

PROTOCOL

ECOLOGICAL RISK ASSESSMENT PROCESS ANNOTATED OUTLINE

The purpose of the annotated outline is to provide a consistent format for ecological risk assessments (ERAs) at the Savannah River Site (SRS) following the "Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments" (USEPA 1997) guidance document. This outline applies to both work plans and baseline risk assessments (BRAs) depending on their current state of development. All new work plans will start at Step 1 of the process provided adequate abiotic data are available for evaluation. Work plans with adequate biological data will contain a minimum of Steps 1 and 2 (screening-level ERA) and may contain Steps 3 and 4 depending on the results of the screening-level ERA. If adequate data are not available, Step 1 will be initiated and documented in the next document submittal (e.g., subsequent work plan phase or in the BRA) once adequate data have been collected. BRAs will begin at Step 1 of the process and will either (1) summarize the steps already conducted in the work plan, (2) initiate the process if not previously conducted in the work plan, or (3) if new data become available after completion of Steps 1 and 2, determine the impact of the data and modify the results of Steps 1 and 2 accordingly.

The prefixes in the section numbering will vary depending on which document this report is contained (e.g., in a BRA, the numbering will be 8.1.2 for the screening-level problem formulation).

Introduction

Provide an introduction including the purpose, scope, scale, and status of the ERA process for the unit under evaluation.

SCREENING-LEVEL PROBLEM FORMULATION AND ECOLOGICAL EFFECTS EVALUATION (Process Step 1)

1.1 INTRODUCTION

The screening-level problem formulation and ecological effects evaluation is part of the initial ecological risk screening assessment. Section 1.2 describes the screening-level problem formulation and Section 1.3 describes the screening-level ecological effects evaluation.

1.1.1 Unit History

Provide a brief history of the unit including its current status, emphasizing those aspects that are important to the ecological risk assessment.

1.2 SCREENING-LEVEL PROBLEM FORMULATION

The screening-level problem formulation requires the development of a brief and preliminary conceptual site model (CSM) that addresses the following four issues:

Environmental setting and contaminants known or suspected to exist at the waste unit (Section 1.2.1);

Contaminant fate and transport mechanisms that might exist at the unit (Section 1.2.2);

A brief discussion of the mechanisms of ecotoxicity associated with broad classes of contaminants (Section 1.2.3); and

Potentially complete exposure pathways (Section 1.2.4).

1.2.1 Environmental Setting and Contaminants at the Site

The discussion of the ecological characterization of the unit, including the results of habitat mapping, field reconnaissance, and any previously conducted ecological studies. The results of the checklist for ecological assessment/sampling for the unit is also discussed here and the checklist is provided as an attachment. This includes a description of physical features such as surface water drainage pathways (both current and historic), soil type(s), vegetative communities, wildlife, threatened or endangered species, and the general categories of contaminants present at the unit.

1.2.2 Contaminant Fate and Transport

Based on the CSM, the potential pathways for the migration of unit-related contaminants are discussed.

1.2.3 Ecotoxicity and Potential Receptors

Given the types of constituents detected at the unit as discussed in Section 1.2.1, toxic mechanisms of the constituents are generically discussed by constituent category (organics, inorganics, and radionuclides).

1.2.4 Complete Exposure Pathways

Potential exposure pathways at the unit are also discussed in Section 1.2.2. For ecological receptors present at the unit, the potentially complete exposure pathways are discussed as well as the routes through which exposure to these pathways may occur.

1.3 SCREENING-LEVEL ECOLOGICAL EFFECTS EVALUATION

The ecological effects evaluation identifies the potential for adverse ecological effects based on conservative assumptions. Ecological screening values (ESVs) are used as the screening-level effects levels. ESVs are abiotic media (surface water, sediment, and soil) concentrations associated with the low risk (approaching the threshold of acceptable/unacceptable risks) to ecological receptors. The uncertainty associated with the screening-level assessment is unidirectional, with a low probability of not identifying contaminants which pose unacceptable risks to ecological receptors.

1.3.1 Preferred Toxicity Data

The preferred toxicity data for the screening-level ecological effects evaluation are the ecological screening values (ESVs) as identified in the “Ecological Screening Values (ESVs)” protocol (WSRC 1999e) and subsequent revisions.

1.3.2 Dose Conversions

The use of any dose conversions in the “Ecological Screening Values (ESVs)” protocol (WSRC 1999e) will be identified in this section.

