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Standard Guide for Risk-Based Corrective Action for Protection of Ecological Resources[1]

This standard is issued under the fixed designation E2205/E2205M; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

This guide for risk-based corrective action for the protection of ecological resources (Eco-RBCA) provides a flexible framework for a tiered approach to ecological risk assessment (ERA) and risk management decision-making at chemical release sites. The framework of the Eco-RBCA guide parallels the framework in Guide E2081 with respect to the tiered approach for data gathering, evaluation and decision-making, and should, when possible, be conducted concurrent with the broader RBCA process activities. The Eco-RBCA guide directs the user to Guide E2081 for development and implementation of a corrective action program. This guide supplements Guide E2081 and was developed after careful consideration of the peer-reviewed published literature and existing federal, regional, and state ecological risk–assessment guidance. The user of this guide, as defined in 3.1.45, needs to be familiar with Guide E2081 and the overall RBCA process. The RBCA process provides a flexible, technically defensible framework for corrective action that has applicability to a wide range of sites and chemicals of concern.

ASTM guides are not federal or state regulations; rather, they are consensus standards that can be followed voluntarily. It is not within the scope of this standard to provide the details of specific regulatory requirements. Collectively, the Eco-RBCA and RBCA guides provide an integrated framework to corrective action. Eco-RBCA is intended to complement rather than replace the decision-making structures of regulatory programs. In addition, Eco-RBCA is intended to provide a framework for sites not covered under regulatory programs, for sites under regulatory programs that lack guidance, or for sites under programs with guidance that lack detail. Eco-RBCA may also provide a useful framework to help merge an approach when multiple regulatory programs apply. Even when a site is not currently governed by a regulatory program, consultation with the appropriate regulatory agency(ies) will ensure regulatory compliance and provide technical guidance.

The Eco-RBCA process is intended to accommodate a diversity of sites and conditions by providing a framework that can address site-specific needs. The appendixes provide useful technical details and case study examples, although the application of this guide does not require their use. Eco-RBCA is a process for evaluating ecological risk and decision making. To facilitate the implementation of Eco-RBCA, the framework is organized into ten steps and three risk assessment tiers that begin with relatively simple analyses and progress to more complex assessments as site conditions warrant (see Fig. 1). Although organized into steps and tiers, the user should recognize that Eco-RBCA progresses conceptually in a linear manner, but may not be implemented in a linear manner. The objective should be to conduct the evaluation in the manner that most appropriately meets the needs and goals of the assessment. Each tier includes five types of activities that increase in complexity and level of effort as the evaluation progresses through the RBCA process. These activities are (*1*) planning and scoping, (*2*) data and information acquisition, (*3*) analysis and evaluation, (*4*) decision making, and (*5*) remedial actions. The details of the activities and how they are implemented can vary, depending on the nature and complexity of the site and the tier level. Early in the Eco-RBCA process, assumptions are biased toward being overly protective (that is, "conservative") because of uncertainties inherent in non–site-specific data. Typically, as the site progresses through the tiered evaluation, more site-specific information is collected and uncertainty decreases; therefore, less-conservative assumptions can be used in the evaluation. As understanding of site conditions improves, confidence often increases. The progression of the evaluation through the tiered process is accompanied by an increasing degree of formalization that could include the documentation of a screening-level assessment or the use of

formal ecological risk assessment (ERA) methods. As additional site-specific information is developed, the uncertainty associated with site conditions is reduced. Commensurate with this reduced uncertainty, the user can employ more site-specific and less conservative estimates and assumptions of exposure and effects. The manner in which uncertainty, conservatism, data quality, and other technical aspects are addressed is by technical policy decisions.

Technical policy decisions (TPDs) are an important part of the Eco-RBCA process, and while it is not within the scope of this standard to identify the TPDs appropriate for a specific site, Appendix X2 and Guide E2081 provide additional insight into their identification, understanding, and development. Technical policy decisions generally fall into three categories: (*1*) those that are identified as existing prior to the Eco-RBCA assessment and will not change (that is, prescribed and without flexibility such as regulations or policy), (*2*) those that are identified as existing prior to the Eco-RBCA assessment but may change or be modified based on site-specific information (for example, sampling protocols, selection of models or other tools, or corrective-action goals), and (*3*) those that are developed specifically for the Eco-RBCA assessment (for example, development of a site-specific model). Technical policy decisions are typically identified, negotiated (if appropriate), and documented in the initial site assessment (see 7.1). It is the responsibility of the user of the Eco-RBCA guide to identify and consider the TPDs and appropriate stakeholders for a site. These TPDs may need to be reevaluated each time the Eco-RBCA evaluation proceeds through an iteration or progresses to a new tier. Both the RBCA and Eco-RBCA processes encourage user-led initiatives and appropriate stakeholder involvement in identifying TPDs and developing the Eco-RBCA program. Laws and regulations may require coordination with federal, state, and natural resource trustees.

This guide serves to complement existing guidance for hazardous-waste sites and facilities and to provide guidance for sites not under regulatory programs. This guide does not substitute for applicable federal, regional, state, local, or other regulatory requirements. This guide is not a regulation itself and may not apply to a particular situation, based on the circumstances.

This guide is not intended to replace professional judgment or to recommend a specific course of action. All aspects of this guide might not be applicable in all circumstances. This guide is not intended to represent or replace the standard of care by which the adequacy of a given professional service is judged, nor should this document be applied without consideration of a project's many unique aspects. The word "Standard" in the title of this document means only that the document has been approved through the ASTM consensus process.

[1] This guide is under the jurisdiction of ASTM Committee E50 on Environmental Assessment, Risk Management and Corrective Action and is the direct responsibility of Subcommittee E50.04 on Corrective Action.

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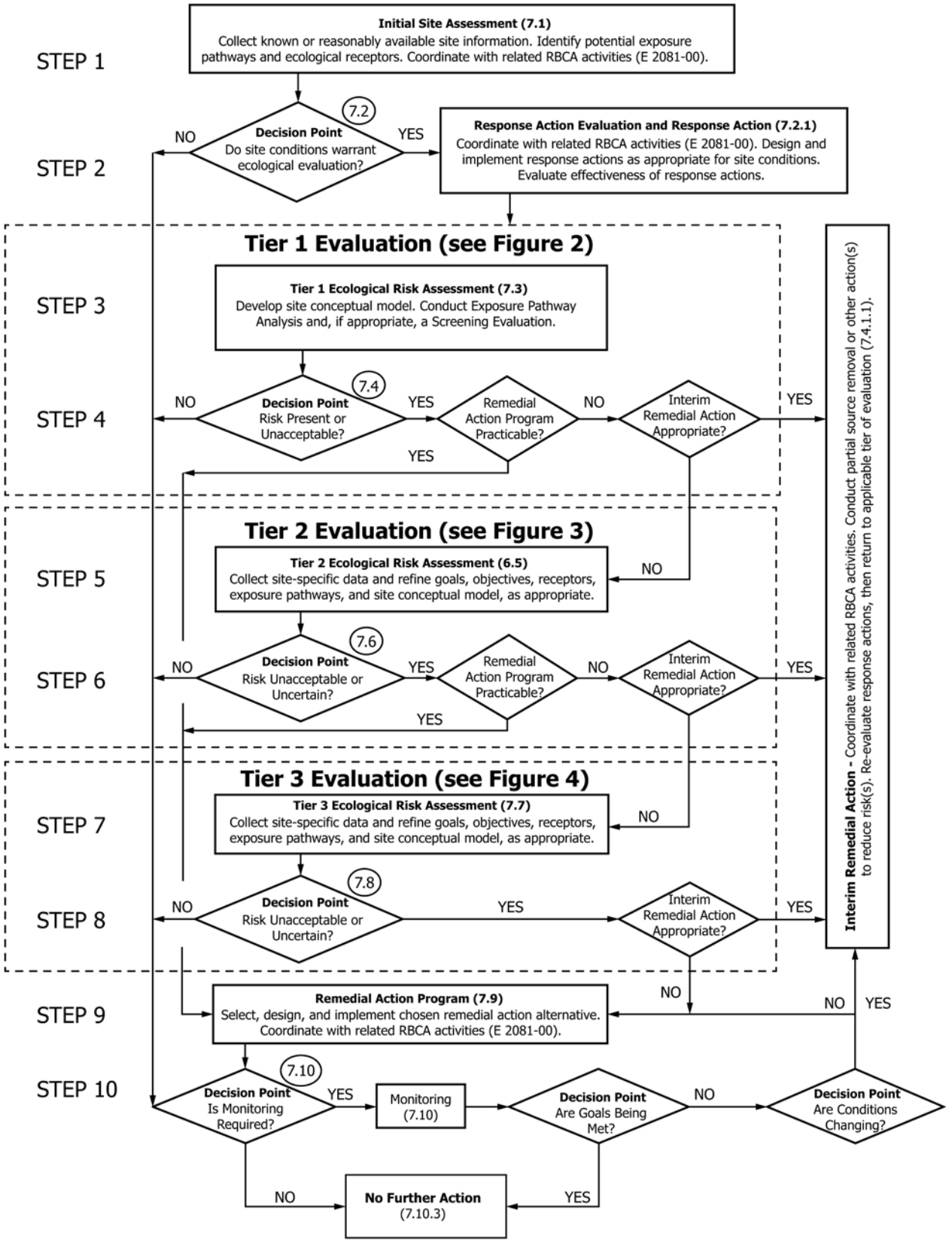

FIG. 1 Eco-RBCA Process Flowchart—Adapted from the RBCA Flowchart (Guide E2081)

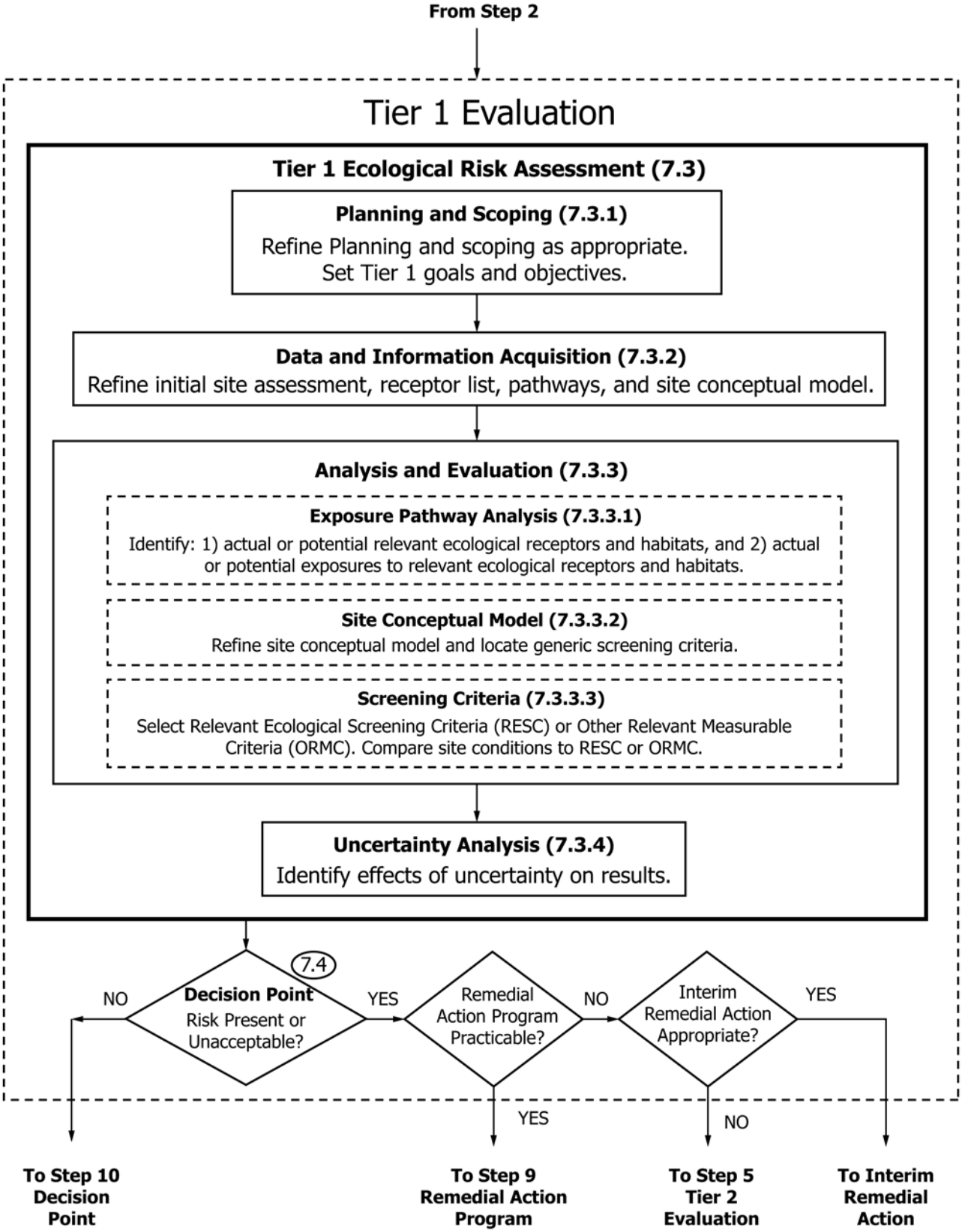

FIG. 2 Tier 1 Evaluation Flowchart

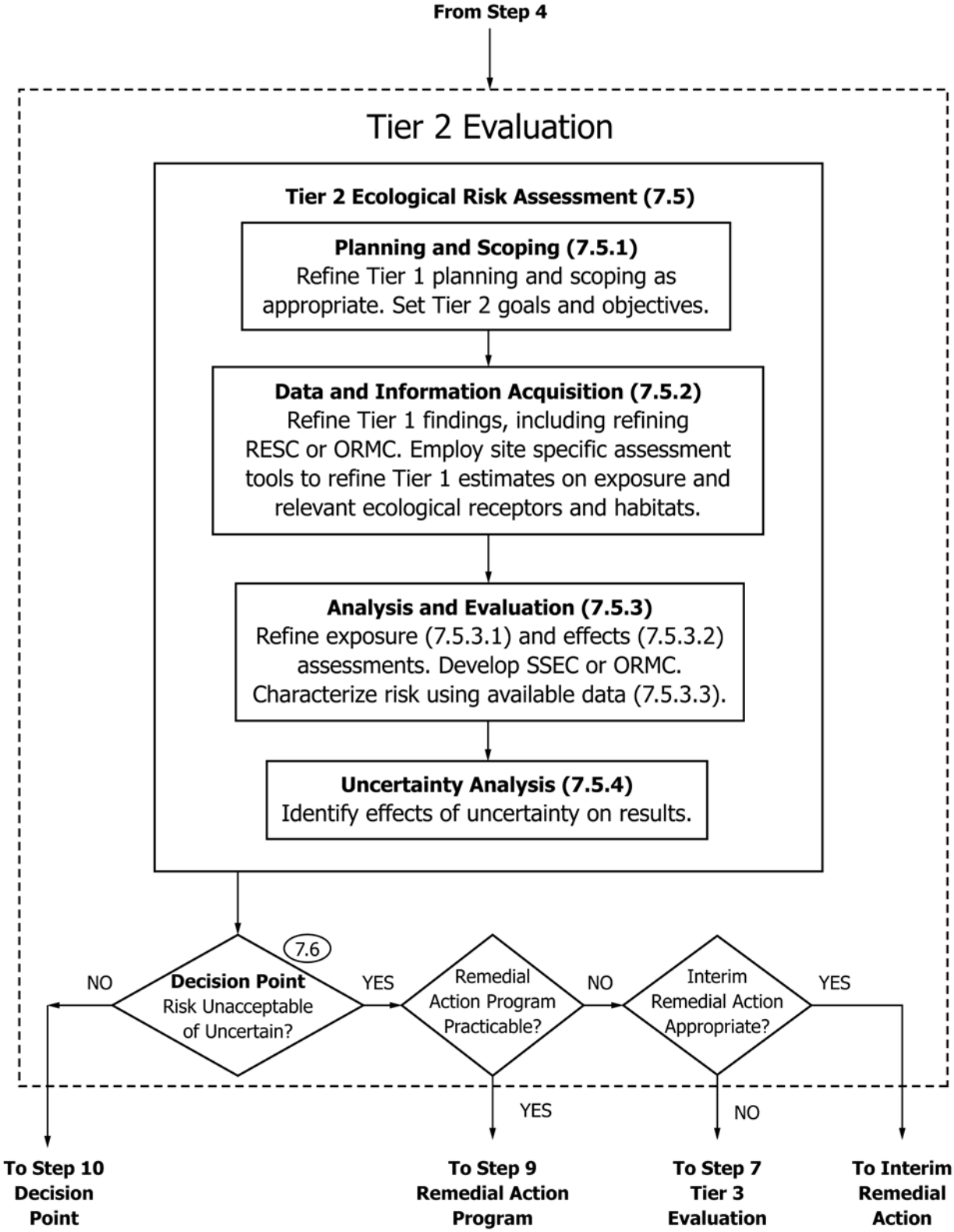

FIG. 3 Tier 2 Evaluation Flowchart

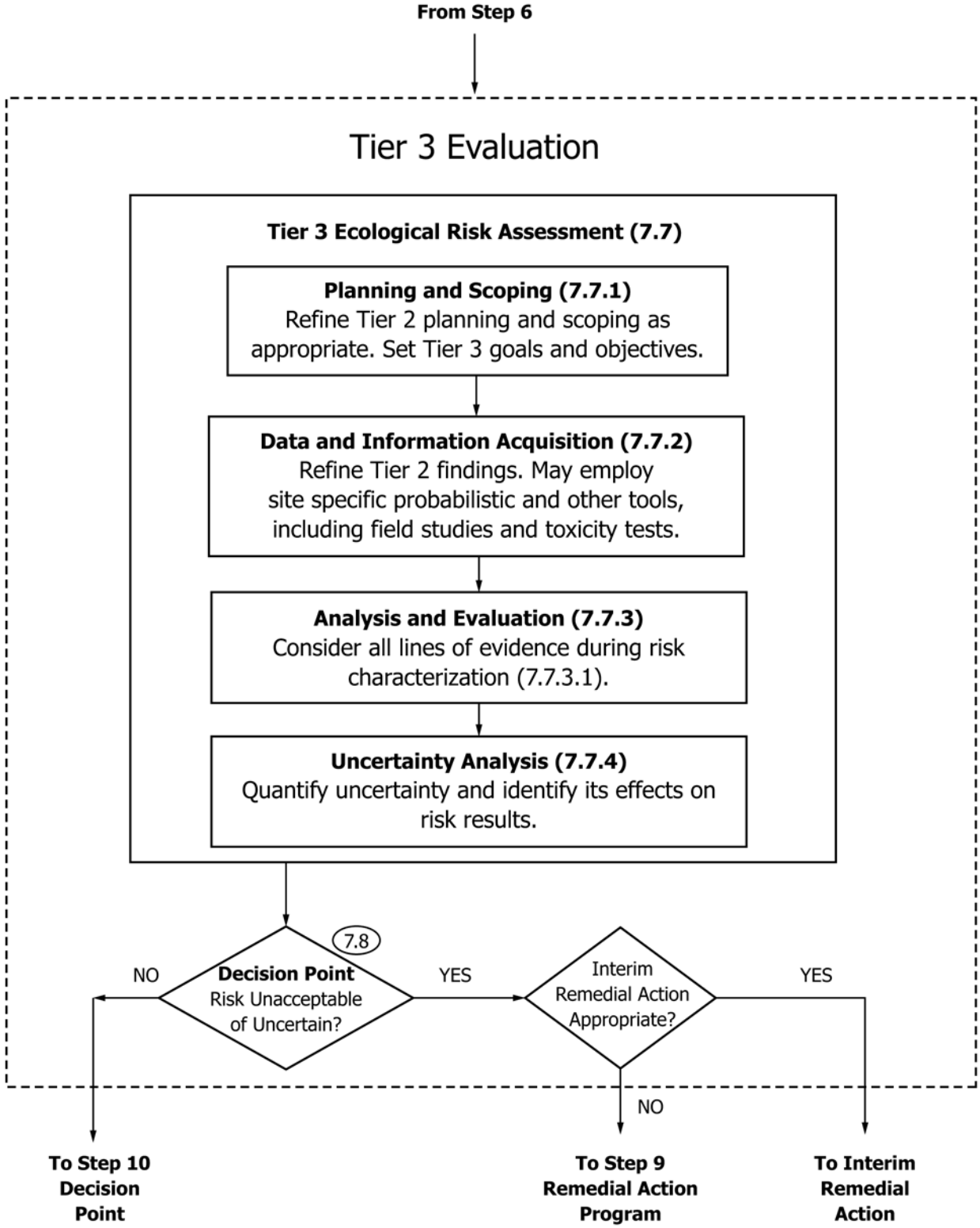

FIG. 4 Tier 3 Evaluation Flowchart

1. Scope

1.1 This is a guide to risk-based corrective action for the protection of ecological resources and supplements the RBCA process (Guide E2081). The primary objective of the Eco-RBCA process is to provide a flexible framework for a tiered approach to ERA and risk management decision making at chemical release sites. To this end, available guidance documents from various federal and state agencies were reviewed and their common attributes incorporated into this guide, where possible. The Eco-RBCA process complements existing technical and regulatory ecological risk guidance (see 4.2). In particular, it is intended to be compatible with the USEPA programmatic guidelines for ERA (**1**)[2], guidance for the Superfund program (**2**), and other USEPA (**3**) risk assessment and corrective-action programs. Eco-RBCA might also be used in conjunction with corrective action strategies that include human health issues (for example, Guide E2081).

