TASKS FOR THE FS

6.1 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 feasability concerns, specific deliverables and level of effort will be determined according to the needs of each site.

6.2 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 7 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.

7.0 RESOURCES

7.1 Human Health Risk Assessment Resources

7.1.1 Agency Guidelines for Risk Assessment

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.) These guidelines include:

- Guidelines for Carcinogen Risk Assessment
- Guidelines for Mutagenicity Risk Assessment
- Guidelines for Health Risk Assessment of Chemical Mixtures
- Guidelines for the Health Assessment of Suspect Developmental Toxicants

More recent risk assessment guidelines:

- *Draft Revisions to the Guidelines for Carcinogen Risk Assessment, Review Draft* (EPA/600/BP-92/003, August, 1994)
- *Report on the Workshop on Cancer Risk Assessment Guidelines Issues* (EPA/630/R-94/005a, November, 1994).
- *The Use of the Benchmark Dose Approach in Health Risk Assessment* (EPA/630/R-94/007, February 1995).
- *Exposure Assessment Guidelines.* 1992. Federal Register, May 29, 1992. 57 FR 22888 - 22938.

Risk Characterization. Memorandum from EPA Administrator Carol Browner, March 21, 1995.

Carcinogen Assesment Approach. EPA 1988. Background Document 2 in Integrated Risk Information System (IRIS), EPA on-line database.

Interim Methods for Development of Inhalation Reference Concentrations. Office of Research and Development. EPA/600/8-90/066A.

RfD Description and Use in Health Risk Assessments. EPA 1988. Background Document 1A in Integrated Risk Information System (IRIS), EPA on-line database.

7.1.2 References for Toxicity Assessment

Integrated Risk Information System (IRIS). EPA on-line database. Contact IRIS User Support (513-569-7254) for information on access to IRIS through vendors.

Health Effects Assessment Summary Tables (HEAST), EPA 1995. (OSWER Pub. 9200.6-303(95-1), or EPA/540/R-95-036). HEAST is available to the public through NTIS (PB 95-921199).

Reports on specific chemicals can be found in *Toxicity Profiles*, from Agency for Toxic Substances and Disease Registry, and in *Health Assessment Documents* and other chemical-specific EPA reports.

7.1.3 References for Exposure Assessment

Draft Exposure Factors Handbook. EPA, 1995 (NCEA). (EPA/600/P-95/002A).

Exposure Factors Handbook. EPA 1989. Office of Health and Environmental Assessment. EPA 600/8-89/043.

Superfund Exposure Assessment Manual. EPA 1988. Office of Remedial Response. EPA 540/1-88/001.

Air Pathway Analysis Procedures for Superfund Applications. EPA 1990. Office of Air Quality Planning and Standards. EPA/450/1-89/001,002,003,004.

Dermal Exposure Assessment: Principles and Applications. EPA 1992. Office of Research and Development, Office of Health and Environmental Assessment. EPA/600/8-91/011B.

Exposure Assessment Guidelines. 1992. Federal Register, May 29, 1992. 57 FR 22888 - 22938.

7.1.4 Superfund Risk Assessment Guidance

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

Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part B, Development of Risk-based Remediation Goals. 1991. Office of Solid Waste and Emergency Response. OSWER Directive No. 9285.7-01B. EPA/540/R-92/003.

Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part C, Risk Evaluation of Remedial Alternatives. 1991. Office of Solid Waste and Emergency Response. OSWER Directive No. 9285.7-01C. EPA/540/R-92/004.

Risk Assessment Guidance for Superfund, Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors. 1991. Office of Emergency and Remedial Response, Office of Solid Waste and Emergency Response, Directive No. 9285.6-03.

Supplemental Guidance to RAGS: Calculating the Concentration Term. 1992. Office of Emergency and Remedial Response, Office of Solid Waste and Emergency Response, Directive No. 9285.7-

081.

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.

Risk-Based Concentration Tables. EPA Region 3 continues to distribute their valuable Risk-Based Concentration Table, however the updates will now be provided semi-annually instead of quarterly. The most recent version at time of release of this guidance can be found in Appendix B of this document. Updated copies for from Region 10 may obtain a copy by contacting Maureen Bagocius at 206-553-8209. These RBC tables may also be downloaded from the World Wide Web at **"http://www.epa.gov/docs/region3/hwmd/riskmenu.htm".**

Soil Screening Guidance, Draft (OSWER 9355.4-14FS; EPA/540/R-94/101; PB95-963529).

Technical Support Document: Parameters and Equations Used in Integrated Exposure Uptake Biokinetic Model for Lead in Children (v 0.99d), (OSWER 9285.7-22; EPA/540/R-94/040; PB94-963505). *(The original guidance manual is designated EPA/540/R-93/081; NTIS order number PB 93-963510; OSWER Publication No. 9285.7-15-1. The NTIS order number for the model software is PB 93-963511; OSWER Publication No. 9285.7-15-2.)*

Superfund Mine Waste Reference Document. [Soon to be released] *(This document will have a human health risk assessment chapter geared towards mining sites, and will also address the larger RI/FS process.)*

7.1.5 Risk Assessment for Incineration

The following is a list of guidance available for conducting risk assessments for incinerators:

- *Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions, Interim Final.* January 1990 (EPA/600/6-90/003).
- *Addendum to Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions, External Review Draft.* November 1993 (EPA/600/AP-93/003).
- *Exposure Assessment Guidance for RCRA Hazardous Waste Combustion Facilities, Draft.* April 1994 (EPA/530/R-94/021).
- *Draft EPA Modification of Screening Guidance Fate and Transport Equations.* November 17, 1994.
- *Further Issues for Modeling the Indirect Exposure Impacts from Combustor Emissions.* (Memorandum dated January 20, 1995.)

7.2 Ecological Risk Assessment Resources

7.2.1 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.)*

7.2.2 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.*

7.2.3 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.

7.3 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.

8.0 REFERENCES

Sigal, L. L. & G. W. Suter II. 1989. *Potential Effects of Chemical Agents on Terrestrial Resources.* Environmental Professionals, Vol. 11, pp 376-384.

U.S. Environmental Protection Agency (EPA). 1996. *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). 1988d. *RfD Description and Use in Health Risk Assessments.* Background Document 1A in Integrated Risk Information System (IRIS), on-line database.

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

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EPA/560/688/001.

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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.

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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

Calculation of Human Health Risk-Based Concentrations for Radionuclides

(Insert Revised Radionuclide PRG Equations from RAGS HHEM Part B Update Release)

draft

Appendix B

Summary Tables of Human Health Exposure Factors

(Insert updated Region 10 Exposure Factors tables)

Appendix C

"The Tool Box"
Region 10 Risk Report Technical Issues

draft

Office of Environmental Assessment

January 1996
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)

draft

Appendix D

Region 10 Risk Report, Special Release Case Study Summaries

Office of Environmental Assessment

January 1996
Release Number 2

Region 10 Risk Report

focus: eco risk

Special Release: Case Study

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

January 1996
Release Number 3

Region 10 Risk Report

focus: eco risk

Special Release: Case Study

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 Commencement Bay Tidelands Ecological Risk Assessment Case Study)

draft

Attachment 1

Human Health Risk-Based Concentrations for Water and Soil

(Attach Region 3 RBC tables package with cover letter)

draft