1.3.3 Uncertainty Assessment

The generic uncertainties associated with the ESVs and the assumptions made in Step 1 of the process will be identified.

1.4 SUMMARY

A brief summary of the information provided in Sections 1 will be provided.

SCREENING-LEVEL EXPOSURE ESTIMATE AND RISK CALCULATION (Process Step 2)

2.1 INTRODUCTION

This step includes estimating exposure levels and screening for ecological risks.

2.2 SCREENING-LEVEL EXPOSURE ESTIMATES

2.2.1 Exposure Parameters

The exposure parameters used, if any, are identified in the “Ecological Screening Values (ESVs)” protocol (WSRC 1999e).

2.2.2 Uncertainty Assessment

The generic uncertainties associated with the ESVs and the assumptions made in Step 2 of the process will be identified.

2.3 SCREENING-LEVEL RISK CALCULATION

The screening-level risk calculation is performed per Steps A and B of the “Ecological Constituents of Potential Concern Selection Process” protocol (WSRC 1999d). Constituents identified as having the potential to bioaccumulate/bioconcentrate per the “Bioaccumulation and Bioconcentration Screening” protocol (WSRC 1999c) will be retained for further evaluation per Step D of the “Ecological Constituents of Potential Concern Selection Process” protocol (WSRC 1999d).

2.4 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

The selection of one of the following three decisions is made:

- (1) There is adequate data to conclude that ecological risks are negligible and therefore no need for remediation on the basis of ecological risk;*
- (2) The information is not adequate to make a decision at this point, and the ecological risk assessment process will continue to Step 3; or*
- (3) The information indicates a potential for adverse ecological effects, and a more thorough assessment is warranted.*

This SMDP will be addressed through a meeting (e.g., conference call) with EPA and SCDHEC for the initial waste units utilizing this outline.

2.5 SUMMARY

A brief summary of the information provided in Section 2 will be provided.

BASELINE RISK ASSESSMENT PROBLEM FORMULATION (Process Step 3)

Step 3 of the process initiates the problem-formulation phase of the baseline ecological risk assessment. Step 3 refines the screening-level problem formulation and, with input from stakeholders and other involved parties, expands on the ecological issues that are of concern at the particular site. Steps 3 through 7 are required only for sites for which the screening-level assessment indicated a need for further ecological risk evaluation.

3.1 THE PROBLEM-FORMULATION PROCESS

Problem formulation establishes the goals, breadth, and focus of the baseline ecological risk assessment and establishes the assessment. The questions and issues that need to be addressed in the baseline ecological risk assessment are defined based on potentially complete exposure pathways and ecological effects. The conceptual model of the site is refined and includes questions about the assessment endpoints and the relationship between exposure and effects.

3.2 REFINEMENT OF PRELIMINARY CONTAMINANTS OF CONCERN

The results of the screening-level risk assessment (Steps 1 and 2) should have indicated which contaminants found at the site could be eliminated from further consideration and which should be evaluated further. Because of the conservative assumptions used during the risk screen, some of the contaminants retained for Step 3 might also pose acceptable levels of risk. At this stage, the remaining constituents are further evaluated based on the following considerations per the “Ecological Constituents of Potential Concern Selection Process” protocol (WSRC 1999d):

- (1) Comparison to unit background /reference (Section 3.2.1);*
- (2) Evaluation-level hazard quotient (HQ) development (Section 3.2.2);*
- (3) Lines-of-evidence (Section 3.2.3).*

3.2.1 Comparison to Unit Background/Reference

Per Step C of the “Ecological Constituents of Potential Concern Selection Process” protocol (WSRC 1999d), constituents are identified for which background/reference media concentrations can be used to eliminate them from further consideration. Remaining constituents are further evaluated in Section 3.2.2.

3.2.2 Evaluation-Level Hazard Quotient Development

Per Steps E and F of the “Ecological Constituents of Potential Concern Selection Process” protocol (WSRC 1999d), evaluation-level HQs are based on exposure doses that are calculated based on receptor-specific input

parameters and average concentrations. Receptors to be considered at this step of the process are determined using the “Assessment and Measurement Endpoint Selection Process” protocol (WSRC 1999b). Terrestrial toxicity reference values (TRVs) are identified based on the terrestrial TRVs protocol (WSRC 1999f). Aquatic TRVs are identified based on the aquatic TRVs protocol (WSRC 1999a). Remaining constituents are further evaluated in Section 3.2.3.