1.2 Chemical release sites vary greatly in terms of complexity, physical and chemical characteristics, and the risk that they might pose to ecological resources. The Eco-RBCA process, as described in Guide E2081, recognizes this variability and incorporates a tiered approach that integrates site assessment, response actions, and remedial actions with ERA. The process begins with relatively simple analyses in Tier 1 and, if necessary, proceeds to more detailed evaluations in Tier 2 or Tier 3. The process of gathering and evaluating data is conducted in such a manner that only those data that are necessary for a given tier's decision making are collected at each tier. Hence, this can facilitate effective use of resources and reduce initial data requirements.

1.3 Eco-RBCA is intended to provide a framework for sites not covered under regulatory programs and for sites under regulatory programs that lack specific guidance. Eco-RBCA may also provide a useful framework to help merge several possible approaches into a single approach when multiple regulatory programs apply. The user should be aware of the federal, state, and local corrective action programs and policies that are applicable for the site and, regardless of the program, that agency approvals might be required to implement the process for completing ERAs.

1.4 Various TPDs will need to be made regarding the aspects of Eco-RBCA. These TPDs may cover both the philosophical and methodological aspects, from what values to protect to exactly how the Eco-RBCA process will be performed. TPDs may affect every stage of the process, from the initial site assessment to development and monitoring of the remedy. It is the responsibility of the user to identify the appropriate TPDs. Section 7, Appendix X2, and Guide E2081 provide more detail regarding TPDs in the Eco-RBCA process.

1.5 The general performance standard for this document requires that:

1.5.1 Applicable TPDs be identified, beginning at the initiation of the Eco-RBCA process, and as appropriate, at later stages;

1.5.2 Data used in the Eco-RBCA process be of sufficient quantity and quality to answer the questions and support the decisions made at the tier of investigation;

1.5.3 Site assessments be distinguished into tiers of appropriate levels of evaluation;

1.5.4 Actions taken should integrate the Eco-RBCA process for the protection of relevant ecological receptors and habitats and RBCA for the protection of human health (see Guide E2081), as appropriate;

1.5.5 Applicable federal, state, and local laws and regulations be followed; and

1.5.6 Potential adverse effects on relevant ecological receptors and habitats be considered when selecting remedial action alternatives. The remedial action alternatives should be consistent with the TPDs and the RBCA process (see Guide E2081).

1.6 Ecological resources are the focus of this guide; risks to human health are addressed for petroleum releases and chemical releases in other ASTM RBCA standards (Guides E1739 and E2081). There are many features common to all three of the RBCA guides. These three guides share the basic elements of RBCA: (*1*) site assessment; (*2*) tiered evaluations of exposure, effects, and risk; (*3*) risk-based decision making; and (*4*) response, remedial action, and monitoring. There are a number of distinctions between human health and ecological risk assessments. For example, while human health risk assessments focus on individuals, evaluations of ecological risk typically focus on populations, communities, or ecosystems. Exceptions are species or habitats designated for special protection (for example, endangered species). Biological data to support an ERA are more amenable to direct field observation than are human exposure and epidemiological data.

1.7 The Eco-RBCA process addresses current and potential future risks to relevant ecological receptors and habitats at chemical release sites. It is not intended to apply to current permitted releases and permit applications.

1.8 Eco-RBCA focuses on chemical stressors. However, the user may need to consider biological or physical stressors at the site or effects from chemical sources unrelated to the site.

1.9 The process described in this guide integrates the principles of current ERA practices with site assessment activities and remedial-action selection to ensure that the risk management decision protects ecological resources. Fig. 1 illustrates the following activities in Eco-RBCA and those described in Section 7 (7.1 – 7.10):

1.9.1 *Step 1*—Initial Site Assessment;

1.9.2 *Step 2*—Decision Point;

1.9.3 *Step 3*—Tier 1 Ecological Risk Assessment;

1.9.4 *Step 4*—Tier 1 Decision Point;

1.9.5 *Step 5*—Tier 2 Ecological Risk Assessment;

1.9.6 *Step 6*—Tier 2 Decision Point;

1.9.7 *Step 7*—Tier 3 Ecological Risk Assessment;

1.9.8 *Step 8*—Tier 3 Decision Point;

1.9.9 *Step 9*—Implementing the Remedial Action Program; and

1.9.10 *Step 10*—Monitoring Programs (7.10).

[2] The boldface numbers in parentheses refer to the list of references at the end of this standard.

1.9.11 The above steps can be applied in a flexible manner. It may not be necessary to conduct a full tier of evaluation if existing site information indicates that a subsequent tier is more applicable to address site-specific concerns. Where experience indicates that a more sophisticated assessment is warranted at a site, the user may elect to proceed conceptually through any earlier tiers to conduct a site-specific assessment typical of Tier 2 or Tier 3. Additionally, the decision points in Steps 4, 6, and 8 allow the user to exit the tiered evaluation process and select the appropriate remedial action once adequate information is available for decision making.

1.10 This guide is organized as follows:

1.10.1 Section 2 lists referenced ASTM documents;

1.10.2 Section 3 defines terminology used in this guide;

1.10.3 Section 4 describes the significance and use of this guide;

1.10.4 Section 5 describes the tiered approach to the Eco-RBCA process;

1.10.5 Sections 6 and 7 presents Eco-RBCA procedures in a step-by-step process; and

1.10.6 The reference section provides all documents cited in this guide.

1.11 This guide also includes the following appendices, which are provided as supplemental information and are not included as mandatory sections of this guide:

1.11.1 Appendix X1 presents information related to risk management issues;

1.11.2 Appendix X2 presents issues regarding TPDs;

1.11.3 Appendix X3 presents information on the activities occurring in each tier of the Eco-RBCA process;

1.11.4 Appendix X4 describes screening criteria and how they can be applied within the Eco-RBCA framework;

1.11.5 Appendix X5 presents the selection and use of relevant ecological screening benchmarks;

1.11.6 Appendix X6 includes two examples of the application of the Eco-RBCA framework; and

1.11.7 Appendix X7 presents information on uncertainty and its role in Eco-RBCA.

1.12 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E1739 Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites

E1848 Guide for Selecting and Using Ecological Endpoints for Contaminated Sites

E2081 Guide for Risk-Based Corrective Action

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

3. Terminology

3.1 *Definitions:*

3.1.1 The user should be familiar with the definitions presented here before reading the remainder of this guide, as many of the terms might have specific regulatory definitions within existing federal, regional, state, or local programs that vary from that used in this guide. The following terms are being defined to reflect their specific use in this guide. The user should not assume that these definitions replace existing regulatory definitions. Where the definition or use of a term in this guide differs from an existing regulatory definition or use, the user should address these differences before proceeding with the Eco-RBCA process. The definitions presented here are intended to be consistent with those provided in Guide E2081.

3.1.2 *acceptable ecological risk*—a condition under which the likelihood of adverse effects to relevant ecological receptors and habitats is within tolerable limits, as defined by TPDs.

3.1.3 *assessment endpoint*—the explicit expression of the environmental value that is to be protected, operationally defined by an ecological entity and its attributes (**1**). The term in this standard for ecological entity is relevant ecological receptors and habitats (see 3.1.26). Additional information regarding assessment endpoints can be found in Guide E1848.

3.1.4 *bioavailability*—the degree to which a material in environmental media can be assimilated by an organism (**2**).

3.1.5 *chemical release*—any spill or leak to, or detection of chemicals of concern in, environmental media other than permitted discharges.

3.1.6 *chemical of concern (COC)*—specific constituent and its breakdown products that are identified for evaluation in the risk assessment process. Identification can be based on a chemical's historical and current use at a site; detected concentration in environmental media; or mobility, toxicity, and persistence in the environment. Chemical(s) of concern may be identified at many points in the RBCA process. The term COC does not imply the degree of risk.

3.1.7 *corrective action*—the sequence of actions that may include site assessment and investigation, risk assessment, response actions, interim remedial action, remedial action, operation and maintenance of equipment, monitoring of progress, making no further action determinations, and termination of the remedial action.

3.1.8 *corrective-action goal*—a remedial action performance criterion that once achieved, is protective of relevant ecological receptors and habitats and requires no further action. Examples include chemical concentrations, environmental quality indices, or physical conditions based on Relevant Ecological Screening Criteria (RESC), Site Specific Ecological Criteria (SSEC), or Other Relevant Measurable Criteria (ORMC) (see 3.1.22, 3.1.27, and 3.1.37). A corrective action goal for a site can vary with each tier of evaluation, dependent on the level of uncertainty associated with each tier. Tier 1 evaluations with higher uncertainty may have more conservative corrective action goals than would subsequent tiers with lower uncertainty.

3.1.9 *data quality objectives (DQO)*—a qualitative or quantitative statement that clarifies study objectives, defines the

appropriate type of data, and specifies the tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data to support decisions. A formal DQO process is presented in USEPA (**3**).

3.1.10 *decision point*—an occasion during the Eco-RBCA process when assessment results are integrated with risk management goals and TPDs for the purpose of risk management decision making. At such points, the user must decide the appropriate course of action.

3.1.11 *ecological-risk assessment (ERA)*—a process for organizing and analyzing data, information, assumptions, and uncertainties to evaluate the likelihood that adverse ecological effects might occur or are occurring as a result of a stressor.

3.1.12 *exposure assessment*—the determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure between a source and a receptor.

3.1.13 *exposure pathway*—the course a chemical of concern takes from the source area(s) to a relevant ecological receptor and habitat. An exposure pathway describes a mechanism by which an individual or population is exposed to a chemical of concern originating from a site. Each exposure pathway includes a source or release from a source of a chemical of concern, a point of exposure, an exposure route, and a relevant ecological receptor and habitat. If the exposure point is not at the source, a transport or exposure medium, or either (for example, soil or water), is also included.

3.1.14 *exposure route*—the manner in which a chemical of concern comes in contact with a relevant ecological receptor and habitat (for example, ingestion or direct contact).

3.1.15 *exposure scenario*—the description of the circumstances, including site properties and chemical properties, or the potential circumstances under which a relevant ecological receptor or habitat could be in contact with chemical(s) of concern.

3.1.16 *facility*—the property where a chemical release has occurred. A facility might include multiple sources of chemical releases and therefore, multiple sites.

3.1.17 *hazard quotient*—the numerical ratio that relates receptor exposure to toxicity by comparing an exposure dose or a media concentration (numerator) to a comparable toxicological benchmark or comparable screening value (denominator).

3.1.18 *initial site assessment criteria*—tools used in Step 1 for determining when an ERA might be appropriate for a site or to identify risks that should be considered in the RBCA process. Such screening criteria are discussed in greater detail in Appendix X5.

3.1.19 *interim remedial action*—an intervening action taken to minimize exposure to relevant ecological receptors and habitats. Interim remedial actions are taken to reduce migration of a chemical of concern or to reduce the concentration of a chemical of concern at a source area or areas. Such actions are typically taken when site conditions are considered hazardous or when there is direct evidence of impact. An interim remedial action may or may not become the final remedial action, but may be undertaken for an intervening time until a final remedy is initiated.

3.1.20 *measure of effect*—a change in an attribute of an assessment endpoint or its surrogate in response to a stressor to which it is exposed (**1**). Measures of effect are also referred to as measurement endpoints.

3.1.21 *natural attenuation*—a reduction in risk due to change in chemical concentration, toxicity, bioavailability, or mobility as a result of naturally occurring physical, chemical, and biological processes (for example, diffusion, dispersion, adsorption, chemical degradation, and biodegradation).

3.1.22 *other relevant measurable criteria (ORMC)*— parameters used to define corrective action goals. The ORMC are concentration values, other numeric values, physical condition, or performance criteria other than RESC and SSEC. Examples of ORMC are regulatory standards, consensus criteria, and aesthetic criteria. Technical policy decisions regarding ORMC may exist, or may need to be made, to determine the appropriate values, conditions, or performance criteria that are used for the corrective action goals.

3.1.23 *potentially complete exposure pathway*— a situation with a reasonably likely chance of occurrence in which a relevant ecological receptor or habitat might become directly or indirectly exposed to the chemical(s) of concern.

3.1.24 *probabilistic analysis*—quantitative procedures used to evaluate the variability or uncertainty, or both, surrounding a distribution when the result depends on a number of factors, each of which has its own variability and uncertainty. Additional detail regarding probabilistic analyses is provided in Appendix X7.

3.1.25 *problem formulation*—the collection and analysis of information needed to determine the appropriate scope and focus of the investigation. Problem formulation is analogous to the planning and scoping phase of Eco-RBCA. The outcome of the problem formulation steps are the selection of the assessment endpoints (see 3.1.3) that will be evaluated in the risk characterization (see 3.1.32) and the identification of the specific measures that will best represent the assessment endpoints. Problem formulation as described in USEPA (**1**) includes characterization of fate and transport, identification of exposure pathways and receptors, potential toxicological effects, development of the conceptual model, identification of the assessment endpoints, and identification of measures of effect.

3.1.26 *relevant ecological receptors and habitats*— the ecological resources that are valued at the site. Identification of relevant ecological receptors and habitats is dependent upon site-specific factors and is a technical policy decision important to the planning and scoping phase of ecological evaluation. Examples may include species or communities afforded special protection by law or regulation; recreationally, commercially, or culturally important resources; regionally or nationally rare communities; communities with high aesthetic quality; and

habitats, species, or communities that are important in maintaining the integrity and biodiversity of the environment. This may be functionally equivalent to assessment end points (3.1.3).

3.1.27 *relevant ecological screening criteria (RESC)*—non–site-specific ecological measures or guidelines used during the Tier 1 evaluation that are applicable to relevant ecological receptors and habitats, exposure pathways, and site conditions. These might include chemical concentrations, biological measures or other relevant generic criteria consistent with the purpose of the assessment, the problem(s) defined at the site, and TPDs (see Appendix X2 and Appendix X4).

3.1.28 *remedial action*—an action taken to minimize or eliminate current or potential future exposure to relevant ecological receptors and habitats. Such activities are conducted to reduce concentrations of chemicals of concern or eliminate pathways of exposures to meet corrective action goals.

3.1.29 *response action*—an immediate course of action taken in Step 2 (before an interim remedial action) to mitigate an imminent or known threat to relevant ecological receptors and habitats. Response actions taken may not differ from interim remedial actions or remedial actions taken later in the RBCA process; the key difference between actions is timing and urgency. Response actions may include abatement or containment measures.

3.1.30 *response action evaluation*—a qualitative site analysis in Step 2 based on known or readily available information to identify the need for and urgency of response actions and the need for further information gathering. The evaluation is also used to identify appropriate early risk reduction steps.

3.1.31 *risk*—the likelihood of, potential for, or probability of an adverse effect. Risk might be expressed qualitatively or quantitatively.

3.1.32 *risk characterization*—the integration of the results of the exposure and ecological effects analysis to evaluate the likelihood of adverse ecological effects associated with exposure to the stressor.

3.1.33 *site*—the area defined by the likely physical distribution of a chemical release. A site could be an entire property or facility, a defined area or portion of a facility or property, or multiple facilities or properties. One facility might contain multiple sites. Multiple sites at one facility might be addressed individually or as a group.

3.1.34 *site assessment*—a characterization of a site through an evaluation of its physical and environmental context (for example, subsurface geology, soil properties and structures, hydrology, and surface characteristics) to determine if a release has occurred. The characterization may identify the concentration and distribution of chemical(s) of concern. Information collected during the site assessment may include data on soil, ground water and surface water quality, land and resource use, and potential receptors. This information is used to develop a site conceptual model and support risk-based decision making.

3.1.35 *site conceptual model (also known as conceptual site model)*—a written description or visual representation, or both, of predicted relationships between relevant ecological receptors and habitats and the COCs to which they may be exposed. Site conceptual models describe predicted relationships among sources of released chemicals, exposure pathways, and relevant ecological receptors and habitats, along with the rationale for their selection. The site conceptual model illustrates these relationships.

3.1.36 *site-specific*—activities, information, and data unique to a particular site.

3.1.37 *site-specific ecological criteria (SSEC)*— risk-based measures or guidelines appropriate for evaluating relevant ecological receptors and habitats identified for a particular site under the Tier 2 or Tier 3 evaluations. These qualitative or quantitative criteria might include chemical concentrations, biological measures, or RESC that can be applied on a site-specific basis consistent with the TPDs (see Appendix X2). SSEC might be revised as data are obtained that better describe the conditions and the relevant ecological receptors and habitats.

3.1.38 *stakeholders*—individuals, organizations, or other entities that affect or are affected by the site conditions or the corrective action, or both. Stakeholders might include, but are not limited to, owners, buyers, developers, lenders, insurers, government agencies, and community groups or members. The number and composition of stakeholders may change throughout the Eco-RBCA process.

3.1.39 *technical policy decision (TPD)*—a consideration that helps form the basis for implementing the Eco-RBCA process for a given site. TPDs are developed for a variety of technical aspects, including context setting in the initial site assessment, analytical approaches, data needs and quality, and action triggers. Paragraphs 6.5 and 7.1.1.1 contain information on TPDs, and Appendix X2 provides supplemental information on TPDs.

3.1.40 *Tier 1 evaluation*—a screening level assessment of ecological risk that uses existing information, generic information, and ecologically protective (that is, conservative) assumptions to ensure that risks are not underestimated. Tier 1 may be comprised of a qualitative ecological screening evaluation for complete and partially complete exposure pathways for relevant ecological receptors and habitats, or relatively simple comparisons of site conditions to RESC, or both. The tier concludes with a risk management decision.

3.1.41 *Tier 2 evaluation*—an assessment of ecological risk that builds on the Tier 1 evaluation by using more site-specific data and assumptions. Tier 2 involves gathering additional information to develop and refine assessment endpoints and measures of effect and compares this additional information to SSEC. The additional information should focus on providing more site-specific information on receptors and their habitats, exposure pathways, and exposure concentrations or doses. The tier concludes with a risk management decision.

3.1.42 *Tier 3 evaluation*—a detailed and quantitative assessment of ecological risk that relies on more site-specific information and sophisticated tools than those used at Tiers 1 and 2. Tier 3 may involve the use of multiple lines of evidence; predictive models; or probabilistic approaches for evaluating

exposure, effects and risk or a combination of these. The tier concludes with a risk management decision

3.1.43 *unacceptable ecological risk*—a condition under which the likelihood of adverse effects to relevant ecological receptors and habitats is not within tolerable limits as defined by TPDs.

3.1.44 *uncertainty*—the lack of knowledge regarding site conditions, the nature of exposure, and effects on relevant ecological receptors and habitats. This lack of knowledge is recognized at each tier of evaluation through an uncertainty analysis.

3.1.45 *user*—an individual or group employing the Eco-RBCA process. Users may include owners, operators, regulators, UST fund managers, government case managers, attorneys, consultants, legislators, and other stakeholders.

3.2 *There are three definitions specific to ASTM that are included here for clarity:*

3.2.1 *standard*—as used in ASTM, a document that has been developed and established within the consensus principles of the Society and that meets the approval requirements of ASTM procedures and regulations.

3.2.2 *guide*—a series of options or instructions that do not recommend a specific course of action.

3.2.3 *practice*—a definitive procedure for performing one or more specific operations or functions that does not produce a test result.

4. Significance and Use

4.1 The Eco-RBCA process presented in this guide is a streamlined decision-making process for implementing corrective action protective of ecological resources at chemical release sites in a consistent manner. Eco-RBCA provides a framework for sites not covered under regulatory programs, for sites under regulatory programs that lack guidance, or for sites under programs with guidance that lack detail. Eco-RBCA may also provide a useful framework to help merge an approach when multiple regulatory programs apply.

4.2 Ecological risk assessment is a science-based process that can be used to provide insight for risk management decision-making. Numerous federal and state programs have guidance for conducting ERA. Available regulatory approaches to ERA were reviewed in preparation for the development of this Eco-RBCA guide. Eco-RBCA was designed to be adaptable to the use of a variety of methods for considering risks to relevant ecological receptors and habitats. Some attributes of the standard are:

4.2.1 Use of a tiered approach, including process flow charts to identify critical steps and facilitate the development of an overview of the entire process;

4.2.2 Identification, development, and use of TPDs from Step 1 and throughout the entire Eco-RBCA process;

4.2.3 Indications of the value and timing of stakeholder involvement, recognizing that some regulations require coordination with federal, state, tribal, and natural-resource trustees, and other stakeholders;

4.2.4 Identification of situations under which an ERA may or may not be necessary; and

4.2.5 Identification of decision points where ERA results are used for risk management decision making.

4.3 Activities described in this guide should involve persons with the appropriate skills and expertise. The user may rely on individuals expert in remediation science and technology, ecology/biology, ecotoxicology, ERA practices, and site characterization techniques.

4.4 This guide and supporting appendices provide examples and technical support for the proper application of the Eco-RBCA process. The user should avoid inappropriate actions or use of Eco-RBCA such as:

4.4.1 Prescribing Tier 1 RESC as presumptive remediation cleanup goals rather than as screening criteria or, when appropriate, as site-specific remediation cleanup goals;

4.4.2 Limiting the use of the Eco-RBCA process to Tier 1 evaluation only and not continuing with Tier 2 or Tier 3 evaluations for sites where further tiered evaluation is appropriate;

4.4.3 Placing arbitrary time constraints on the corrective action process that do not reflect the actual urgency and risk posed by the site;

4.4.4 Using Eco-RBCA only at sites where active remedial action is not technically feasible;

4.4.5 Initiating remedial action(s) before determining applicable corrective action goals;

4.4.6 Limiting options to a single class of remedial action for all sites;

4.4.7 Using unjustified or inappropriate exposure factors;

4.4.8 Using unjustified or inappropriate toxicity parameters;

4.4.9 Using modeling that is not supported by the available data or knowledge of site conditions;

4.4.10 Using measurement or assessment endpoints that are ambiguous or insufficiently defined;

4.4.11 Drawing conclusions that are not supported by available data;

4.4.12 Failing to monitor the effectiveness of engineering or institutional controls;

4.4.13 Using an interim remedial action not to reduce risk but solely to delay the Eco-RBCA process;

4.4.14 Failing to consider the long-term effectiveness, reliability, and risks to relevant ecological receptors and habitats of potential remedial action options; or,

4.4.15 Continuing monitoring or remedial action at sites that have achieved remedial action goals (unless monitoring is specifically required for an engineering or institutional control or other regulatory requirements).

5. A Tiered Approach to Eco-RBCA

5.1 Eco-RBCA is a process that integrates site assessment, ERA, remedial action, and risk management such that corrective-action decisions protective of relevant ecological receptors and habitats can be made in a consistent manner. At the initiation of the Eco-RBCA process, the user should identify the stakeholders and TPDs appropriate for the site. Supplemental information on TPDs is provided in Appendix X2.

5.2 Eco-RBCA is a process for evaluating ecological risk and decision making. To facilitate the implementation of Eco-RBCA, the framework is organized into ten steps and three risk assessment tiers (Fig. 1 and Appendix X3). Although organized into steps and tiers, the user should recognize that Eco-RBCA does not have to be implemented in a linear manner. Instead, the objective should be to conduct the evaluation in the manner that most appropriately meets the needs and goals of the assessment.

5.3 Eco-RBCA can be used in a flexible manner. As the user proceeds to higher tiers, the understanding gained about the site is used to tailor the degree of investigation needed. In some cases, completion of a detailed evaluation in a given tier may be unnecessary. For example, the user may determine that conducting a detailed Tier 1 evaluation is unnecessary because of the wealth of historical data available at a site. Starting the evaluation at Tier 2 in this case would be a more efficient means of achieving corrective action goals.

5.4 Throughout the Eco-RBCA process, appropriate DQOs (see 3.1.9) should be determined for the initial site assessment and all subsequent tiers of evaluation. These objectives integrate site-specific data needs for each task and applicable regulatory requirements. To meet these objectives, the user might generate site-specific data for key physical characteristics or make reasonable estimates from readily available site data. Sufficient quantity and quality of data should be collected to meet the DQOs for each tier of the Eco-RBCA process conducted. The user is referred to USEPA (**3**) for a more detailed discussion of DQOs. Data quality objectives are TPDs.

5.5 The results of all of the completed tiers of analyses may be compiled into one Eco-RBCA report at the end of the evaluation. Reporting requirements and approvals could be determined based on federal, state, and local programs if they apply to the site. Otherwise, guidance on reporting is provided in 7.11 and in Guide E2081.

6. Eco-RBCA Process Overview

Eco-RBCA is a process that provides a framework for evaluating the potential for adverse effects to ecological resources at sites where a chemical release has occurred; this evaluation is then linked to the RBCA process (Guide E2081) to implement appropriate corrective action. The multistep process (Fig. 1 and Appendix X3) begins by using available site information to support the initial site assessment. If at any point in the evaluation the site information suggests potential unacceptable risk to relevant ecological receptors and habitats, Eco-RBCA guides the user to acquire and evaluate additional data, and make appropriate decisions such as the collection of appropriate data and refine goals, objectives, receptors, exposure pathways, and site conceptual model. As the Eco-RBCA process proceeds, data and conclusions reached at each step help focus subsequent steps into a more detailed evaluation. Within the Eco-RBCA process, there are discrete steps when decisions for potential unacceptable ecological risks and appropriate risk management actions are made. For each assessment step, the user collects only the information and data required to support a risk-based decision, resulting in decisions for appropriate risk management decisions to be reached as early as possible in the process without unnecessary data collection and evaluation. This results in both an efficient, cost-effective decision-making process and timely corrective action responses. In addition, chemicals of concern and sites that pose an acceptable risk to relevant ecological receptors and habitats can be screened out of the process as early as practicable, thereby minimizing unnecessary and potentially costly investigation. When Eco-RBCA indicates that corrective action is warranted, the decision-making process should be integrated with human health risk-based corrective action decisions (Guide E2081 [RBCA]) to ensure that efficient and effective actions protective of both human health and the environment are implemented.

6.1 *Eco-RBCA Ten-Step Process*—The ten-step Eco-RBCA process is organized into four discrete levels of investigation, evaluation, and decision making (see Fig. 1). Eco-RBCA is conducted in an iterative, step-wise manner. Based on the results obtained at any step of the evaluation, the user may decide to advance or to return to an earlier step. It is important to note that the tiered evaluation proceeds sequentially through the steps of the Eco-RBCA process, though not all tiers of evaluation may require formalized documentation until the completion of the site evaluation. This approach permits the user to use professional judgment and an experience base for effective management of resources. The process begins with the initial site assessment (Step 1) where, based on existing site data and other readily available information, a preliminary site conceptual model is developed. Based on an evaluation of this information, it is decided whether there is the potential for unacceptable risk to relevant ecological receptors and habitats (Step 2). If it is concluded that there is a potential unacceptable ecological risk, then a response action (Step 2) or further tiered evaluation is initiated (Step 3). Eco-RBCA is organized into three tiers within this guide, with each tier varying in detail, effort, and resources. The Tier 1 Eco-RBCA (Steps 3 and 4) is a screening-level evaluation that uses limited site-specific data and conservative screening criteria to determine: (*1*) whether potential ecological risks are acceptable, (*2*) if a remedial action is warranted, or (*3*) if a more detailed evaluation is appropriate. In the latter case, a Tier 2 evaluation is conducted that expands the use of site-specific data for exposure and effects assessment. Ultimately, the assessment process may lead to a Tier 3 evaluation, which is a detailed, site-specific evaluation involving quantitative approaches to assess site-specific ecological risk. The ten steps of the Eco-RBCA process are described below. Supplementary technical information that supports this discussion is provided in the appendices of this guide.

6.2 *Eco-RBCA Process Elements*—Several process elements are common to all tiers of the Eco-RBCA process. At each tier, the results from previous tiers are considered so that the Eco-RBCA process can be focused on only potentially unacceptable risks. These elements include:

6.2.1 Planning and scoping; conceptually analagous to the ERA problem formulation (see 3.1.25 and (**1**));

6.2.2 Data and information acquisition;

6.2.3 Analysis and evaluation;

6.2.4 Decision-making; and

6.2.5 Remedial action (as appropriate).

6.3 *Eco-RBCA Flexibility*—The Eco-RBCA process provides a framework that supports a consistent approach for making defensible risk-based decisions. This framework permits flexibility in how details of the ecological evaluation are conducted to be tailored by the user to the site conditions and requirements, and to be modified as additional data become available. Based on site-specific factors and requirements, the specific approaches and components for each Eco-RBCA element are expected to change or evolve as the process progresses from tier to tier. Flexibility in the evaluation of information is necessary due to the wide variety of methods and approaches that may be used to evaluate ecological risk. The specific elements and details of the ecological evaluation should be focused and provide the quality and quantity of data required to support the risk-based decisions at each tier.

6.4 *Timing and Urgency of Response Actions*—Data collected during the Eco-RBCA process can be used to identify sites where a timely remedial response can mitigate significant ecological risks. For example, a response action can be implemented early in the Eco-RBCA process (Step 2) to mitigate a known threat to relevant ecological receptors and habitats. In later steps, it could be decided to implement an interim remedial action prior to completing the ecological risk assessment, or to implement a comprehensive remedial action to addresses all potential ecological risks.

6.5 *Technical Policy Decisions*—Technical policy decisions (TPDs) are critical components of Eco-RBCA that should be identified in the initial site assessment and then reexamined at all planning and scoping phases of the Eco-RBCA process. The three general categories of TPDs are (*1*) those that are identified as existing prior to the Eco-RBCA assessment and will not change (that is, prescribed and without flexibility such as regulations or policy), (*2*) those that are identified as existing prior to the Eco-RBCA assessment but may change or be modified based on site-specific information (for example, sampling protocols, selection of models or other tools, or corrective action goals), and (*3*) those that are developed specifically for the Eco-RBCA assessment (for example, development of a site-specific model). The user identifies applicable TPDs at the outset of the Eco-RBCA process in concert with appropriate stakeholder input. Each time the Eco-RBCA evaluation proceeds through an iteration or progresses to a new tier, the TPDs should be reviewed and revised as appropriate to reflect any change in stakeholders and their involvement. TPDs and the basis for their selection and revision should be documented in the Eco-RBCA report (see 7.11). Appendix X1 and Appendix X2 provide supplemental information that may be useful for identifying TPDs and appropriate stakeholders.

6.6 *Development of Corrective Action Goals*—At each tier of Eco-RBCA, the user identifies the applicable corrective action goals. Corrective action goals are considered TPDs in the RBCA process. Corrective action goals (see 3.1.8) are performance criteria that, once achieved, protect relevant ecological receptors and habitats and ultimately lead to no further risk management action. The corrective action goals should be identified during the planning stages of the assessment, and can be based upon chemical concentrations or exposure levels protective of relevant ecological receptors and habitats. Additionally, the corrective action goals for Eco-RBCA should be integrated into the RBCA decision-making process (Guide E2081) to ensure protection of both human health and the environment.

6.7 *Data and Information Acquisition*—The data and information collected for each site should be sufficient to support technically defensible risk-based decisions. Data and information should support, but are not limited to supporting, decisions about (*1*) causality between levels of contamination and potential effects, (*2*) whether the observed or potential adverse effects on the relevant ecological receptors and habitats are unacceptable, and (*3*) the appropriateness of risk management alternatives given regulatory, political, or other considerations. Appendix X1 provides supplemental information that may be useful for judging data and information needs and for determining whether unacceptable ecological risk exists.

6.8 *Integration with Human Health RBCA*—It is possible that corrective actions taken to mitigate potential ecological risks could have adverse impacts to human health or may not be consistent with corrective actions selected to protect human health. Therefore, to ensure protection of both human health and the environment, Eco-RBCA decisions concerning corrective actions for risk to ecological receptors and habitats should be integrated with corrective action decisions for human receptors as outlined in RBCA (Guide E2081). The integration of Eco-RBCA and human health RBCA decisions should be done during the remedial action evaluations that accompany the decision points (Steps 2, 4, 6, and 8). Decisions as to how to appropriately balance the protection of human health with the protection of relevant ecological receptors and habitats are TPDs.

7. Eco-RBCA Procedures

7.1 *Step 1. Initial Site Assessment*—Eco-RBCA begins with the initial site assessment (Step 1) and a risk management decision as to the appropriate action (Step 2). The initial site assessment includes planning and scoping (conceptually analogous to the ERA problem formulation (see 3.1.25 and **(1)**), data and information acquisition, and analysis and evaluation. The specific activities completed under Step 1 will depend on site conditions, the TPDs, and the data necessary to support the decision (Step 2) as to whether the site conditions warrant additional ecological evaluation or a response action (see 7.2.1).

7.1.1 *Planning and Scoping*—Planning and scoping are used at the beginning tier to focus the Eco-RBCA activities through definition of the assessment goals and objectives, definition of the corrective action goals, the identification of the applicable TPDs and other decision criteria, and the development of a site conceptual model. During planning and scoping, appropriate stakeholders should be identified and their involvement in the process defined. Planning and scoping activities should include development of a preliminary site conceptual model, identification of applicable TPDs and screening criteria, identification of relevant ecological receptors and habitats, and identification of applicable regulatory

frameworks. Information appropriate for an initial site assessment could include historical site information and data, site visit field observations, and limited sample results used for characterizing the site or to fill other data gaps. The data and information compiled during the initial site assessment should be sufficient to identify site-related chemicals of concern, and potentially affected environmental media, relevant ecological receptors and habitats potentially exposed to the chemicals of concern, potentially completed exposure pathways, and to understand the potential fate and transport of site chemicals of concern. If sufficient data are not available to complete the initial site assessment, a work plan should be developed to guide the acquisition of the necessary data to complete the initial site assessment, or Tier 1 made the next step. As part of planning and scoping in the initial site assessment, TPDs should be identified (see 7.1.1.1) and a preliminary site conceptual model developed (see 7.1.1.2).

7.1.1.1 *Identification of Technical Policy Decisions (TPDs)*—During planning and scoping, applicable TPDs should be identified and, as appropriate, agreed upon by stakeholders. The identified TPDs should be consistent with the appropriate regulatory framework and should include criteria for exiting the Eco-RBCA process (see Appendix X4). TPDs may include statutory or regulatory requirements (see Appendix X2) or other factors that can substantially influence the outcome of the ecological evaluation and the risk-based decisions resulting from this evaluation. Some regulatory agencies have identified TPDs to assist in the definition of incomplete and potentially complete exposure pathways as well as the criteria used to either exclude sites or conditions from further evaluation or require the same (for example, threshold quantities and quantity of a chemical release). More information on the selection of TPDs can be found in Appendix X2.

7.1.1.2 *Site Conceptual Model*—A preliminary site conceptual model is developed during the initial site assessment to facilitate overall understanding of the site and to assist in the decision-making process. The site conceptual model can serve as a valuable tool to communicate the understanding of the site to stakeholders. The site conceptual model describes the hypotheses that form the basis of the Eco-RBCA evaluation by relating the potential chemicals of concern, fate and transport mechanisms, potential exposure pathways, and relevant ecological receptor and habitats. For example, to identify relevant ecological receptors and habitats, the user may consider current and reasonably anticipated future use of the site and surrounding land. Ecological resources unlikely to exist at the site because of habitat requirements that are inconsistent with the current or future land use should not be identified as "relevant ecological receptors and habitats." An exposure pathway analysis conducted during analysis and evaluation (see 7.1.3) will be conducted to evaluate potentially complete and incomplete exposure pathways. Complete and incomplete exposure pathways are identified for the relevant ecological receptors and habitats based on an understanding of the natural resources and site data and information about fate and transport of the chemicals of concern. Since limited site data are typically available for the initial site assessment, the site conceptual model is considered preliminary and should be iteratively revised and updated as additional site information is obtained.

7.1.2 *Data and Information Acquisition*—During planning and scoping, the data and information needs for the initial site assessment should be defined according to the goals and objectives for the site. Existing data and information for the site are to be identified and compiled for evaluation. Data and information acquisition is required if the data are insufficient to develop a preliminary site conceptual model, or insufficient to support a decision (Step 2) about whether site conditions warrant additional evaluation or a response action (see 7.2.1). Additional data and information should be acquired in accordance with a work plan. Information that could support the initial site assessment risk management decision include:

7.1.2.1 Applicable TPDs and regulatory requirements;

7.1.2.2 Information on site conditions such as chemical(s) of concern, source area(s), potentially affected environmental media, chemicals-of-concern fate and transport mechanisms, and relevant ecological receptors and habitats. Such information may be acquired from existing reports and prior site assessments, site visits, records of historical site activities, or chemical releases or spills; and

7.1.2.3 Current and reasonably anticipated future use of the site and surrounding land.

7.1.3 *Analysis and Evaluation*—The site data should be analyzed to evaluate the potential for adverse effects to ecological receptors. The evaluation should include a preliminary site conceptual model developed during planning and scoping, a preliminary exposure pathway analysis, and a comparison of the site data to the TPD screening criteria (Appendix X4) identified during planning and scoping. The preliminary site conceptual model developed during planning and scoping should be revised and updated using any additional data collected, or when new information becomes available. Based upon the revised preliminary site conceptual model, a preliminary exposure pathway analysis should be conducted to identify potentially completed exposure pathways to relevant ecological receptors and habitats. For potentially completed exposure pathways, the site data should be compared to the TPD screening criteria. Since these criteria are typically generic (that is, not site specific) and applicable to a broad range of sites or conditions, they are likely to be conservative and overly protective to ensure that risks are not overlooked. Evaluation of information on the exposure pathway analysis, comparison to TPD screening criteria, and other considerations form the basis for the risk management decisions (Step 2).

7.2 *Step 2. Decision Point*—Based on the results of the initial site assessment, a decision should be made as to whether or not the site conditions warrant further tiered evaluation. Advancing to the next tier of evaluation is predicated on having potentially complete exposure pathways for relevant ecological receptors and habitats and concentrations of chemicals of concern at exposure point concentrations exceeding TPD screening criteria. One of three decisions is possible based on the initial site assessment: (*1*) an immediate ecological impact exists that warrants an immediate, interim response action (continue with Step 2); (*2*) additional ecological evaluation is

required (continue to Step 3); or (*3*) ecological conditions are acceptable (continue to Step 10).

7.2.1 *Response Action*—The data evaluated during the initial site assessment may support a conclusion that unacceptable ecological conditions exist and a response action(s) is appropriate to mitigate the ongoing threat. For an initial site assessment, the urgency of any response action should be based on easily observed and readily quantifiable site conditions. Response actions should be conducted according to appropriate regulatory requirements (for example, National Oil and Hazardous Substances Pollution Contingency Plan–40 CFR 300), legal requirements, and best management practices). In addition, the response action should be coordinated with decisions based on the RBCA assessment for protection of human health (see 6.8). The response action may not differ from interim remedial action or remedial action that may be evaluated later in the Eco-RBCA process (in Steps 4, 6, or 8). The timing and urgency for corrective action are the key differences between a response action and a remedial action. Depending on site conditions and the scope of the response action, the response action may or may not eliminate the need for additional ecological investigation. As a result, the effectiveness of the response action in mitigating impact needs to be evaluated by repeating the initial site assessment (Steps 1 and 2) to determine if ecological conditions are unacceptable and further ecological evaluation is needed.