3.2.3 Lines-of-Evidence

Per Steps F and G of the “Ecological Constituents of Potential Concern Selection Process” protocol (WSRC 1999d), constituents with an evaluation-level HQ greater than one are further evaluated based on the following lines-of-evidence: preliminary assessments involving alternate toxicity reference values (e.g., no observed versus lowest observed adverse effects level comparisons), frequency of detections (i.e., analytical qualifier evaluation), and patterns of detections (i.e., pattern of hits indicating contamination migration from a source). This evaluation is based on an interpretation of the available data, interpretation of the available information, and professional judgement. Information from previous ecological studies, if available, should also be evaluated in this step as additional lines of evidence for retaining or eliminating constituents. Constituents remaining upon completion of this evaluation are identified as final COPCs.

3.3 LITERATURE SEARCH ON KNOWN ECOLOGICAL EFFECTS

The initial literature search conducted in Steps 1 and 2 should be expanded to obtain the information needed for the more detailed problem formulation phase of the baseline ecological risk assessment. The literature search should identify NOAELs, LOAELs, exposure-response functions, and the mechanisms of toxic responses (presented in toxicological profiles for each final COPC either within Section 3.3 or as an appendix for contaminants for which those data were not collected in Steps 1 and 2.

3.4 CONTAMINANT FATE AND TRANSPORT, ECOSYSTEMS POTENTIALLY AT RISK, AND COMPLETE EXPOSURE PATHWAYS

The contaminant fate and transport, ecosystems potentially at risk, and complete exposure pathways identified in the screening ecological risk assessment should be reevaluated and refined as necessary in this step.

3.4.1 Contaminant Fate and Transport

Information on how the final COPCs will or could be transported or transformed in the environment physically, chemically, and biologically are presented and used to identify the exposure pathways that might lead to significant ecological effects.

3.4.2 Ecosystems Potentially at Risk

The ecosystems or habitats potentially at risk should be identified based on information gathered and refined from Steps 1 and 2 of the process.

3.4.3 Complete Exposure Pathways

The potentially complete exposure pathways identified in Steps 1 and 2 are described in more detail on the basis of the refined contaminant fate and transport evaluations (Section 3.4.1) and evaluation of potential ecological receptors (Section 3.4.2).

3.5 SELECTION OF ASSESSMENT ENDPOINTS

Assessment endpoints are selected and identified here based on the "Assessment and Measurement Endpoint Selection Process" protocol (WSRC 1999b).

3.6 THE CONCEPTUAL MODEL AND RISK QUESTIONS

The conceptual site model from Section 1.2 is refined, if necessary, and presented here to establish the complete exposure pathways that will be evaluated in the ecological risk assessment and the relationship of the contaminants to the assessment endpoints. In the conceptual model, the possible exposure pathways are depicted in an exposure pathway diagram and are directly linked to the assessment endpoints identified in Section 3.5. Developing the conceptual site model and risk questions are described in Sections 3.6.1 and 3.6.2, respectively.

3.6.1 Conceptual Model

The CSM developed in Step 1 is refined based on knowledge of the contaminants present, exposure pathways, and the assessment endpoints.

3.6.2 Risk Questions

Ecological risk questions are developed to address the questions about the relationships among assessment endpoints and their predicted responses when exposed to unit contaminants. The risk questions are based on the assessment endpoints and provide a basis for developing the study design

(Step 4) and for evaluating the results of the site investigation in the analysis phase (Step 6) and during risk characterization (Step 7). An evaluation as to if and how these risk questions should be addressed must be completed at this step. This is a critical step since additional studies should only be performed if necessary to reduce critical uncertainty in the unit evaluation. Two circumstances may eliminate or reduce the need for additional data collection for ecological purposes. First, if the clean up levels for the remaining ecological COPCs are known to be higher than those required based on human health concerns (through surficial exposure or contaminant fate and transport), additional data collection to reduce the uncertainties surrounding the ecological COPCs may not be warranted and the ERA process may be suspended (if the anticipated human health remedial action is not implemented, the ERA process would continue). Second, if clean up remedies are limited at the unit and will result in the elimination of the ecological exposure pathways of concern, additional data collection to reduce the uncertainties surrounding the ecological COPCs may not be warranted.

3.7 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

The SMDP consists of agreement on four items: constituents of potential concern (final COPCs), assessment endpoints, exposure pathways, and risk questions. These items will be proposed in the report and approval of the document by EPA and SCDHEC will indicate agreement of this SMDP.