7.2.2 *Further Ecological Evaluation*—Based on the results of the initial site assessment, the user may determine that additional ecological risk evaluation is required (Step 2). If the Step 2 decision is that site conditions warrant further ecological evaluation and no response action is implemented, the Eco-RBCA process continues to a Tier 1 evaluation (Step 3). If a response action is implemented (see 7.2.1), the need for additional ecological evaluation is reassessed by repeating the initial site assessment (Steps 1 and 2) after the response action is completed to determine the effectiveness of the response action.

7.2.3 *Acceptable Risk Determination*—Based on the results of the initial site assessment, the data and evaluation may support the decision that the potential risk to relevant ecological receptors and habitats does not exist, or exists at a level below the screening criteria established by the TPDs. Consequently, further ecological evaluation or remedial action would not be necessary. If the results of the initial site assessment can be used to conclude that no potentially complete exposure pathways exist or that site conditions do not require further ecological evaluation based on regulatory or screening criteria, or based upon agreed TPDs, Eco-RBCA progresses to Step 10 (see 7.10) to decide if site monitoring, other corrective action, or no further action is appropriate.

7.3 *Step 3. Tier 1 Ecological Risk Assessment*—The Tier 1 ERA (Fig. 2) consists of two steps: a screening level ecological risk assessment (Step 3) and the risk management decision for appropriate action (Step 4). The Tier 1 evaluation may include definition of goals and objectives, refinement of the site conceptual model, revision of the exposure pathway analysis, selection or development of relevant ecological screening criteria (RESC), and review and revision of the TPDs. The Tier 1 assessment should use the data and information collected for the initial site assessment, additional screening criteria and site-specific data regarding the specific chemicals of concern, and potential relevant ecological receptors and habitats. As a screening level evaluation, the level of complexity is relatively low, and the degrees of uncertainty and conservatism are high. In Tier 1, as elsewhere in the Eco-RBCA process, the data and results should be sufficient to allow decision-makers to make appropriate risk management decisions. If these data are not available in the Tier 1 evaluation, additional tiered evaluation may be required.

7.3.1 *Tier 1 Planning and Scoping*—Tier 1 planning and scoping (conceptually analogous to the ERA problem formulation (see 3.1.25 and (**1**)) should include definition of the assessment goals and objectives, review and revision of the corrective action goals, selection of screening criteria, restatement or refinement of the TPDs, and identification of data needs and gaps to complete the Tier 1 assessment. To facilitate the Tier 1 planning process and to provide support for later steps in the Eco-RBCA process, communication with appropriate stakeholders should be considered during Tier 1 planning and scoping. This communication provides the basis for integrating the risk management objectives and stakeholder involvement into the Eco-RBCA process.

7.3.2 *Tier 1 Data and Information Acquisition*—Data from the initial site assessment (Steps 1 and 2) may be of sufficient quantity and quality for the Tier 1 screening level evaluation; therefore, limited additional data acquisition may be necessary for Tier 1. Further review of the existing data and additional site visits may be sufficient to complete the data requirement for the Tier 1 ERA. However, during Tier 1, data gaps may be identified that require additional data to be collected for completion of the Tier 1 ERA. Work plans should be developed, as appropriate, for any data collection activities to ensure that the data are collected in a manner consistent with the TPDs that have been decided upon (for example, data quality objectives).

7.3.2.1 *Screening Criteria*—During Tier 1, relevant ecological screening criteria (RESC) or other relevant measurable criteria (ORMC) pertinent to the site are obtained from published sources (see Appendix X5 for more detailed information). If published RESC or ORMC are not available, then the user has the option to develop RESC and ORMC. Identification and development of RESC and ORMC are TPDs, and may involve communication with regulatory agencies. Tier 1 screening criteria are conservative and biased to overprotectiveness due to the level of uncertainty typically associated with using limited site-specific information. The absence of significant ecological risk can be reasonably assumed if the RESC and ORMC are not exceeded, due to their conservative nature. When these criteria are exceeded, it indicates only that there is the possibility that a potential risk exists and that further evaluation or risk management is appropriate. The user should understand use limitations of screening criteria. For example, Tier 1 RESC and ORMC may not be practicable or appropriate as default cleanup goals. Appendix X5 presents additional information regarding the development and use of RESC and ORMC.

(1) For a Tier 1 evaluation, the selected RESC or ORMC will typically be conservative and will not account for site-specific conditions. In some cases, readily available site-specific information, such as pH, total organic carbon content in soil or sediment, or regional factors may be applied to tailor screening criteria to a specific site. Similarly, screening criteria for upper trophic level receptors may be used, along with simple dose calculations to address risks to upper trophic level receptors.

(2) Other relevant measurable criteria (ORMC) may be identified during the screening criteria selection. These ORMC may include concentrations and other numeric values, physical conditions, or performance criteria (see 3.1.22 and Appendix X1). The screening of site conditions with ORMC should be consistent with the nature of the criteria and should reflect the uncertainties associated with a Tier 1 ecological evaluation.

(3) Chemicals that bioaccumulate may require separate consideration because many published screening criteria do not consider bioaccumulation. Bioaccumulative compounds should be identified and defined per TPDs. If screening criteria have not considered bioaccumulation, then bioaccumulative compounds may need to be considered in a subsequent tier of evaluation.

7.3.3 *Tier 1 Analysis and Evaluation*—The Tier 1 analysis and evaluation should consist of a refined site conceptual model, an exposure pathway analysis, a comparison of data to screening criteria, and an uncertainty analysis. The site conceptual model and exposure pathway analysis developed in Step 1 are revised based on the understanding gained from the initial site assessment conducted in Step 1 and the acquisition of additional data and information (Step 3). Based on the revised site conceptual model and exposure pathways analysis, data are compared to screening criteria to assess the potential for unacceptable ecological risk. As an example, the hazard quotient approach **(1)** has been used to assess the potential for unacceptable ecological risk in this manner.

7.3.3.1 *Refining the Exposure Pathway Analysis*—As part of the Tier 1 ERA, the exposure pathway analysis is refined to further evaluate the complete and potentially complete exposure pathways identified in the site conceptual model. This refinement focuses the analysis on chemicals and environmental media to which relevant ecological receptors and habitats may be exposed. The exposure pathway analysis may include identification of the following:

(*1*) Chemical(s) of concern;

(*2*) Sources of the chemical(s) of concern and source area(s);

(*3*) Relevant ecological receptors and habitats that could be exposed to the chemical(s) of concern;

(*4*) Potentially significant transport and exposure pathways for relevant ecological receptors and habitats (for example, soil runoff to surface water or migration of groundwater to surface water); and,

(*5*) Current and reasonably anticipated future use of the site and surrounding land.

7.3.3.2 *Refining the Site Conceptual Model*—The preliminary site conceptual model developed in Step 1 should be refined as part of the Tier 1 analysis and evaluation based on the newly acquired site-specific data, a more advanced understanding of exposure pathways and relevant ecological receptors and habitats, and more focused goals and objectives. Considerations for revising the site conceptual model could include:

(*1*) Relationship between environmental media and biota with regard to potential transfer of chemicals;

(*2*) Field data and observations of direct effects to relevant ecological receptors and habitats as an indication of potential exposure;

(*3*) Field data and observations of source(s) and potential for complete exposure pathways;

(*4*) Current and reasonably anticipated future land uses; and

(*5*) Applicable TPDs.

7.3.3.3 *Comparison of Site Conditions with Screening Criteria*—The RESC and ORMC identified via TPDs should be compared to site data to determine if potential ecological risk exists. In Tier 1, the maximum chemical concentrations found in environmental media are often used for a conservative comparison with chemical-specific RESC. When the quantity and quality of site data are sufficient, a statistically derived concentration may be used instead of the maximum concentration. Background chemical concentrations (for example, inorganic chemicals or naturally occurring radionuclides) may also be considered during Tier 1. Decisions as to the appropriate data to be used (for example, statistically derived or background concentrations) are defined and implemented by TPDs.

7.3.4 *Tier 1 Uncertainty Analysis*—The Tier 1 uncertainty analysis is performed to provide the user with an opportunity to document those uncertainties that may either overestimate or underestimate risk to relevant ecological receptors and habitats. The Tier 1 uncertainty analysis anticipates that risk management decisions for the site are protective of ecological resources because the likelihood of underestimating the potential risk is extremely small. Because the uncertainty in Tier 1 is generally high, based on limited data and data that are biased toward being conservative, the probability of concluding that the risk is acceptable, when in fact the risk is actually unacceptable, is minimized. In other words, the likelihood of committing a Type II error (that is, concluding that the risk is acceptable when in fact the risk is actually unacceptable) is minimized. A thorough analysis of Tier 1 uncertainty should lay the groundwork for the refinement of specific assumptions in successive tiers, and should support informed risk-management decisions. Uncertainty is discussed in greater detail in Appendix X7.

7.4 *Step 4. Tier 1 Decision Point*—Based on the comparison of site conditions with the Tier 1 screening criteria (that is, RESC and ORMC), the potential for ecological risks associated with current site conditions is evaluated and an appropriate risk management decision is made. One of three decision s are possible based on the Tier 1 evaluation: (*1*) a potential ecological risk exists that warrants either a remedial action or an interim remedial action (continue Step 4), or (*2*) additional ecological evaluation (continue to Step 5), or (*3*) ecological risks are acceptable and the process continues to Step 10.

7.4.1 *Evaluation of Remedial Action*—Based on the Tier 1 results, it may be concluded that implementing a remedial

action is warranted. Depending on site-specific considerations, the remediation can be completed as an interim remedial action or as a remedial action. Interim remedial actions are used to address the most significant concerns in an expedited manner. In some cases, an interim remedial action may be more practical than attempting to implement a remedial action: for example, when the desired remedial action is not currently feasible due to technology or resource limitation. Furthermore, if interim remedial action can immediately reduce or eliminate an immediate threat to relevant ecological receptors and habitats, implementation of interim remedial action could be considered prior to conducting further tiered evaluation. As part of the decision-making process, the effectiveness and benefits of the interim remedial action relative to a remedial action should be considered. Any decision to proceed with interim remedial action or remedial action should be coordinated and integrated into RBCA decisions for protection of human health (see Guide E2081) and be consistent with appropriate regulations.

7.4.1.1 *Interim Remedial Action*—Based on the Tier 1 results, an interim remedial action may be selected as the appropriate short-term risk management alternative. The interim remedial action might include removal or treatment of source area(s) with complete or potentially complete exposure pathways, or address the most significant exposure concerns to reduce transport of chemicals of concern and facilitate reassessment of the Tier 1 evaluation. At this point, the decision-making process should consider risks to human health (RBCA) to ensure that the two processes are integrated (see 6.8). Once the interim remedial action is completed, a reassessment in Tier 1 may be appropriate (iteration of Steps 3 and 4) to determine if unacceptable ecological risks still exists. Further tiered evaluation might also be pursued in cases where unacceptable risk remains after remedial action.

7.4.1.2 *Remedial Action*—One possible Tier 1 decision is to proceed with remedial action to address unacceptable risk and meet corrective action goals. The decision to proceed with a remedial action in Tier 1 will be influenced by a variety of factors, including the degree of uncertainty of the Tier 1 results, costs associated with conducting further tiered evaluation, the ability to justify remedial goals and objectives based on the existing data, the feasibility of implementing the remedial action, the achievement of site management goals, and the maintenance of ecological protectiveness. If remedial action is selected as part of the Step 4 decision point, the Eco-RBCA process proceeds to Step 9.

7.4.2 *Further Tiered Evaluation*—If the Tier 1 results support the conclusion that a potential unacceptable ecological risk exists and interim remedial action or remedial action is not practicable or appropriate, further evaluation in Tier 2 is required. The breadth and scope of any further tiered evaluation should focus on those exposure pathways for which Tier 1 RESC or ORMC were not available, and on those ecological risks that are potentially unacceptable. The applicability and uncertainty of RESC and ORMC and the costs associated with remedial actions at Tier 1 may also influence whether the Eco-RBCA process proceeds to further tiers.

7.4.3 *Acceptable Risk Determination*—If acceptable ecological risk is determined because concentrations of chemicals of concern or site conditions do not exceed RESC and ORMC, a high level of confidence can be assumed for a recommendation of no further tiered evaluation, because the RESC and ORMC are highly conservative and overprotective, in some cases. This applies when the information for the site is sufficient to meet the criteria for acceptable risk as defined by the TPDs. If acceptable risk is determined, the Eco-RBCA process may proceed to Step 10 to decide if site monitoring, other corrective action, or no further action is appropriate.

7.5 *Step 5. Tier 2 Ecological Risk Assessment*—The Tier 2 evaluation (Fig. 3) consists of a more refined ecological evaluation (Step 5) and the risk management decision as to the appropriate action (Step 6). The Tier 2 assessment may include revision of the goals and objectives, revision of the corrective action goals, refinement of the site conceptual model, revision of the exposure pathway analysis, identification of assessment endpoints and measures of effect (see 3.1.3 and 3.1.20), development of site-specific ecological criteria (SSEC), and review and revision of the TPDs. The information obtained during the initial site assessment and Tier 1 evaluation is expanded in Tier 2 with more site-specific information and data. The additional information collected for Tier 2 should focus on providing more site-specific information on relevant ecological receptors and habitats, exposure pathways, or exposure concentrations and doses. The Tier 2 evaluation may include refining the Tier 1 screening analysis, expanding the tiered evaluation to include modeling such as food chain models, or the refinement of toxicity values. The focused Tier 2 evaluation often results in fewer exposure pathways, fewer relevant ecological receptors and habitats, and fewer chemicals of concern that need to be considered because some were eliminated from consideration during the Tier 1 evaluation.

7.5.1 *Tier 2 Planning and Scoping*—The Tier 2 planning and scoping, conceptually analogous to the ERA problem formulation (see 3.1.25 and (**1**)), incorporates the results from Tier 1 to review and revise the goals and objectives, redefine corrective action goals, refine the site conceptual model, revise the exposure pathway analysis, and review and revise TPDs. As in Tier 1, the scope and objectives for the Tier 2 assessment should be clearly defined at the onset to focus on specific chemicals of concern, exposure pathways, and ecological receptors and habitats. Work plans should be developed for data collection to ensure consistency with TPDs. The planning and scoping should involve appropriate stakeholders to ensure that the data and evaluation will be useful and sufficient for decision making.

7.5.2 *Tier 2 Data and Information Acquisition*—The Tier 2 data and information acquisition will be more site specific than Tier 1, and will depend on the goals and objectives, assessment endpoints and measures of effect, and approach identified during the planning and scoping phase. Data may be collected to fill data gaps identified during Tier 2 planning and scoping. Specific data collection activities may include the following:

7.5.2.1 *Acquisition of Information on Relevant Ecological Receptors and Habitats*—Data or field observations may be used to refine the site conceptual model by documenting what

is present or expected to be present at or near the site. In addition, the data and field observations may be used to provide direct information on the observed health of relevant ecological receptors and habitats and to refine exposure estimates by taking into account species-specific information such as feeding habits and site use. For example, screening criteria for fish and wildlife species presume either sensitive or generic guilds as surrogates for other species to ensure adequate protection of all species. Site-specific information can be used to determine whether the underlying technical justification for using such criteria is appropriate for relevant ecological receptors. If there are important technical differences between site-specific receptors and the surrogate species used to develop the Tier 1 screening criteria, such information should be used to derive site-specific ecological criteria (SSEC).

7.5.2.2 *Acquisition of Information on Exposure*—As the user progresses through the Eco-RBCA process, refinement of exposure estimates could occur through measuring the concentrations of chemicals of concern along gradients or by calculating area-weighted averages based on receptor foraging areas relative to area of contamination. Site-specific estimates of exposure could also be developed using fate and transport models or exposure models that incorporate site-specific data. As the user progresses through the tiered evaluation, the acquisition of information on exposure should always contribute to a better understanding of the exposure estimates based on site-specific factors.

7.5.2.3 *Review of Toxicity Information*—Literature reviews of toxicity information for site-specific receptors or guilds representative of site-specific receptors can generate information that can be used to derive toxicity data appropriate for the receptors that actually (or potentially) use the site and surrounding area.

7.5.3 *Tier 2 Analysis and Evaluation*—The Tier 2 analysis and evaluation focuses on more site-specific exposures and effects than was conducted in Tier 1. In some cases, the data may be a direct measure of exposures or may be data used to calculate site-specific exposures. Data may be used to compare site ecological receptor exposures with those of reference area conditions and, as such, the evaluation may consist of a direct comparison of site data to site-specific ecological criteria (SSEC) or ORMC. In Tier 2, ORMC could include concentration values or other numeric values, physical condition, or performance criteria other than the SSEC. Similar to Tier 1, the evaluation may use hazard or other evaluation tools appropriate to the type of data available and the evaluation that will be conducted. The Tier 2 evaluation considers more site-specific information so that the exposure levels or effect-based levels are equivalent to SSEC. Tier 2 evaluations may also involve relatively simple and deterministic risk assessments. More sophisticated and complex risk assessment techniques are typically beyond the scope of Tier 2 assessments and may be more appropriately considered in Tier 3.

7.5.3.1 *Tier 2 Exposure Assessment*—The refined site conceptual model is used as the basis for identifying the exposure pathways and relevant ecological receptors and habitats to be evaluated in Tier 2. Tier 2 may include the development and application of site-specific data to quantify potential chemical exposure levels that represent exposures at specified points or areas relative to the source. Exposure pathways may include those that result in direct exposure, such as chemicals in environmental media, or those that result in indirect exposure, such as exposure through the consumption of food sources on the site, as shown by food chain and food web models. Tier 2 exposure assessments could use point estimates of exposure based on steady-state or equilibrium conditions, to the extent that site-specific data support the use of point estimates. However, in the absence of site-specific data, the user may use conservative exposure assumptions to manage uncertainty. Ranges of values can also be used to evaluate the potential variability and sensitivity of the exposure estimates to the input assumptions. As a result, Tier 2 exposure estimates are site-specific, deterministic, and while less conservative than Tier 1, still expected to overestimate rather than underestimate exposure, since the exposure assessments for Tier 2 are still simplified representations of actual exposure.

7.5.3.2 *Tier 2 Effects Assessment*—Tier 2 evaluation of effects involves the use of either toxicity values used in Tier 1 with site-specific estimates of exposure, or site-specific ecological criteria derived as part of the Tier 2 evaluation. Site-specific toxicity values would typically be developed from available scientific literature that address the following factors:

(*1*) *Consideration of the Form or Species of the Chemical Present at the Site*—Toxicity of a chemical of concern may vary dramatically, depending upon the form in which it is found in ambient setting (for example, element mercury versus methyl mercury, and hexavalent chromium versus trivalent chromium). It may be appropriate to determine the site-specific speciation or chemical characterization of chemicals of concern at a site that supports the selection of the most appropriate toxicity values from the literature.

(*2*) *Potential Combined Effects of Mixtures of Chemicals with Similar Toxicity Mechanisms*—Some materials occur in the environment as mixtures of chemicals (for example, polycyclic aromatic hydrocarbons, polychlorinated biphenyls, and petroleum products). Other chemicals may be released individually but occur in mixtures and exert additive toxicity due to similar toxicity mechanisms (for example, narcosis by nonionic organic compounds or biological ligand binding by divalent cationic metals). Considerations for evaluation of mixtures should be developed as one of the TPDs for the site.

(*3*) *Receptors or Guilds of Species that Actually or Potentially Use the Site*—Toxicity values used for Tier 1 screening purposes may be derived using ecological characteristics that may not be appropriate for the site under evaluation. The derivation of screening criteria used in Tier 1 may be based on sensitive species or well-studied species, or be derived from many species; as such, they may not be appropriate for the Tier 2 evaluation. In such cases, it may be appropriate to review the literature for toxicological data that are more applicable to the relevant ecological receptors and habitats at the site. These toxicological data can be combined with information on the ecological characteristics of relevant ecological receptors and habitats to derive SSEC.

7.5.3.3 *Risk Characterization*—The Tier 2 exposure and effects assessments are integrated during the risk characterization step to quantify the potential risks to relevant ecological receptors and habitats. The Tier 2 exposure and effects data are evaluated using either SSEC or ORMC. For SSEC, risks are characterized by comparing site-specific exposure estimates for complete and potentially complete exposure pathways. For ORMC, the data and site conditions are evaluated relative to the specific type of ORMC. Based on the comparisons to SSEC and ORMC, the exposure pathways and chemicals of concern that pose unacceptable risk to relevant ecological receptors and habitats are identified. Those pathways, chemicals and receptors that are considered acceptable risk are screened from further consideration. Cumulative risks and additive effects resulting from exposure to multiple chemicals also can be considered, as appropriate.

7.5.4 *Tier 2 Uncertainty Analysis*—As with Tier 1, the Tier 2 uncertainty analysis should be conducted to assess the potential for an unacceptable risk, with a slight bias towards overestimating risk, to be protective. Because of the uncertainty associated with using generic literature values, and to a lesser degree with site-specific values, the potential for under- or overestimating risk should be considered and evaluated. In general, the Tier 2 uncertainty analysis should be more rigorous than Tier 1, with a reduced level of conservatism in the assessment due to the use of site-specific data that have been acquired or generated. As in Tier 1, the Tier 2 uncertainty analysis will usually be qualitative in nature. Appendix X7 presents more information on uncertainty.

7.6 *Step 6. Tier 2 Decision Point*—Based on the results of the Tier 2 evaluation, the potential for ecological risk associated with current site conditions is assessed, and a risk-management decision is made to determine an appropriate action. One of three decisions are possible based on the Tier 2 evaluation: (*1*) an ecological risk exists that warrants an interim remedial action (continue with 7.6.1); (*2*) further tiered evaluation is required (continue to Step 7); or (*3*) ecological risks are acceptable (continue to Step 10).

7.6.1 *Evaluation of Remedial Action*—Based on the Tier 2 evaluation, it may be concluded that implementing a remedial action is warranted. Depending on site-specific considerations, the remediation may be implemented as an interim remedial action or as a remedial action. Interim remedial actions are used to address the most significant concerns in an expedited manner. In some cases, an interim remedial action may be more practicable than attempting to implement a remedial action: for example, when the desired remedial action is not feasible due to technology or resource limitations. Furthermore, if an interim remedial action can reduce or eliminate a significant threat to relevant ecological receptors and habitats, implementation of an interim remedial action should be strongly considered prior to conducting further tiered evaluation. As part of the decision-making process, the effectiveness and benefits of the interim remedial action relative to a remedial action should be considered. Any decision to proceed with an interim remedial action or remedial action should be considered and integrated into RBCA decisions for protection of human health (see Guide E2081) and consistent with appropriate regulations.

7.6.1.1 *Interim Remedial Action*—Based on the Tier 2 evaluation, an interim remedial action may be selected as the appropriate short-term risk management alternative. The interim remedial action might include removal or treatment of source area(s) that contribute to complete or potentially complete exposure pathways, or otherwise address the most significant exposure concerns to reduce or eliminate the transport of chemicals of concern and to facilitate reassessment of the Tier 2 evaluation. At this point, the decision-making process should consider human-health concerns to ensure that the two processes are integrated (see 6.8). Once the interim remedial action is completed, further tiered evaluation may be appropriate to determine the success of the remedial action and whether unacceptable ecological risks still exist (iteration of Steps 3 and 4).

7.6.1.2 *Remedial Action*—The decision to proceed with a remedial action following Tier 2 will be influenced by various factors, including the degree of uncertainty of the Tier 2 results, costs associated with further tiered evaluation, the ability to justify remedial goals and objectives based on the existing data, the feasibility of implementing the remedial action, the achievement of site management goals, and the maintenance of ecological protectiveness. If remedial action is selected in the decision-making process, the process proceeds to Step 9.

7.6.2 *Further Tiered Evaluation*—Further tiered evaluation may be required after the Tier 2 evaluation if it is concluded that a potential unacceptable ecological risk may still exist, and neither an interim remedial action or a remedial action is practicable or appropriate; in this case, a Tier 3 evaluation (Step 7) is required. As part of the Tier 3 evaluation, additional site assessment information should be collected to further refine existing SSEC or ORMC, to define new SSEC and ORMC, and to support the selection of risk management alternatives. The breadth and scope of the Tier 3 evaluation should be limited to the completed exposure pathways that were determined to pose a potentially unacceptable risk identified during the Tier 2 evaluation.

7.6.3 *Acceptable Risk Determination*—If concentrations of COCs or site conditions do not exceed SSEC and ORMC, and multiple lines of evidence support acceptable ecological risk, then further ERA is not warranted. At this point, the process proceeds to Step 10 to decide if monitoring, other corrective action, or no further action is appropriate.

7.7 *Step 7. Tier 3 Ecological Risk Assessment*—The Tier 3 evaluation (Fig. 4) consists of a detailed ERA (Step 7) and a risk management decision as to the appropriate action (Step 8). The Tier 3 evaluation uses the Tier 2 results to support the refinement of or development of the TPDs for the site such as the goals and objectives of the evaluation, the corrective action goals, site conceptual model, exposure pathway analysis, and SSEC. The Tier 3 ERA is focused on those chemicals of concern, exposure pathways, and relevant ecological receptors and habitats that were identified in Tier 2 as contributing to ecological risk. Tier 3 may use data from multiple lines of evidence (for example, measures of effects and exposure), predictive models, and probabilistic approaches to evaluate the site-specific exposures, effects, and risk. Relative to Tier 2, approaches and tools used for Tier 3 ERA are more

sophisticated, employ more site-specific information, and require more resources to implement.

7.7.1 *Tier 3 Planning and Scoping*—The Tier 3 planning and scoping builds upon the Tier 1 and Tier 2 evaluations. To focus the Tier 3 investigation, a work plan for the data collection should be developed to ensure consistency with TPDs. Additionally, the work plan should address the Tier 3 goals and objectives, corrective action goals, refinement of the site conceptual model, and the revision of measures of effect and assessment endpoints (as appropriate) to reflect increased site-specific considerations. Assessment endpoints need to be identified to provide the basis for judging risks at Tier 3. Assessment endpoints and measures of effect need to be clearly defined and should relate to the goals and objectives of the Tier 3 ERA. As in previous tiers, appropriate stakeholder input should be considered in the planning and scoping of the Tier 3 evaluation.

7.7.2 *Tier 3 Data and Information Acquisition*—The Tier 3 data and information acquisition will most likely involve gathering additional site-specific toxicological and ecological data (for example, measures of effect) to support assessment of exposure and effects. Tier 3 data and information acquisition may encompass a wide range of activities, including bioassays and field surveys, and may involve either direct measurements or modeling to estimate exposure, effects, or both. Data acquisition may include field studies for factors such as species diversity, population growth, or reproductive success evaluation, and data evaluation may include use of probabilistic tools, numerical models for chemical fate, and transport predictions. Data may also be needed to address spatial and temporal scales, or to assess effects associated with individual or multiple stressors. Specific types of data or information that may be collected during Tier 3 include the following:

7.7.2.1 Direct measures of toxicity from field samples (that is, toxicity testing);

7.7.2.2 Indices of quality or condition (for example, field survey, *in situ* tests, substrate colonization, etc.);

7.7.2.3 Community or habitat structure and function;

7.7.2.4 Population modeling;

7.7.2.5 Population or community level effects;

7.7.2.6 Site-specific or chemical-specific benchmarks; and

7.7.2.7 Bioavailability factors.

7.7.3 *Tier 3 Analysis and Evaluation*—As in Tier 2, the Tier 3 analysis and evaluation includes assessment of exposure and effects associated with chemicals of concern at the site. However, due to the complexities typically associated with sites that require Tier 3 ERAs, the Tier 3 ERA should also use multiple lines of evidence to develop technically defensible conclusions. Under such an approach, information provided by each line of evidence (for example, bioassays or field surveys) is evaluated concurrently, combining lines of evidence in a hierarchical or logical way, and interpreted with respect to other information for the site. The following factors should be considered when generating Tier 3 data: (*1*) the strength of association between the measure of effect and the assessment endpoint, (*2*) site-specificity, (*3*) stressor specificity, (*4*) quality of the data and overall study design, (*5*) availability of an objective measure for judging risk, (*6*) sensitivity of the measure for detecting changes or differences, (*7*) spatial representativeness, (*8*) temporal representativeness, (*9*) ability to quantify either exposure or effects, (*10*) ability to correlate a stressor to a response, (*11*) acceptability or defensibility of the method, and (*12*) levels of detection for analytical measurements. Lines of evidence analyses are organized around each identified assessment endpoint. Examples of lines of evidence methodologies can be found in Suter **(4)** and Menzie et al. **(5)**. As part of the Tier 3 analysis and evaluation, the strengths and limitations of the data and interpretations should be identified in the Tier 3 uncertainty analysis (see 7.7.4).

7.7.3.1 *Tier 3 Risk Characterization*—The Tier 3 risk characterization integrates data on exposure and effects into a conclusion regarding risks as they relate to the assessment endpoints. The basis for assessing risk is a TPD that should be identified during the Tier 3 planning and scoping. The risk characterization should state the results of the Tier 3 analysis in an objective and straightforward manner. Where multiple lines of evidence are involved, the risk characterization should identify how the lines of evidence are related to the assessment and measurement endpoints and present any evidence that conflicts with the overall conclusions. The risk characterization should be based on the strength of the data from all lines of evidence, in consideration of the uncertainties associated with the assessment. A particular line of evidence should not be discounted if the design and the means of evaluating the risk have been previously agreed to as a TPD. The risk characterization should present the results of the assessment and supporting information clearly to support decision making.

7.7.4 *Tier 3 Uncertainty Analysis*—The Tier 3 uncertainty analysis should be rigorous, reflecting the complexity associated with Tier 3 data and the interpretation of risk from multiple lines of evidence. The Tier 3 uncertainty analysis will usually be quantitative in nature, and depending on the data, might include calculation of confidence limits as well as power analysis. In cases where a probabilistic approach is used, both variability and uncertainty can be characterized to provide more information about the range of potential risks and the likelihood of their occurrence. Although data are collected with the intent of reducing uncertainty in the Eco-RBCA process, additional data may add uncertainty because the data may not accurately reflect site conditions. The possibilities for this and its implications should be avoided through the careful examination and development of the TPDs for Tier 3. With well-defined TPDs and collection of appropriate sampling data and assumptions, the relative contributions of uncertainty and variability in the exposure and risk estimate can be evaluated **(3)**. See Appendix X7 for more information on uncertainty.

7.8 *Step 8. Tier 3 Decision Point*—Based on the Tier 3 evaluation, a risk management decision is required as part of the Eco-RBCA process. This decision should address the ecological risk identified at the site and should be consistent with applicable TPDs, regulations, site owner management plans and controls, community values, and other stakeholder involvement and comments. Two decisions are possible based on the Tier 3 evaluation: (*1*) an unacceptable ecological risk exists that warrants an interim remedial action or remedial

action (continue to Step 9) or (*2*) ecological risks are acceptable (continue to Step 10).

7.8.1 *Remedial Action*—If the site is determined to pose an unacceptable risk following the Tier 3 evaluation, risk management alternatives should be identified and evaluated; the most appropriate risk management alternative should be selected consistent with regulatory, TPDs, and other applicable considerations. The remedial action could be conducted as an interim remedial action or could follow the development of a remedial action program (Step 9). The detailed information and data collected during the Tier 3 ERA should be sufficient to define and select risk management alternatives that result in the recovery or maintenance, or both, of healthy local populations/communities of biota. Any decision to proceed with an interim remedial action or remedial action should be considered and integrated into RBCA decisions for protection of human health and be consistent with appropriate regulations.

7.8.2 *Acceptable Risk Determination*—If, based on the Tier 3 evaluation, it is concluded that the ecological risks are acceptable, the Eco-RBCA process proceeds to Step 10 to decide if monitoring, other corrective action, or no further action is appropriate.

7.9 *Step 9. Remedial Action Program*—Remedial alternatives should be evaluated for sites determined to have unacceptable ecological risk and warranting remedial action. At this point, the Eco-RBCA process should be integrated with the human health evaluation completed in the RBCA process (see Guide E2081). The corrective action goals should be reviewed and clarified to ensure that the appropriate remedial action is selected that can satisfy the corrective action goals. Corrective action goals, which are defined by TPDs, should be used to determine the level of protection needed for a given remedial action. In general, remedial action for Eco-RBCA should protect populations and communities, and should not be selected based on protection of individual organisms except for those designated as protected resources (such as listed or candidate threatened and endangered species or treaty-protected species). Appendix X1 provides additional information that can be used to apply corrective action goals. To support the selection of the appropriate remedial action, additional data such as feasibility and engineering studies may be required. During the remedial action selection process, it is important to consider that remedial action itself can pose risks, including significant physical, biological, and chemical stresses on relevant ecological receptors and habitats, as well as on human health. As a result, the proposed remedial action should be balanced against the short- and long-term risks and the ecological benefits consistent with the TPDs.

7.9.1 *Evaluation of Remedial Action Alternatives*—The evaluation of remedial alternatives should be consistent with the TPDs defined throughout the Eco-RBCA process and may also consider:

7.9.1.1 Effectiveness of the remedial action in protecting and restoring relevant ecological receptors and habitats;

7.9.1.2 Long-term reliability and probable success in meeting the corrective action goals and objectives both now and in the future;

7.9.1.3 Short-term risks posed by the implementation of the remedial action relative to the longer-term ecological benefits;

7.9.1.4 Amenability of the remedial action to integration with property development plans;

7.9.1.5 Acceptability of the remedial action to the stakeholders;

7.9.1.6 Implementability and technical practicability of the remedial action; and

7.9.1.7 The cost-effectiveness of the options to meet the remedial action goals.

7.9.2 *Remedial Action Design*—Once the remedial action has been selected, detailed design specifications should be developed for its implementation. For ongoing remedial action operations, monitoring may be needed until such time as concentrations of chemicals of concern are below SSEC or ORMC.

7.9.3 *Remedial Action: Other Considerations*—During the remedial action program, additional ecological investigations may be required, or alternative remedial actions may need to be considered. Some examples of when additional investigations may be required or alternative remedial actions may be needed include:

7.9.3.1 Land uses change in a manner that was not considered in the original site assessment;

7.9.3.2 New data (such as toxicity data for the chemicals of concern) or site-specific exposure factors that are better refined or become available that would substantially impact the corrective action goals;

7.9.3.3 Concentrations of chemicals of concern decrease to an asymptotic level that is greater than the corrective action goals; and

7.9.3.4 It is demonstrated that risk-based corrective action goals cannot be met by the selected remedial alternative, and additional remedial actions are necessary.

7.10 *Step 10. Decision Point: Monitoring*—The user should determine whether monitoring and site maintenance are required before achieving a no-further-action decision. Monitoring may not be necessary if ecological risk is acceptable and is not expected to change. Monitoring may be required to (*1*) demonstrate the effectiveness of the remedial action used to achieve the corrective action goals, (*2*) confirm that current conditions persist or improve with time, or (*3*) support a no-further-action decision. Such monitoring ultimately needs to be designed and implemented within the context of the overall RBCA process (see Guide E2081) and be consistent with appropriate regulations. Due to the uncertainty inherent with an ecological evaluation, monitoring may also be appropriate to confirm that: the extent of contamination is fully known; there are no continuing chemical releases; all exposure pathways to relevant ecological receptors and habitats are incomplete; or “no remedial action” was an appropriate decision. Monitoring should also be considered after a tiered evaluation when site conditions indicate that corrective action goals have been met but unacceptable uncertainty still exists with respect to the future conditions. These cases could arise if site conditions are altered due to changes in either source releases or the extent of contamination. To avoid this situation,

the user should collect data sufficient to conclude that corrective action goals will be met in the future.

7.10.1 *Monitoring: Potential Uses*—Monitoring can be useful for assessing the effectiveness of a remedial action. At some sites, estimated risks might be marginal, and remedial action measures might themselves be environmentally damaging in excess of longer-term environmental benefits; in addition, the desired technology might not be technically feasible or cost-efficient. At such sites, a carefully designed monitoring program for a limited time period, with specific triggers for action, may be a desired strategy. If monitoring does not demonstrate the effectiveness of the remedial action, the user should reevaluate the remedial action (see 7.9). In cases where it is demonstrated that risk-based corrective action goals cannot be met by the selected remedial alternative, and additional remedial alternatives are judged not to be appropriate, monitoring should be evaluated and implemented to determine the acceptability of residual risk via TPDs.

7.10.2 *Monitoring Triggers for Further Evaluation*—If the monitoring data show that a chemical concentration is increasing or a pathway of ecological exposure is becoming evident, monitoring may be used to track changes through time. The monitoring program should include triggers for additional investigation or remedial action. If the monitoring does not confirm that current conditions persist or improve with time, or verify model assumptions and conditions, then the user should return to the applicable tier evaluation to assess risks and make appropriate risk management decisions.

7.10.3 *No-Further-Action Determination*—"No further action" is appropriate when ecological risk is acceptable, when site conditions are stable and not expected to change, or when corrective action goals have been demonstrated for a predetermined period of time. Under these circumstances, monitoring and site maintenance (for example, physical barriers, capping, hydraulic controls, and institutional controls) are no longer required to ensure safety to human health and the environment. If these conditions are met, the basis for no further action should be documented in the Eco-RBCA report (see 7.11).

7.11 *Eco-RBCA Report*—A report should be prepared to document the Eco-RBCA process. The report content will depend on the specific site and regulatory agency requirements, but it should include all information on TPDs, as well as all data collected to support the decisions made. It should clearly state which issues have been resolved and those for which resolution is still pending. Remaining uncertainties should be evaluated to determine whether they can be reduced further, based on the available data, or if these uncertainties are still a barrier to decision making. Recommendations regarding the need for and extent of remediation should be clearly outlined and discussed. More detail regarding the content of RBCA reports is presented in Guide E2081.

8. Keywords

8.1 ecological risk assessment; remedial action; risk-based corrective action; site assessment; technical policy decisions; tiered approach

APPENDIXES

(Nonmandatory Information)

X1. RISK MANAGEMENT AND RISK ASSESSMENT

X1.1 Purpose

X1.1.1 The purpose of this appendix is to highlight the relationship between ecological risk assessment and risk management. In general, risk assessment and risk management are two distinct activities. Risk assessment is a technical and scientific evaluation of the likelihood of adverse effects. Risk management selects a course of action in response to those effects and is based on many factors (social, legal, political, and economic) in addition to the risk assessment results (**6**).

X1.2 Principles for Risk Assessment

X1.2.1 In risk assessment, scientific information is selected, evaluated, and presented without considering nonscientific factors, including how the scientific analysis might influence the regulatory decision (**6**).

X1.2.2 A good risk assessment does the following:

X1.2.2.1 Generates a credible, objective, realistic, and balanced analysis;

X1.2.2.2 Presents information on actual and potential hazards; and

X1.2.2.3 Clearly delineates uncertainties and assumptions along with the impacts of those factors (for example, confidence limits, use of conservative/nonconservative assumptions) on the overall assessment.

X1.2.3 The risk assessor does not make decisions on the acceptability of any risk level for protecting the environment or decisions on steps to reduce risks (**6**).

X1.3 Principles for Risk Management

X1.3.1 In risk management, the technical information used to develop the risk assessment is combined with information from other fields. Risk managers consider many factors. Legal mandates and political, social, and economic considerations may lead risk managers to make decisions that are more or less protective. Reducing risk to the lowest level may be too expensive or not technically feasible. Thus, although ecological risk assessments provide critical information to risk managers, they are only part of the ecological decision-making process (**7**).

X1.3.2 Risk management decisions occur at various decision points throughout the RBCA process. Some of these

decisions focus exclusively on ecological issues. Other decisions (for example, those involving the design and implementation of corrective action) involve the considerations of a number of risk and non–risk-related factors. Site decisions could be formed by comparisons to relevant ecological screening criteria (RESC) site-specific ecological criteria (SSEC), other relevant measurable criteria (ORMC), human health considerations, and other factors that apply to the site. Good risk management decisions should take all these considerations into account, as appropriate and as authorized; all state, federal, and local statutes and regulations; and other legal requirements such as permit terms that may apply to the decisions.

X1.3.3 Site decisions are influenced by factors such as ORMC that are not strictly risk based; the user needs to be aware of how such factors should be considered in the RBCA process. ORMC are identified within the RBCA process as a way to capture non–risk-based factors that may inform or drive decision making. Technical policy decisions regarding ORMC may exist or may need to be made to determine the appropriate values, conditions or performance criteria that are used for the corrective action goals. Because the RBCA process, as outlined in Guide E2081, takes into account human and ecological considerations, ORMC may also address issues of concern to humans (for example, aesthetic criteria and nuisances) as well as factors that may be of ecological concern. The latter might include considerations of soil quality (for example, the ability of the soil to support plant and animal life), criteria for "readily apparent harm" and criteria related to identification and protection of special habitats.