3.8 SUMMARY

The information presented in Step 3 will be briefly summarized here.

STUDY DESIGN AND DATA QUALITY OBJECTIVE PROCESS (Process Step 4)

Step 4 will establish the measurement endpoints (Section 4.1) and study design (Section 4.2), if needed for a given unit.

4.1 ESTABLISHING MEASUREMENT ENDPOINTS

Measurement endpoints are selected based on the assessment endpoints selected using the "Assessment and Measurement Endpoint Selection Process" protocol (WSRC 1999b).

4.1.1 Species/Community/Habitat Considerations

Considerations of the species, communities, and habitat present at the unit

that impact the selection of measurement endpoints and their relationship to the assessment endpoints will be discussed here.

4.1.2 Relationship of the Measurement Endpoints to the Constituents of Potential Concern

The inherent properties (such as the physiology or behavioral characteristics of the species) or life history parameters that make a species useful in evaluating the effects of site-specific contaminants will be discussed here.

4.1.3 Mechanisms of Ecotoxicity

The mechanisms of ecotoxicity for the final COPCs that may influence the selection of measurement endpoints will be discussed here.

4.2 STUDY DESIGN

The lines of evidence to be used in addressing the risk questions posed in Section 3.6.2 will be identified in this section.

4.2.1 Bioaccumulation and Field Tissue Residue Studies

The appropriateness of bioaccumulation and field tissue residue studies for the waste unit will be discussed here and detailed as necessary. The justification for the parameter values which will be used in the food web analysis will be given and the variables identified. The interpretation of the results of the modeling will be discussed and the unacceptable risk levels will be defined. The appropriateness of detection levels of COPCs will be verified by the contaminant levels associated with unacceptable risks.

4.2.2 Population/Community Evaluations

The appropriateness of population/community evaluations for the waste unit will be discussed here and detailed as necessary. The interpretation of the results of population and community evaluations will be discussed including defining acceptable and unacceptable results.

4.2.3 Toxicity Testing

The appropriateness of toxicity testing for the waste unit will be discussed here and detailed as necessary. The interpretation of the toxicity tests will be discussed including the defining of acceptable and unacceptable effects.

4.3 DATA QUALITY OBJECTIVES AND STATISTICAL CONSIDERATIONS

The concept of data quality objectives (DQOs) and statistical considerations will be briefly introduced here.

4.3.1 Data Quality Objectives

The specific DQOs for the unit will be identified here.

4.3.2 Statistical Considerations

Statistical considerations that must be addressed for the unit will be identified here.

4.4 CONTENTS OF WORK PLAN AND SAMPLING AND ANALYSIS PLAN

A brief introduction as to the contents of the ecological work plan and sampling and analysis plan (SAP) sections and how they relate to other sections of the Remedial Investigation (RI) work plan will be discussed here.

4.4.1 Work Plan

The critical decisions and evaluations made during problem formulation will be identified here as well as additional investigative tasks needed to complete the evaluation of risks to ecological receptors. Information detailed in other reports will only be summarized and the reader directed to the appropriate report for details.

4.4.2 Sampling and Analysis Plan

Details of the ecological SAP will be discussed here. The quality assurance project plan (QAPP) will reference the existing QAPP for the unit and provide supplemental information only when not included in the existing QAPP.

4.4.3 Field Verification of Sampling Plan and Contingency Plans

To the extent possible, field verification of the SAP will be performed and contingency plans developed and documented here.

4.5 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

This SMDP consists of agreement on the study design, work plan, and SAP. These

items will be proposed in the report and approval of the document by EPA and SCDHEC will indicate agreement of this SMDP.

4.6 SUMMARY

The key elements of Step 4 will be discussed here.

FIELD VERIFICATION OF SAMPLING DESIGN (Process Step 5)

5.1 PURPOSE

The purpose of field verification of the sampling design will be discussed here.

5.2 DETERMINING SAMPLING FEASIBILITY

Field verification of the sampling design will be performed, as possible, and documented here.

5.3 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

This SMDP consists of agreement on sampling feasibility. These items will be proposed in the report and approval of the document by EPA and SCDHEC will indicate agreement of this SMDP. If schedules do not permit the verification of sampling feasibility, a separate letter will be sent to EPA and SCDHEC subsequent to the work plan submittal documenting the conclusions of the field verification.

5.4 SUMMARY

The key elements of Step 5 will be discussed here.