X1.3.4 A good risk management decision does the following **(8)**:

X1.3.4.1 Addresses a clearly articulated problem;

X1.3.4.2 Has clearly articulated goals and objectives;

X1.3.4.3 Considers the views of appropriate stakeholders affected by the decision;

X1.3.4.4 Examines a range of regulatory and nonregulatory risk management options;

X1.3.4.5 Is based on the best available scientific, economic, and technical information;

X1.3.4.6 Accounts for multisource, multimedia, multichemical, and multirisk contexts;

X1.3.4.7 Is feasible, with benefits reasonably related to their costs;

X1.3.4.8 Gives priority to preventing risks, not just controlling them;

X1.3.4.9 Uses alternatives to command-and-control regulation, where applicable;

X1.3.4.10 Is sensitive to political, social, legal, and cultural considerations;

X1.3.4.11 Promotes the use of incentives for innovation, evaluation, and research;

X1.3.4.12 Can be implemented effectively, expeditiously, flexibly, and with stakeholder support;

X1.3.4.13 Can be shown to have the required impact on the risks of concern based on risk management goals and objectives; and

X1.3.4.14 Can be revised and changed when significant new information becomes available, according to the risk management framework developed for the site.

X1.4 Interaction Between Risk Assessment and Risk Management in Planning and Scoping

X1.4.1 Ecological risk assessments are conducted to enable risk managers to make informed environmental decisions. To ensure that risk assessments meet this need, risk managers and risk assessors and, where appropriate, interested parties, engage in a planning dialogue as a critical first step toward defining risk management goals and objectives and a clearly articulated problem for the risk assessment to address **(7)**.

X1.4.2 During the planning dialogue, risk managers and risk assessor bring important perspectives to the table. Risk managers help ensure that risk assessments provide information relevant to their decisions by describing why the risk assessment is needed, what decisions it will influence, and what they want to receive from the risk assessor **(7)**. In turn, risk assessors ensure that the necessary scientific information is obtained and effectively used to address ecological and management concerns. Risk assessors describe what they can provide to the risk manager, where problems are likely to occur, and where uncertainty may be problematic. In addition, risk assessors may provide insights to risk managers about alternative management options likely to achieve stated goals because the options are ecologically based **(7)**.

X1.5 Participation by Interested Parties

X1.5.1 In some risk assessments, interested parties, or stakeholders, also take an active role in planning, particularly in goal development. Interested parties may communicate their concerns to risk managers about the environment, economics, cultural changes, or other values potentially at risk from environmental management activities. Involvement by interested parties is not always needed or appropriate. It depends on the purpose of the risk assessment, the regulatory requirements, and the characteristics of the management problem **(7)**.

X1.5.2 There is no single stakeholder model which applies to all sites. Who are appropriate stakeholders, plus how and to what degree they are involved is clearly a function of the site characteristics and the regulatory context. For example, an unauthorized release of materials beyond the fence line would indicate the need to engage adjacent property owners while the same release contained within property boundaries may not, especially in cases where the potential for offsite migration is minimal.

X1.5.3 Criteria for involving stakeholders could include: (*1*) the magnitude of the potential problem, (*2*) the degree to which they will be affected by the decision, (*3*) their importance as a source of valuable information for the assessment and the decisions, and (*4*) their level of interest. These criteria also guide how to identify stakeholders. Some statutes may mandate public participation, in which case stakeholder involvement is a legal requirement, not simply a management option.

X1.5.4 There are some common situations that may involve stakeholder participation. For example, stakeholder involvement is almost always sought when:

X1.5.4.1 Forming local, state, provincial, or federal policy guidance and laws;

X1.5.4.2 Evaluating the environmental impact of new facilities or operations;

X1.5.4.3 Permitting new major dischargers;

X1.5.4.4 Using public lands for harvesting and extraction of natural resources;

X1.5.4.5 Planning for regional and watershed management; and

X1.5.4.6 Evaluating unregulated releases of chemicals from large sites that extend beyond the property boundaries of a facility.

X1.5.5 Stakeholder involvement is sometimes sought during:

X1.5.5.1 Formation of a policy or operational decision for a specific facility (for example, an industrial practice);

X1.5.5.2 Periodic reviews of existing discharge or operational permits;

X1.5.5.3 Development of private lands where abutters may be impacted; and

X1.5.5.4 Unregulated release of chemicals from large sites that do not extend beyond the property boundaries of the facility

X1.5.6 Stakeholder involvement is seldom sought during:

X1.5.6.1 Routine operations and activities conducted in accordance with policy decisions and laws that have been arrived at with stakeholder involvement;

X1.5.6.2 Performance monitoring of various facilities (for example, discharge permits) by government agencies; and

X1.5.6.3 Unregulated releases of chemicals from small sites that do not extend beyond the property boundaries of the facility.

X1.6 Development of Clear Management Goals

X1.6.1 The characteristics of an ecological risk assessment are directly determined by agreements reached by risk managers and risk assessors during planning dialogues. These agreements include clearly established and articulated management goals, which are further refined through development of measurable assessment endpoints (**7**). The ultimate objective is generally not to protect organisms on an individual basis (the exception being individuals with protected status, such as threatened, endangered, or treaty-protected species) but to protect local populations and communities of biota (**9**).

X1.6.2 Case studies of risk assessments by the U.S. Environmental Protection Agency have consistently identified as shortcomings the absence of clearly defined goals and the use of endpoints that are ambiguous and difficult to define and measure. For example, frequently cited concepts such as "sustainability" or "ecological integrity" are often open to considerable interpretation and rarely provide sufficient guidance to a risk assessor (**7**).

X1.6.3 Clearly established and articulated management goals, by contrast, provide an effective basis for risk assessment design. Goals such as "no unreasonable effects on bird survival" or "maintaining areal extent of wetlands" will generally provide this clarity (**7**).

X1.7 Development of Clear Assessment Endpoints

X1.7.1 Assessment endpoints are measurable ecosystem characteristics that adequately represent management goals. Assessment endpoints provide the transition between broad management goals and the specific measures used in a risk assessment (**7**).

X1.7.2 What distinguishes assessment endpoints from management goals is their neutrality and specificity. Assessment endpoints do not represent a desired achievement. As such, they do not contain words like "protect," "maintain," or "restore," or indicate a direction for change such as "loss" or "increase." For example, an assessment endpoint may identify effects on nesting and feeding conditions for a specific species of bird, or may identify the presence or absence of effects on broader species diversity (**7**).

X1.7.3 Risk managers are more willing to use a risk assessment for making decisions when it is based on ecological values that people care about. However, selection of assessment endpoints based on public perceptions alone could lead to management decisions that do not consider important ecological information. While responsiveness to the public is important, it does not obviate the requirement for scientific validity. The challenge for risk managers and risk assessors is to use their interaction to find ecological values that meet the necessary scientific rigor as assessment endpoints and that are also recognized as valuable by risk managers and the public (**7**,**10**).

X1.7.4 Selection of assessment endpoints can also provide an opportunity to integrate the ecological investigation with any parallel RBCA investigation of human health or other factors relating to the site. It will often be practical to collect data and other information that will be useful beyond the ecological assessment.

X1.8 Risk Communication

X1.8.1 When an assessment is complete, risk assessors will have estimated ecological risks and should be able to indicate the overall degree of confidence in the risk estimates, cite lines of evidence supporting the risk estimates, and interpret the adversity of ecological effects. Usually this information is included in an Eco-RBCA report consistent with paragraph 7.11 of this guide (sometimes referred to as a risk assessment report or risk characterization report) (**7**).

X1.8.2 Like the risk assessment itself, an Eco-RBCA report may be brief or extensive, depending on the nature of and the resources available for the assessment. The report need not be overly complex or lengthy; it is most important that the information required to support a risk management decision be presented in a manner that is clear, concise, and transparent (**7**).

X1.8.3 Transparency, in particular, requires that scientific conclusions be identified separately from policy judgments (including technical policy decisions) made in the course of the risk assessment. Major differing viewpoints regarding scientific judgments should also be identified. Uncertainties and assumptions should be acknowledged in a forthright manner (**7**).

X1.8.4 After characterizing risks and preparing a risk assessment report, risk assessors discuss the results with risk managers. Risk characterization provides the basis for communicating ecological risks to interested parties and the general public. This task is usually the responsibility of risk managers, but it may be shared with risk assessors. Managers should clearly describe the sources and causes of risks and the potential adversity of the risks, including nature and intensity, spatial and temporal scale, and recovery potential. The degree of confidence in the risk assessment, the rationale for the risk management decision, and the options for reducing risk are also important. Legal mandates and political, social, and economic considerations that enter into the risk management decision should be described with the same kind of rigor as the elements of the risk assessment (**7**).

X1.9 Risk Balancing

X1.9.1 Risk balancing is the process by which the risk manager evaluates short- and long-term risks associated with remedial action (**11**,**12**). It should also balance these within the context of temporal and spatial information in the risk characterization. Examples of risk balancing follow in the next three paragraphs:

X1.9.1.1 *Remedial Action Impacts Versus Leaving the Chemical Release In Situ*—A potential ecological risk may be identified at a site, but the feasible options for elimination of the risk would themselves involve significant habitat disturbance. For example, excavation of wastes or contaminated soils may require the use of heavy equipment that would destroy bottomland hardwood forest vegetation. If field observations show that long-term recovery of healthy local populations and communities of biota at various trophic levels is, in fact, occurring naturally, then it may be appropriate to leave the chemical release *in situ*. Active remediation and short-term habitat disturbance would likely be necessary, by contrast, if a permanent impairment of the natural recovery process would otherwise result.

X1.9.1.2 *Impact That Remedial Action(s) to Benefit One Species May Have on Another*—A potential risk that a chemical release could impact nearby surface waters might be prevented, for example, by altering the drainage at a site to prevent stormwater run-off from reaching the surface water body. If the stormwater instead accumulates on-site, the flooding may kill existing trees or other vegetation. New species may thrive in the flooded areas, even as existing species are driven out of old habitats. The desirability of the changed drainage as a remedial option would depend on factors such as the severity and likelihood of the risk to the surface water body, the existence of any protected species or species of special community interest in the existing habitat, and the availability of alternative habitat in nearby locations.

X1.9.1.3 *Natural Attenuation and Remedial Action(s) to Protect Human Health Adversely Affects Ecological Receptors and Habitats, or Vice Versa*—Natural attenuation may be sufficient at a particular site to allow full ecological recovery, but ongoing migration of chemical constituents to groundwater might pose a health risk to people using drinking water wells on adjacent properties. In this context, active remediation would likely be necessary, even if it caused disruption of existing habitats. On the other hand, natural attenuation and recovery might be required, even if potential ecological risks have been identified, where active remediation could be accomplished only through heavy construction work that would pose significant risks to workers. In each of these examples, the result might be different if the ecological value is high, such as protection of an endangered species. In this context, it might be necessary to provide alternative water supplies on a long-term basis to adjacent properties that might be affected by groundwater migration, thus preserving the existing habitat. Similarly, active remediation to protect truly important ecological values may be reasonable even in the face of significant human health risks.

X1.9.2 The nature of risk balancing conducted as part of the risk management decisions should be fully explained as part of risk communication and should be integrated, where practical, with human health decisions at the site.

X1.10 Integration into the Overall RBCA for Chemical Releases Process (see Guide E2081)

X1.10.1 This guide is a companion document to Guide E2081, which is a document of broader scope than this guide. Users of this guide should be familiar with Guide E2081 and the overall RBCA process and should seek to integrate the respective approaches.

X1.11 Conclusion

X1.11.1 This appendix has attempted to highlight the relationship between risk assessment and risk management. The user is responsible for identifying applicable regulatory requirements and, where appropriate, working closely with the regulatory agency(s) and stakeholders. The user of this guide is directed to Guide E2081 for further information to complement the approaches outlined in this appendix.

X2. TECHNICAL POLICY DECISIONS (TPDs) IN THE Eco-RBCA PROCESS

X2.1 Purpose

X2.1.1 Technical policy decisions (TPDs) are an important part of the Eco-RBCA process. The purpose of this appendix is to provide a general understanding of TPDs and how they operate throughout the Eco-RBCA process. While it is not within the scope of this appendix to identify specific TPDs appropriate for any given site, the appendix provides additional insight into their identification, adaptation, and application in the context of RBCA.

X2.1.2 The user of this guide should recognize that the examples of TPDs used in this appendix are intended to aid the general understanding of TPD concept and are not provided as mandatory guidance. There is no intent on the part of the authors to advocate the use of any specific TPD.

X2.1.3 The user is responsible for identifying points in an Eco-RBCA program that require a TPD, understand the context in which they are operating, and use appropriate professional judgement in establishing any TPD for specific application. If the user is operating under a regulatory framework, many TPD selections may be predetermined. Even so, the user is responsible for recognizing statutory or regulatory constraints associated with TPDs and seeking regulatory approval before applying them in the context of the site.

X2.2 Introduction

X2.2.1 Throughout the Eco-RBCA process, there are points where technical and policy considerations must be addressed to design an evaluation for a given site. These considerations are linked to how data are collected, analyzed, and used in making management decisions. Such considerations and their associated design decisions are key influences on the proper design and execution of Eco-RBCA. These considerations are referred to in RBCA by the term-of-art technical policy decisions (TPDs).

X2.2.2 Existing regulations, organizational policies and the best-available science provide a range of supporting information for reasonably valid TPD choices for risk assessors and risk managers. The specific choice selected will reflect both technical considerations (because some choices will have a stronger scientific basis than others) as well as policy considerations (to reflect risk management objectives).

X2.2.3 Technical policy decisions generally fall into three categories: (*1*) those that are regulatory, which are identified, may be imposed, and will not change; (*2*) those that are selfidentified and should not change unless the Eco-RBCA evaluation has a fundamental change; (*3*) and those that may change with new information or site-specific data.

X2.2.4 The TPD-related choices can be either broadly programmatic or uniquely site specific in nature. In some cases, the boundaries for these choices are mandated by statute or regulation. Commonly, these choices represent exercises of professional judgment by users or regulatory agencies involved in the Eco-RBCA process within the context of site-specific knowledge. Technical policy decisions are not equivalent to the result or decision that is reached in the Eco-RBCA process. TPDs do not dictate a particular result; rather, they address how the Eco-RBCA process to achieve useful results will be conducted.

X2.2.5 Such choices generally are associated with the five general categories of activities in any Eco-RCBA program: (*1*) planning, (*2*) data and information gathering, (*3*) evaluation, (*4*) decision points and (*5*) response actions. Certain types or categories of TPDs can be generally associated with these Eco-RBCA activities. Examples of these associations are shown in Table X2.1.

X2.2.6 Technical policy decisions are typically identified, negotiated (if appropriate), and documented early in the Eco-RBCA process. Additionally, TPDs may need to be reevaluated each time the Eco-RBCA evaluation proceeds through an iteration of an existing tier or progresses to a new tier. Various policy decisions will need to be made regarding the technical aspects of Eco-RBCA. These TPDs may cover both the philosophical and methodological aspects, from what values to protect to exactly how an ERA will be performed. TPDs may affect every stage of the process, from the initial site assessment to development of the remedy. It is the responsibility of the user of the Eco-RBCA guide to identify appropriate technical considerations and define the associated TPDs. Both the RBCA (see Guide E2081) and Eco-RBCA processes

TABLE X2.1 Examples of Technical Policy Decision (TPDs) Categories

NOTE 1—Although these possible TPDs are identified with the specific stages of the Eco-RBCA process, it may be appropriate to consider the TPD at other stages.

Stage	Example TPD
Planning	Stakeholder input required
	Site characterization data requirements specified
	Land- or water-use category requirements (current/future)
	Screening criteria
	Threatened/endangered species regulations/considerations
	Exposure pathway assessment requirements
	Endpoint selection
Risk Analysis	Data quality objectives
	Sampling/data acquisition requirements
	Analytical detection limits
	Bioavailability considerations
	Toxicity data interpretation
Risk Characterization	Uncertainty analysis requirements
	Regulatory definitions of risk
	Role of professional interpretation
Management Decisions	Cost/benefit analysis
	Stakeholder input/considerations
	Criteria of acceptable risk/impact
	Regulatory requirements (for example, cleanup criteria)
	Political/public considerations
Remedial Actions	Technical feasibility assessment
	Monitoring requirements
	Remediation objectives/requirements
	Compliance with regulatory/policy requirements

encourage user-led initiatives and appropriate stakeholder involvement in identifying TPDs and developing the Eco-RBCA program. Laws and regulations may require coordination with federal, state, tribal, and natural resource trustees on the selection of TPDs. Because of the iterative nature of the Eco-RBCA process, the five Eco-RBCA activities listed above are revisited as the user moves through the tiers of the Eco-RBCA framework. Therefore, as these categories are revisited to test planning assumptions and the need for additional data or analytical design, it is likely that the user will revisit some previous TPDs (as appropriate) and evaluate their relevance in subsequent Eco-RBCA tiers.

X2.2.7 The degree to which TPDs are dynamic or fluid in the Eco-RBCA framework will be a function of the business, regulatory and social context in which the user is operating. The flexibility of a user in making a TPD can be constrained by mandatory technical elements imbedded in organizational policy or government regulation. Flexibility in setting the TPD-related choices generally comes with greater knowledge about site-specific conditions and is essential in optimizing the ultimate response action to site-specific business, regulatory, and social contexts.

X2.3 Context Influences TPD Selection

X2.3.1 The business, regulatory, and social contexts in which an Eco-RBCA program is designed and ultimately performed will influence the considerations and choices made in response to any existing TPD. The ultimate questions to be answered relevant to any specific TPD are (*1*) Does an existing TPD apply in the context of this specific application of the Eco-RBCA process?, and (*2*) If the TPD applies, how does it effect the design and execution of Eco-RBCA in this application? Fig. X2.1 attempts to graphically represent the influence of context on the TPD-related choices, while Fig. X2.2 provides a generalized representation of the decision process for determining the applicability of a given TPD.

X2.3.2 Although there is a common framework for Eco-RBCA, how each of the steps in that framework is designed may vary depending on the site context. Some general contextual aspects that could influence TPDs would include (*1*) chemical, (*2*) ecological, (*3*) socio-economic, and (*4*) regulatory or organizational. Some examples of these contextual influences are discussed in X2.3.2.1 – X2.3.2.4.

X2.3.2.1 *Chemical Context: Types and Source of COCs*— The type of contamination and the associated source have a major influence on decisions about site assessment, analytical methods to be used, and data quality considerations. The physical-chemical properties of a chemical will be good predictors of its behavior in the environment. An example of how chemical context could influence a TPD would be the selection of an appropriate exposure model. A compound that

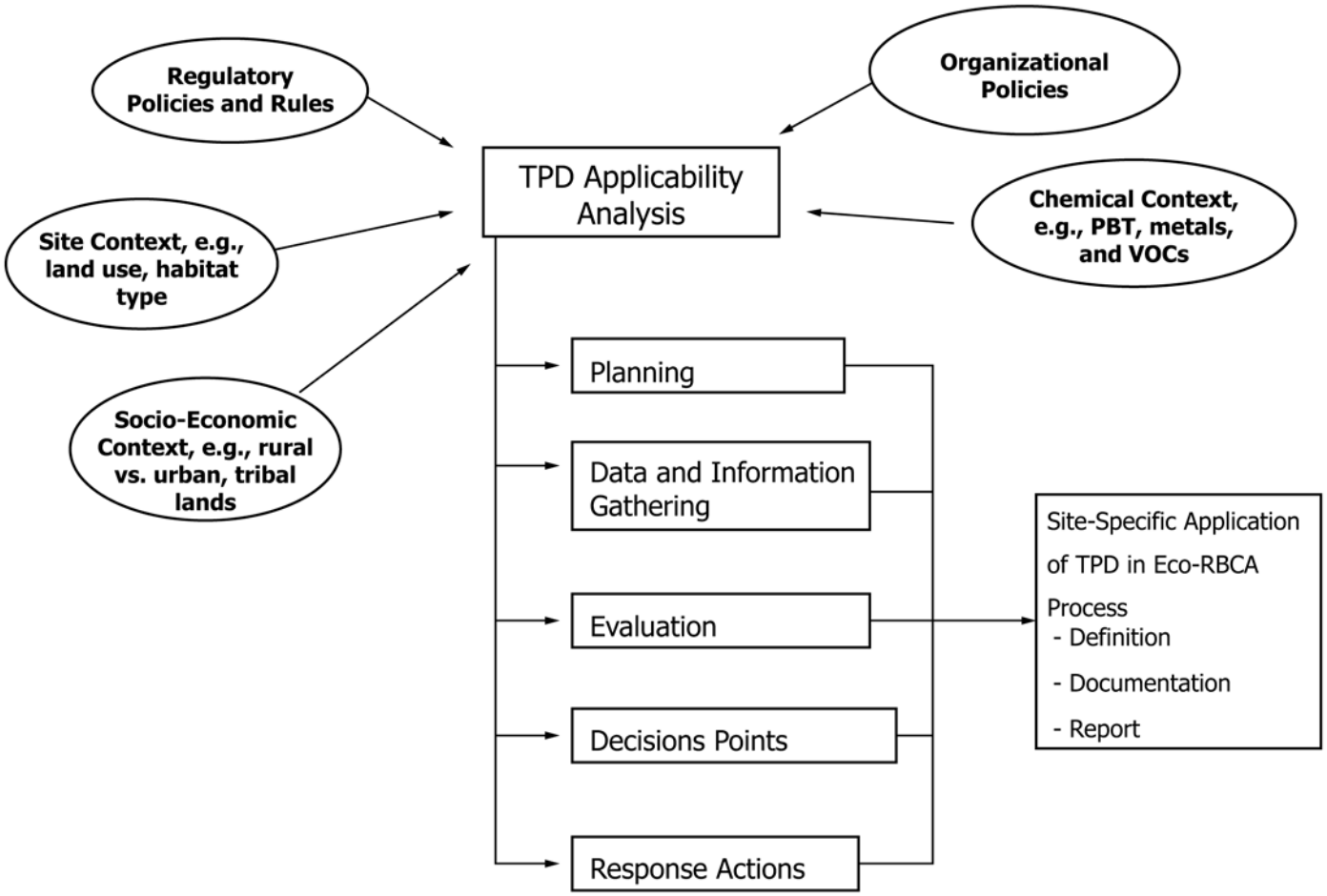

FIG. X2.1 Influence of Context on TPD Applicability

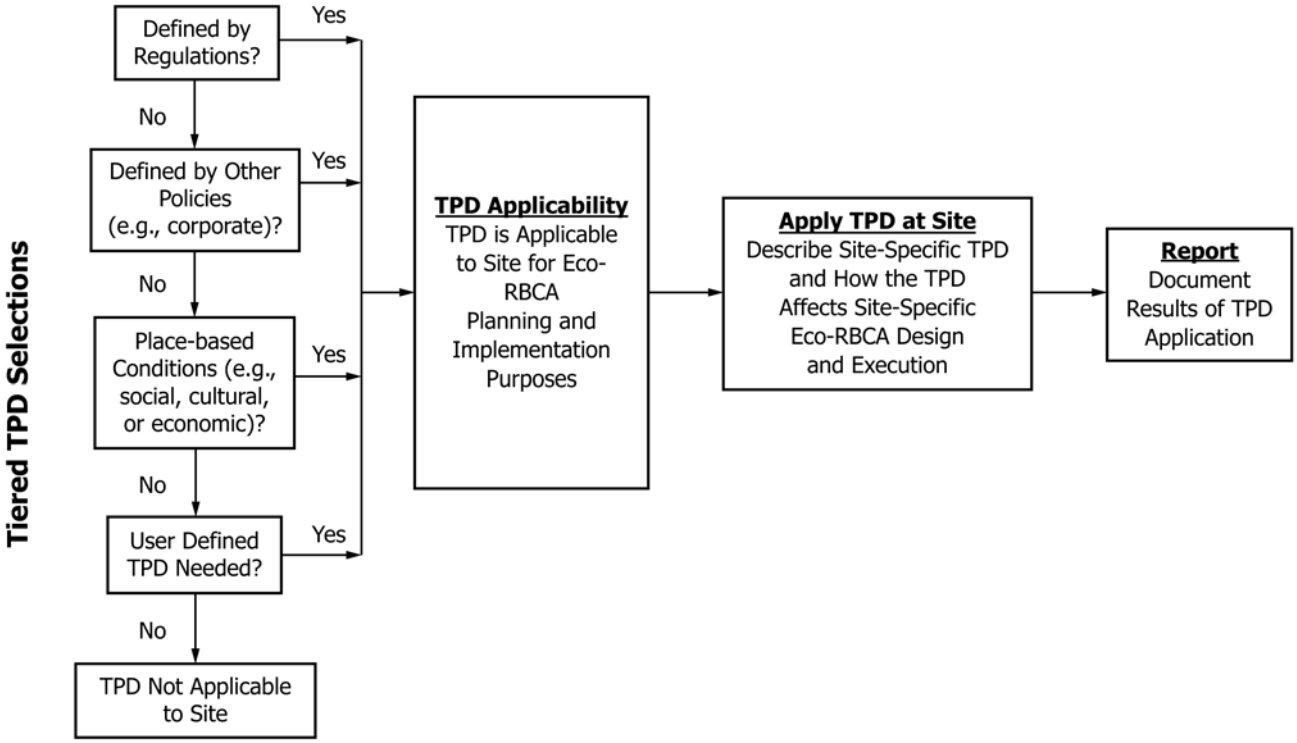

FIG. X2.2 Technical Policy Decision Applicability Flowchart

is expected to have significant potential for persistence in the environment will more likely be a bioaccumulation concern and require the use of food chain modeling. Conversely, a chemical with less persistence may only require a simple first-order exposure assessment. In this case, the physical-chemical attributes of COCs (see 3.1.6) influence the choice of the exposure assessment method.

X2.3.2.2 *Site Condition Context: Regional Ecological Conditions*—The type of environment in which the Eco-RBCA framework is being applied will be a major influence on the technical design and execution of any ERA. Even within a single ecoregion, differences in local habitat will result in a number of technical policy differences, even for similar sites. For example, as the habitat changes, the receptors at risk will differ, the media sampled and analytical methods may change, and the effect and exposure models selected may differ. All of these technical decisions in the design of any assessment of ecological risk would come under the umbrella of setting TPDs.

X2.3.2.3 *Socio-Economic Context: Local Community Values*—The focus of any ERA is the ecological resource that is valued. The ultimate decision to be tested is whether this resource is under significant environmental stress and a response action is needed. For any given site, there are often many possible ways to see value. Therefore, very similar types of contaminated sites may be valued differently and this will result in different outcomes to TPDs. For example, a river might be valued by a community as a recreational resource at the same time it is valued as a commercial fishery and a drinking water source. Which of these values is selected to drive the assessment could make a difference in the types of data and models that will be used to assess the need for a response action.

X2.3.2.4 *Regulatory or Organizational Context: Controlling Regulatory Authority and Existing Regulations*—Whether the execution of an Eco-RBCA program is voluntary or falls under a specific regulatory program will likely influence the selection of TPDs for the site. Regulatory programs may have imbedded TPDs that have statutory or regulatory public review requirements in order to modify them. For example, some TPDs are initiated only on the occasion that special or protected species or habitats are present. The presence of a protected species could influence the choice and priority of receptors selected in assessing risk and to what level of biological organization the protection goals are set. As well, there may be differences in technical policies for the same regulatory program when administered at different level of government, such as regional verses national administration. The user of this standard should review appropriate regulatory guidance for their category of activity and, as needed, contact regulators to clarify technical policies and to negotiate any site-specific exceptions.

Eco-RBCA Activity Categories

X2.4 As previously stated, there are five general categories of activities that occur at each tier in any Eco-RCBA program. These categories of activity are (*1*) planning, (*2*) data and information gathering, (*3*) evaluation, (*4*) decision points, and (*5*) response actions. As the user progresses through the tiers,

these activities will be revisited and their associated TPDs may be tested, based on new site data or as more sophisticated analysis at higher tiers are performed. The user should recognize that TPD decisions might be revised when advancing to higher tiers of Eco-RBCA evaluation. What follows is a general discussion of TPDs relative to those categories of activity. Table X2.1 provides some general categories of TPDs that may be associated with these Eco-RBCA activities, while Table X2.2 provides the user with some specific examples of how TPDs may actually be applied in the context of a specific Eco-RBCA application.

X2.4.1 *Planning:*

X2.4.1.1 Planning is a critical element of the Eco-RBCA process, beginning at the initial site assessment. Through each of the tiers there are numerous technical decisions that must be made to properly design and execute an Eco-RBCA process. The identification of TPDs and their application within the context of a site evaluation starts as part of the planning of the initial site assessment. During this step, the review of available site information will be used to ultimately determine the need to perform an ERA in Tier 1.

X2.4.1.2 In building the proper context for an Eco-RBCA evaluation of a site, it may be necessary to identify and elicit local community and relevant stakeholder perspectives. The selection of relevant ecological receptors and habitats can be influenced not only by their ecological importance but also by their social and economic value to the surrounding community. The ability to use such community input may be influenced by existing organizational and regulatory TPDs.

X2.4.1.3 In the initial site assessment, the source and type of contamination is identified; the aerial extent of contamination is estimated; and potential exposure pathways, receptors and habitats are projected. Each of these preceding elements of the initial site assessment can be guided by regulatory or other organizational technical policies and result in TPDs. Definiing the extent of the initial site or study area is used to illustrate this point. When the potential for ecological harm is evaluated at a site, one of the first TPDs will often be to define the extent of the initial site or study area. In almost every case, a range of reasonable alternatives will be available. The initial study area might be selected based on:

(1) The extent of a confirmed or likely spill or other chemical release—This area may be appropriate where the purpose of the investigation is to determine the extent of the specific spill or release;

(2) An area or areas of unknown history—This area may be appropriate for an investigation mandated by legal requirements;

(3) An area or areas where it is believed that no chemical release has occurred, but confirmation is desired—This area may be appropriate for property transfers, where the purchaser desires additional, objective information; and

(4) The location of habitat for an important ecological resource—This may be appropriate where the objective of the investigation is to ensure protection of a specific resource.

X2.4.1.4 As these choices indicate, the selection of the size and location of the initial study area is not a purely technical question. Technical considerations serve to define the probable extent of the area, by eliminating some locations that are too distant or for which the possibility of a significant chemical release is sufficiently low. Within this area, a number of technical alternatives can be valid based on the management objectives for the site investigation.

X2.4.1.5 Under some regulatory regimens, appropriate conditions may be tested to ascertain the need to perform further Eco-RBCA evaluation in Tier 1. This category of TPDs is known as screening criteria (see Appendix X4). Such criteria may test adequate aerial extent of contamination, degree of contamination relative to natural levels, completeness of exposure pathways, or availability of relevant receptors of concern.

TABLE X2.2 Examples of Technical Policy Decisions (TPDs) That May Be Applicable at Various Stages of the Eco-RBCA Process

NOTE 1—Although these possible TPDs are identified with the specific stages of the Eco-RBCA process, it may be appropriate to consider the TPD at other stages.

Eco-RBCA Stage	TPD Category	Explanation	Example TPD
Planning	Screening Criteria (see Appendix X4)	Regulations may provide criteria that allow exclusion of some sites from assessment and corrective action.	Spatial exclusion or site size (for example, 4047 m) is sometime used as a criteria to decide whether assessment is appropriate. Sites that have areas less than the criteria do not require assessment.
Data and Information Gathering	Data Quality Objectives (DQOs)	Regulations or guidelines may specify that DQOs be developed.	DQOs may be set such that the results of quality control analysis be within a specified limit (for example, 10 %). Data not meeting this DQO are not acceptable for use.
Evaluation (of Risk)	Risk Quantitation Model	Tools such as hazard indices, and deterministic and probabilistic models, can be used to quantify risk	At Tier 1, a hazard quotient (HQ) can be used as the basis to define acceptable risk. Exceedance of the HQ (for example, >1), may indicate that risk is greater than acceptable.
Decision Point	Regulatory Requirements	Regulations may drive the decision point.	Regulations specifying special protection for rare and endangered species (for example, U.S. Endangered Species Act) will influence what decisions are required based on the occurrence of endangered species at the site.
Response Action	Remediation Objectives	The implementation of the response action needs to be based on the remedial action objectives.	The corporate policy may be that all free product resulting from releases during operations will be removed from the site; therefore, interim action is necessary to address a site spill.

For example, under some regulatory regimens, an area of contamination less than one acre (0.4046 hectare) in size under a parking lot in an urban setting that is not in communication with surface water would be excluded from the need to perform an ERA. The user is cautioned that the use of such screening criteria in a regulatory context will be most useful if it has a regulatory policy in place. A scientifically sound rationale will be required to use exclusion criteria outside of an existing regulatory policy.

X2.4.1.6 As the user progresses from the initial site assessment to Tier 1, these elements will need to be more formally developed into a site conceptual model of how the COCs may migrate through the environment via exposure pathways to relevant ecological receptors and habitats. How this site conceptual model is designed may well be guided by existing TPDs. For example, a TPD may exist such that the assessment of the impact of a chemical that has a high bioaccumulation potential may need to include exposures via a food chain model. On the same site, a different COC without the propensity to accumulate through food chains may only require investigation of first-order exposures between a relevant receptor and the contaminated media. Other TPDs may exist that will prioritize evaluation of specific receptors in the evaluation which will then influence what toxicological data are relevant for the ERA. The presence of these species of special legal, regulatory, or ecological significance in a study area may not limit the ability to analyze other species, but often will influence such key components of the ERA such as the assessment endpoints or what level of risk being tested for significance.

X2.4.2 *Data and Information Gathering:*

X2.4.2.1 Gathering data related to the study site needs to be aligned with and support the analysis of risk to relevant receptors from exposures to COCs via relevant pathways. Therefore, it is important for the user to recognize that the TPDs that drove planning decisions in the initial site assessment will either directly or indirectly influence data and information gathering throughout the Eco-RBCA process.

X2.4.2.2 Information that is needed for an Eco-RBCA evaluation at a site will depend on site conditions, presence of COCs, relevant receptors and habitats, and the regulatory context. Technical guidance and protocols are readily available in the technical literature, as is regulatory guidance for any particular program. Sorting through these sources of guidance to make decisions about the quality and quantity of data and information needed will be the basis for making TPDs about data and information gathering to thoroughly assess chemical contamination at a site. These TPDs will determine such critical design elements as:

(1) The pattern and frequency of sampling to establish the extent of contamination for any COC;

(2) The protocols for sample collection, preservation, and analysis for COCs; and

(3) Methods for reporting data and for testing differences from natural conditions.

X2.4.2.3 Other information relevant to the site could include existing information on COCs relevant to their physical-chemical properties and hazard potential studies of relevance to understanding their behavior in the environment. As conflicting information on these attributes may arise, TPDs will need to be identified or created to address the proper selection among conflicting data for a specific site or regulatory regimen.

X2.4.2.4 Another category of information that needs to be gathered during the Eco-RBCA process and will likely be influenced by organizational or regulatory TPDs is that of ecological criteria. The main body of the standard recognizes three generic categories of these criteria:

(1) Relevant ecological screening criteria (RESC)—Generic, non–site-specific ecological measures or guidelines used during the Tier 1 evaluation that are determined to be applicable to relevant ecological receptors and habitats, exposure pathways, and site conditions (see 3.1.27).

(2) Site-specific ecological criteria (SSEC)—Risk-based measures or guidelines appropriate for evaluating relevant ecological receptors and habitats identified for a particular site under the Tier 2 or Tier 3 evaluations (see 3.1.37).

(3) Other relevant measurable criteria (ORMC)—Parameters used to define corrective action goals (see 3.1.22).

X2.4.2.5 The actual type and sources of data that might be acceptable for use as an RESC, SSEC, or ORMC are often predetermined in TPDs under a regulatory program. What specific value might be used will be influenced by site-specific considerations, but the set of acceptable values may be prescribed. An example of this would be the use of media-specific screening values to determine if COCs require further tiered evaluation. Multiple sources of no-effect sediment concentration values presumed to be protective for COC screening may be available, but the organization or regulatory program may have created a TPD that has either predetermined the values to be used or prioritized the use of these values.

X2.4.3 *Evaluation:*

X2.4.3.1 Evaluation as a category of activity in the Eco-RBCA process is not likely to be the source of new TPDs. Rather, evaluation is an activity where many of the TPDs identified and adapted in the planning stage will be executed. For example, a TPD for the use of exclusion criteria may have been identified in the planning phase of the initial site assessment and relevant information gathered, but the actual analysis of that data and comparison to any exclusion criteria or process would occur as an evaluation activity.

X2.4.3.2 The models or methods that were determined to be appropriate for the site to properly characterize exposure and receptor response will be performed during the evaluation phase. The risk characterization model appropriate for the type, quantity, and quality of data identified in planning and subsequently gathered will also be applied in the evaluation. For example, different regulatory regimens may have technical guidance that differs on how to perform an initial screen on specific COCs for their ecological risk potential against specific media. Making a TPD to select among those existing technical policies and gathering the appropriate data will occur prior to the evaluation activity. The actual screening of COCs and the documentation of whether to advance to further tiers will occur in the evaluation phase.

X2.4.3.3 As the user progresses to higher Eco-RBCA tiers, the evaluation methods will likely be more sophisticated,

moving from simple use of exposure and effects ratios such as hazard quotients to more sophisticated expressions of exposure and risk such as probabilistic methods. Once again, which of these approaches is selected will be based on TPDs that are consistent with existing site information, data on COCs, and the regulatory context in which the user is operating. For example, the use of probabilistic risk characterizations is precluded in some regulatory regimens. Therefore, if the user was working in such a regulatory program, a TPD would be in place to preclude the use of probabilistic methods. The user would then have to select other risk characterization models, unless an exception to that policy can be negotiated based on site-specific conditions.

X2.4.4 *Decision Points:*

X2.4.4.1 As was discussed for evaluation activities (see X2.4.3), the TPDs related to the ecological criteria upon which decisions are made and the actual types of decisions to be made will likely be identified in the planning activity for each tier in Eco-RBCA. Depending on organizational policies and regulatory context, TPDs that define the specific decision points in the site assessment and the questions or issues being addressed at those specific points may differ.

X2.4.5 *Response Actions:*

X2.4.5.1 The decision to proceed with a remedial action depends on a number of factors, including the uncertainty of the results, costs associated with proceeding to higher tiers, the feasibility of implementing the remedial action, the achievement of site management goals, and the maintenance of ecological protectiveness. The determination of the relative practicability of a given remedial action is guided by TPDs. Under some organizational or regulatory programs, presumptive remedies may be defined or a process to test their appropriateness may be prescribed.

X2.4.5.2 Since initial or intermediate response actions may occur at any tier of the Eco-RBCA process, the remedial action may have the effect on the process of sending the site back to the planning process to retest the need for any previously applied TPDs. Eliminating contamination or reducing its extent could in effect send the process back to the point of retesting screening criteria or screening COCs for the need to perform further tiered evaluation.

X2.5 Summary and Conclusions

X2.5.1 This appendix has attempted to highlight the relationship between site conditions, regulatory context, and relevant technical and socioeconomic aspects of any given site; these can affect the selection, development, and ultimate use of TPDs for site-specific planning. Examples have been provided in the context of the principle category of Eco-RBCA activities occurring within each tier.

X2.5.2 The user is again reminded that the examples in this appendix are for illustration only and are not intended as a basis for defining or selecting TPDs for a specific application. Although several topics have been discussed and examples presented, there is no intention to advocate one specific position or TPD over another. The user is responsible for working closely with the regulatory agency(s) to develop and streamline the Eco-RBCA process in a manner that establishes consensus among all of the major stakeholder groups. The user of this guide is directed to Guide E2081 for further information to complement the approaches outlined in this appendix.

X3. THE TIERED Eco-RBCA APPROACH

X3.1 *Purpose*—The purpose of this appendix is to provide the user with a basic understanding of the types of activities that can occur within each tier of the Eco-RBCA process.

X3.2 The tiered approach to Eco-RBCA is adaptable to the ecological risk assessment (ERA) process in the same way that it lends itself to human health risk assessments (HHRA) (see Guide E2081). Although HHRA and ERA proceed in a parallel manner through the RBCA process, there are differences. These differences are particularly noticeable in the early stages of the process and all stakeholders should carefully consider the technical policy decision (TPD) issues that will arise during the initial site assessment and the development of an ERA.