SITE INVESTIGATION AND ANALYSIS PHASE (Process Step 6)

6.1 INTRODUCTION

A brief overview of the concept of site investigation and analysis phase will be discussed here. In the event that significant changes to the ecological SAP occur during field implementation or during analyses of the data, EPA and SCDHEC will be notified and briefed on the impact of the changes and the recommended course of action.

6.2 SITE INVESTIGATION

The site investigation should be a direct implementation of the ecological SAP. If changes to the SAP occurred, they should be documented in this section.

6.2.1 Changing Field Conditions

Changing field conditions resulting in the modification of the ecological SAP will be identified.

6.2.2 Unexpected Nature or Extent of Contamination

Any unexpected findings in regards to nature and extent of contamination and its impact to the implementation of the ecological SAP will be evaluated and an appropriate course of action will be developed.

6.3 ANALYSIS OF ECOLOGICAL EXPOSURES AND EFFECTS

An overview of the intent of the analysis phase will be discussed here.

6.3.1 Characterizing Exposures

An exposure profile and a description of associated uncertainties and assumptions will be discussed here.

6.3.2 Characterizing Ecological Effects

Evidence for existing and potential adverse effects on the unit's assessment endpoints is discussed here.

6.4 SCIENTIFIC/MANAGEMENT DECISION POINT (SMDP)

This SMDP is only required if alterations to the ecological SAP were necessary. Any significant changes to the SAP will have been communicated to EPA and SCDHEC.

6.5 SUMMARY

The key elements of Step 6 will be discussed here.

RISK CHARACTERIZATION (Process Step 7)

7.1 INTRODUCTION

An overview of risk characterization will be discussed here.

7.2 RISK ESTIMATION

Documentation of the risk estimates will be discussed here.

7.3 RISK DESCRIPTION

The intent of the risk description is discussed here.

7.3.1 Threshold for Effects on Assessment Endpoints

Contaminant media concentrations representing the threshold(s) at which environmental effects may occur will be discussed here. However, clean up levels for the final ecological constituents of concern will be identified in Chapter 10 where ARAR, human health, contaminant migration, and ecological clean up levels are identified.

7.3.2 Likelihood of Risk

A qualitative or quantitative evaluation of the likelihood of risk will be discussed in this section.

7.3.3 Additional Risk Information

Other factors influencing the potential risk at the unit will be discussed here.

7.4 UNCERTAINTY ANALYSIS

An overview of the uncertainty analysis process will be discussed here. It should be noted that an additional uncertainty analysis will be performed in conjunction with human health, contaminant migration, and ARAR considerations in Chapter 9 of the RI/BRA report. This additional uncertainty analysis may result in a modification of the final list of ecological constituents of concern identified in the ERA.

7.4.1 Categories of Uncertainty

The possible categories of uncertainty for the waste unit evaluation will be discussed here.

7.4.2 Tracking Uncertainties

Documentation of the method for tracking uncertainties, to have been agreed to in Step 4 of the process, will be discussed here.

7.5 SUMMARY

The key elements of Step 7 are discussed here.

RISK MANAGEMENT (Process Step 8)

Step 8, risk management, of the ERA process is acknowledged as a distinctly different process from risk assessment and encompasses a broader range of considerations and potential documents (e.g., Feasibility Studies, etc.). Therefore, this step is not included in the outline for the ERA process for development of work plans and BRAs.

References

- USEPA. 1997. Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments. Interim Final. EPA 540-R-97-006. June 1997.
- WSRC. 1999a. Aquatic Toxicity Reference Values (TRVs). Draft, November 1999, Westinghouse Savannah River Company, Savannah River Site, Aiken, SC.
- WSRC. 1999b. Assessment and Measurement Endpoint Selection Process. April 1999, Westinghouse Savannah River Company, Savannah River Site, Aiken, SC.
- WSRC. 1999c. Bioaccumulation and Bioconcentration Screening. April 1999, Westinghouse Savannah River Company, Savannah River Site, Aiken, SC.
- WSRC. 1999d. Ecological Constituents of Potential Concern Selection Process. April 1999, Westinghouse Savannah River Company, Savannah River Site, Aiken, SC.
- WSRC. 1999e. Ecological Screening Values (ESVs). April 1999, WSRC-TR-98-00110, Westinghouse Savannah River Company, Savannah River Site, Aiken, SC.
- WSRC. 1999f. Terrestrial Toxicity Reference Values (TRVs). April 1999, Westinghouse Savannah River Company, Savannah River Site, Aiken, SC.