X3.3 The TPD of identifying potential relevant ecological receptors and habitats should be considered in the early stages of an ERA. Considerable effort above what is required for a comparable tier early in a HHRA must be made to ensure an effective and efficient site assessment that maintains the required level of ecological protectiveness throughout the process; however, it should always be borne in mind that data may be collected that will serve the needs of both the HHRA and the ERA. Integral to this is the consideration of risk management issues concurrent with the risk assessment process at each tier of evaluation.

X3.4 Each tier includes five types of activities that increase in complexity and level of effort as the evaluation progresses through the Eco-RBCA process. These activities are (*1*) planning, (*2*) data and information gathering, (*3*) evaluation, (*4*) decision point(s), and (*5*) response actions. The details of the activities and how they are implemented can vary depending on the nature and complexity of the site and the tier level. Table X3.1 presents examples of activities and issues to consider in each of these activity categories within the different tiers of the evaluation. It is important to bear in mind that many similar activities occur in more than one tier; this will depend upon the site-specific nature of the evaluation. Additionally, it must be remembered that the activities within each tier are conducted concurrent with one another. New information in one activity category must be interrelated with the other activities to bring the overall understanding of the site to as advanced a level as is practicable for the stage of the evaluation. It is highly unlikely that these activities would progress in a linear manner.

TABLE X3.1 Elements of Eco-RBCA Tiers

Tier	Planning	Data/Information Gathering	Evaluation of Data/Information	Decision Point	Response Actions
Initial Site Assessment	Coordinate with other site management activities, especially RBCA (Guide E2081) Review available site information Consider stakeholder and regulatory role Consider potential exposure pathways, receptors and habitats Identify and implement TPDs appropriate for this tier	Collect historical/existing information Identify relevant exclusion criteria (for example, scale, land use) Collect the quality and quantity of data needed to justify decision being made	Exclusion criteria comparisons	Do site conditions warrant Tier 1 evaluation? Is the site adequately characterized? Are data sufficient to make these decisions?	Remedial action program practicable? Interim remedial action appropriate? Develop remedial action program, if appropriate
Tier 1	Refine exposure pathways and receptors Consider site conceptual model development Consider stakeholder and regulatory role Set Tier 1 objectives Select screening approaches/options Identify and implement TPDs appropriate for Tier 1	Collect historical/existing data/info Sample appropriate environmental media Conduct limited habitat or receptor surveys Perform exposure pathway analysis Locate generic screening criteria (RESC and ORMC) Locate generic exposure factors for dietary exposure model calculations	Identify completed pathways and relevant ecological receptors and habitats Compare site conditions to RESC and ORMC Identify pathways and receptors to focus assessment Use quotient or similar method to assess risk	Are exposure pathways complete or potentially complete? Risk unacceptable or uncertain?	Remedial action program practicable? Interim remedial action appropriate? Develop remedial action program, if appropriate
Tier 2	Refine Tier 1 screen Refine problem formulation and site conceptual model, if appropriate Hold discussions with stakeholders and regulators, as appropriate Set Tier 2 objectives (refinement of Tier 1) Identify appropriate site specific approaches/options Identify and implement TPDs	Collect historical/existing data/info Sample appropriate environmental media Conduct exposure pathway analysis Locate site specific screening criteria (SSEC and ORMC) Identify and use site specific exposure factors for dietary exposure model calculations Use site specific toxicity values	Employ deterministic approach (usually exposure focused) Usually addresses single line of evidence Identify completed pathways and relevant ecological receptors and habitats to focus the assessment Compare site conditions to SSEC and ORMC Use quotient or similar method to assess risk	Risk unacceptable or uncertain?	Remedial action program practicable? Interim remedial action appropriate? Develop remedial action program, if appropriate
Tier 3	Formalize problem formulation and site conceptual model Hold discussions with stakeholders and regulators, as appropriate Set Tier 3 objectives Identify appropriate site specific approaches/options Identify and implement TPDs	Collect data to support measures of exposure and effect Obtain distribution information on model parameters	Conduct deterministic or probabilistic analysis Usually addresses multiple lines of evidence *In situ* studies or field conditions Quantitative analyses of uncertainty	Risk unacceptable or uncertain?	Remedial action program practicable? Interim remedial action appropriate? Develop remedial action program, if appropriate

X3.5 Early in the Eco-RBCA process, conservatism is high because of uncertainties inherent in non–site-specific data. As the site progresses through the tiered evaluation, conservatism decreases because the data become more site specific and the scope more focused; as understanding of site conditions improves, confidence increases. The progression of the evaluation through the tiered process is usually accompanied by an increasing degree of formalization that could include the conduct of a screening-level assessment or the use of formal ERA methods. Uncertainty, conservatism, data quality, and problem formulation are addressed through establishing and developing TPDs during the initial site assessment.

X3.6 The initial site assessment provides the basis for planning and scoping the need for or the approach to the ERA, or both. It is at this stage of the RBCA process that the tiered decision-making approach incorporates discussions including TPDs. This planning and scoping provides the opportunity for interactive, iterative discussions among appropriate stakeholders at both the early stages of the assessment and throughout the process, if the site proceeds into a tiered evaluation. Early in these discussions, the first components of the site conceptual model are developed and the need for an ERA determined. Steps in the early development of the site conceptual model should include consideration of the ecological significance of the risk identified. Planning and scoping also provides a mechanism by which stakeholders can agree that no reasonable risk exists, or that an ERA would not provide value added to the risk management decisions.

X4. SCREENING CRITERIA

X4.1 Introduction

X4.1.1 Screening criteria are useful tools for evaluating potential risks at a site based on readily available information. Another class of criteria, not discussed in this appendix, concerns the use of information gained early in an investigation that would lead to an immediate response action. Many states use screening criteria to determine whether a risk assessment is needed and which pathways and chemicals are important to consider. Often, these criteria include considerations of exposure pathways, the magnitude of contamination, and the use of chemical benchmarks. The use of chemical benchmarks is described in Appendix X5. The use of screening criteria varies and it is important for the ecological risk assessor to learn about approaches that apply or are acceptable at the local, state, and federal levels. For example, Massachusetts uses a Stage I assessment to judge the need for an assessment and to identify specific media and chemicals that should be considered if an assessment is judged to be warranted. Some states have formalized these screening level approaches. For example, Texas relies on a checklist for making judgements concerning the need for ecological assessment (Table X4.1). In addition, because screening criteria are intended to be simple but conservative tools, it is desirable that they be easily applied and that they err on the side of including rather than excluding sites where ecological issues might exist.

X4.1.2 Screening criteria may be applied at early stages in the RBCA process and may also be useful later in the process. The purpose of this appendix is to identify the types of criteria that are in use but not to prescribe where or how they should be applied. This appendix serves to provide ideas that can be useful starting points for developing criteria appropriate for a particular state or region of the country.

X4.2 Types of Screening Criteria or Guidelines

X4.2.1 States and other regulatory bodies have used a variety of methods either implicitly or explicitly to guide decision making regarding ecological issues associated with past, ongoing, or future activities. The following types of criteria or guidelines are common and provide a starting point for identifying how sites might be evaluated:

TABLE X4.1 Example of a Checklist for Screening (Adapted from TNRCC 2001 (13))

NOTE 1—Purpose: Determine if there is a need to perform an ecological risk assessment for a contaminated property where corrective action is being pursued.

NOTE 2—Operating Premise: All ecological exposure pathways are either incomplete or insignificant.

NOTE 3—Checklist Translation: The table of questions below is a simplification of the Tier 1 Checklist from the Texas Natural Resource Conservation Commission (TNRCC) Texas Risk Reduction Program (TRRP).

Question	Yes is the Answer	No is the Answer
1. Is there any unauthorized release to surface waters or associated sediments of the state and do natural communities routinely use surface water as valuable habitat?	Exclusion criterion not met. Initiate ERA most likely at benchmark screening phase. Also, go to Question 2 to evaluate soil pathway.	Exclusion criterion met. Go to Question 2.
2. Is the site wholly contained under impervious surfaces such as pavement?	Exclusion criterion met. ERA not needed unless site conditions change.	Exclusion criterion met. Go to Question 3.
3. Is the contamination wholly contained under the plant root zone (below 5 ft (1.52 m) in Texas)?	Exclusion criterion met. ERA not needed unless site conditions change.	Exclusion criterion not met. Go to Question 4 to evaluate *de minimus* land area.
4. Does the contaminated property serve as habitat, foraging area, or refuge to threatened/endangered or other protected species?	Exclusion criterion not met. Initiate ERA most likely at benchmark screening phase.	Exclusion criterion met. Go to Question 5.
5. Does similar but unimpacted habitat exist within a 0.5-mile (0.804 km) radius of the contaminated property?	Exclusion criterion not met. Initiate ERA most likely at benchmark screening phase.	Exclusion criterion met. Go to Question 6.
6. Is the affected property within 0.25 miles (0.402 km) of sensitive wildlife areas (for example, rookeries, preserves, management areas)?	Exclusion criterion not met. Initiate ERA most likely at benchmark screening phase.	Exclusion criterion met. Go to Question 7.
7. Is the contamination areas less than *de minimus* acreage (1 acre (0.4046 hectare) in Texas) and expected to remain so?	*De minimus* exclusion criterion met. ERA not needed unless site conditions change.	*De minimus* exclusion criterion not met. Initiate ERA, most likely at benchmark screening phase.

X4.2.1.1 Environmental performance criteria,

X4.2.1.2 Proximity of release to relevant ecological receptors and habitats,

X4.2.1.3 Presence of physical barriers that limit exposure,

X4.2.1.4 Media-specific chemical benchmarks or screening levels,

X4.2.1.5 Identification of conditions that warrant an immediate response action, and

X4.2.1.6 Use of field observations and toxicity tests in screening-level assessments.

X4.3 Environmental Performance Criteria

X4.3.1 Certain activities with the potential for environmental harm are regulated using performance criteria that are established *a priori* by federal, state, or local agencies. These criteria are intended to set the bounds on what is acceptable for a specific action or type of action. Where agencies have established such criteria and where sites meet the conditions for application of such criteria, they can serve as a basis for judging the acceptability of environmental harm or conditions associated with the particular actions. Examples include (*1*) conditions judged acceptable, based on environmental impact reports (EIRs) or environmental impact statements (EISs); and (*2*) conditions covered by regulatory permits. In these cases, regulatory agencies seek to ensure that the action will not cause unacceptable environment harm. Thus, these examples provide a basis for identifying what is or what is not unacceptable. Such decisions are specific to the particular regulatory program, some of which may not be strictly risk based. Nevertheless, they reflect decisions that have been made. Caution should be exercised in the application of performance criteria as screening criteria. Typically, they are intended for specific sets of conditions and are covered by an agency's technical policy decisions or regulations. If a site does not meet these conditions, available performance criteria may not be appropriate. In such cases, it is important to check with the appropriate regulatory agencies to determine whether available performance criteria could be applied.

X4.3.2 Environmental impact reports, or EISs, serve as regulatory tools to evaluate proposed actions with the potential for impacting or harming the environment. For example, proposed facility siting, mining, use of renewable natural resources, and construction of highways generally often require an EIR or EIS. Decisions to permit the actions involve weighing benefits against costs. The potential for environmental harm is a factor in the decision and the acceptability of that risk is judged within the context of the benefits and costs of the proposed action. Once the action is implemented, the resultant environmental conditions can be judged against those that were considered acceptable within the context of the decision. The EIR, EIS, or project-specific permits serve as bases for making these evaluations. Monitoring may be employed during and following project implementation to determine if environmental conditions are within acceptable bounds.

X4.3.3 Regulatory permits or registrations cover many activities with the potential for environmental harm. Examples include discharges to water, atmospheric emissions, applications of agricultural chemicals, forest management, and waste disposal. General or project-specific environmental permits are issued where it is demonstrated that these activities will not cause unacceptable environmental harm. This reflects a risk management decision for those specific actions. The performance of the activity is judged against permit limits through various monitoring and inspection programs. The bases for the permits and the permit limits provide the screening criteria for judging the acceptability of the permitted activity. Permit criteria may include (*1*) narrative descriptions related to the ability of land or water to support particular ecological functions, (*2*) concentration criteria, (*3*) toxicological criteria, and (*4*) size criteria (for example, mixing zones, mass of emissions). Permit criteria may be revisited from time to time to ensure that they remain applicable and that environmental harm is within acceptable bounds.

X4.4 Proximity to Relevant Ecological Receptors or Habitats, or Both

X4.4.1 Many agencies consider the site setting and proximity to ecological receptors or habitats, or both, when considering the need for a formal ecological assessment. In order to apply such screening criteria, consideration must be given to how to recognize if ecological receptors or habitats are present and how to judge proximity. Proximity needs to be judged on a chemical/material, transport pathway, setting, and volume basis. This can sometimes be informed by sampling. Experience gained from spills with similar characteristics (for example, petroleum spills from service stations), can serve to guide judgements concerning proximity. It should be noted that proximity can also be influenced by the presence of conduits that could convey material from a source to an ecological receptor. If conduits currently exist or existed previously to convey contaminated material to an ecological receptor, media sampling should be performed as appropriate.

X4.4.2 Identifying receptors and habitats for screening-level analysis should be consistent with the concept that these are the ecological resources that are to be protected at the site. Identification of receptors and habitats is ultimately a technical policy decision that may come from various federal and state regulations governing environmental resources, and appropriate agencies should be contacted to confirm the chosen relevant receptors and habitats for a given site.

X4.4.3 Comprehensive assessments of receptors and habitats is usually beyond the scope of a screening-level analysis. Instead, for the purpose of site screening, it is desirable to have relatively simple methods for determining if receptors and habitats potentially exist at or near the site. This can be accomplished by using checklists that include the major categories of species, habitats, or ecosystems known to be important regionally or that are specifically identified for protection by resource agencies. Receptors often listed by resource agencies include (*1*) rare, threatened, or endangered species, (*2*) ecologically important species, and (*3*) recreationally or commercially important species. Habitats listed usually include (*1*) wetlands; (*2*) aquatic habitats such as streams, rivers, lakes, and estuaries; (*3*) forests and other ecologically important terrestrial habitats; and (*4*) habitats that have been designated as sensitive or special interest. Table X4.2 provides

TABLE X4.2 Example List for Receptors and Habitats

NOTE 1—If the answer to any one question is Yes, go to pathway evaluation (Table X4.3).

NOTE 2—If the answer to all questions is No, no further action is required.

Question	Yes/No
Are wetland habitats such as marshes, swamps, or tidal flats on or near the site?	
Are aquatic habitats such as rivers, lakes, or streams on or near the site?	
Are forested habitats on or near the site?	
Are grassland habitats on or near the site?	
Are there federal or state rare, threatened, or endangered species on or near the site?	
Are there one or more sensitive environments, such as critical habitat for endangered or threatened species, a national park, or a national or state wildlife refuge on or near the site?	
Are there local or regional receptor or habitat concerns that may need to be addressed?	

an example checklist that reflects these broad categories. The example checklist includes ecosystems that are commonly identified for protection. Ecologically, recreationally, and commercially important species could live in one or more of the listed ecosystems and therefore they are not explicitly included in the checklist. This simplifies site screening. These important species would typically be considered in a quantitative ecological assessment, if needed. Site characterization information can be helpful for screening include:

X4.4.3.1 Surface area of the site (square kilometres, acres, hectares, square miles, square feet) and its present use (heavy industrial, light industrial, urban, residential, rural);

X4.4.3.2 Land use surrounding the site;

X4.4.3.3 Topography of the site;

X4.4.3.4 Presence of sensitive environments or species on or near the site (for example, parks, wildlife refuges, or preserves);

X4.4.3.5 Degree of site disturbance (for example, erosion, agriculture, mining, soil moving equipment, or natural events);

X4.4.3.6 Evident signs of a chemical release (odor, sheen, slick);

X4.4.3.7 Percentage of the site that is terrestrial, aquatic, or wetland;

X4.4.3.8 Accurate site maps indicating features such as structures and sampling locations; and

X4.4.3.9 Past and future uses of the site.

X4.4.4 Operational units and areas including permitted and properly operating waste disposal units are typically not considered habitats as defined here. These areas are usually judged to be in industrial or commercial use and not intended to serve as valued ecological entities. Some states also provide guidance on what types of receptors might be excluded from site screening. For example, Massachusetts guidance states: "Adverse effects on past and opportunistic species that populate an area because of artificial conditions ... do not make appropriate subjects for MCP Environmental Risk Characterization." Examples of such species may include house mice, Norway rats, and pigeons in populated areas (**14**). Ecological risk assessments in the United States typically exclude domestic species; however, British Columbia does include these animals in their guidance.

X4.4.5 Receptors and habitats that may be present at a site can be identified by direct observations or contacting local or regional natural resource agencies, or both. These efforts will depend on the site. In some cases, the presence or absence of habitats will be apparent. For example, the site may be immediately adjacent to a river or large wetland. Alternatively, it may be in the center of an industrialized area. Other sites may be present within diverse ecosystems and a biological reconnaissance survey by a knowledgeable person can be helpful to identify the types of habitats and receptors that may be present.

X4.4.6 The proximity of ecological receptors and habitats to a release site might be considered in terms of "at" or "near." "At" simply means the release site is coincident with the habitat or receptors. "Near" is more ambiguous. Some states have chosen to specify distances (for example, Rhode Island specifies 500 ft (0.152 km), while California uses 0.5 mile (0.804 km) In cases where state guidance has identified specific distances, these should be used. In the absence of state guidance, the investigator may define "near" based on site, chemical, and transport conditions. In these cases, an assessment could be made of the potential zone of influence of the site via particular transport pathways (for example, surface runoff or groundwater transport). Simple checklists can be helpful for judging proximity within a screening-level analyses. The example provided in Table X4.3 can help the user identify and consider possible pathways.

X4.4.7 *Spatial and Temporal Scales as Screening Criteria*—The concepts of spatial and temporal scales are widely discussed in ecological assessment guidance and literature both for determining if potentially significant exposure conditions exist (**14**,**15**) and for determining if risk estimates are ecologically significant (**16**,**17**,**7**). Issues related to spatial and temporal scales should be discussed during the site management dialog that should occur at the onset of the ecological assessment process. This is further discussed in Appendix X1 on risk management. A third scale that may be important as a screening criterion is the magnitude of the stress. This may be reflected either as a concentration or a mass of chemical.

X4.4.7.1 Spatial scales of exposure might be considered during screening as well as throughout the rest of the tiered assessment process. Space or size of a contaminated area is directly related to the potential for ecological exposure. However, the scale of local populations also can vary from one species to the next. Ecological risk assessments may be conducted at the individual level, the population level, the community level, or the ecosystem level. A consideration of spatial scale can help focus an ecological assessment or

TABLE X4.3 Example List of Exposure Pathways

NOTE 1—If the answer to questions 1, 2, 3, 4, or 5 is Yes, further assessment may be required.

NOTE 2—If the answer to questions 1, 2, 3, 4, and 5 is No, no further action is appropriate.

Question	Yes/No
1. Could chemicals reach receptors via groundwater? (Check Yes if you answer Yes to Questions a, b, and c)	
a. Can chemicals leach or dissolve to groundwater?	
b. Are chemicals mobile in groundwater?	
c. Does groundwater discharge into relevant ecological receptor habitats?	
2. Could chemicals reach receptors via migration of nonaqueous phase liquids (NAPL)? (Check Yes if you answer Yes to Questions a and b, or a and c)	
a. Is NAPL present at the site?	
b. Is NAPL migrating toward relevant ecological receptors?	
c. Could NAPL discharge contact relevant receptors or their habitat?	
3. Could chemicals reach receptors via runoff? (Check Yes if you answer Yes to Questions a, b, and c)	
a. Are chemicals present in surface soils?	
b. Can chemicals be leached from or eroded with surface soils?	
c. Is there a relevant receptor habitat located down-gradient of the eroded surface soil?	
4. Could chemicals reach receptors via direct contact? (Check Yes if you answer Yes to a and b)	
a. Is a receptor located or using the area where the chemical exists?	
b. Is the location of the contamination such that the receptor could contact it?	
5. Are there visible indications of stressed receptors or habitats on or near the site that may be a result of a chemical release?	

provide a basis for determining that an ecological assessment is not needed for a site. Spatial scale can be useful as a screening criterion in conjunction with other considerations, such as the valued ecological resources that may be present at the site, the likelihood for contaminant migration from the site, the proximity to a valued or sensitive ecological habitats, temporal scale, and land use.

X4.4.7.2 Ecological receptors and habitats respond to exposures at various spatial scales. For example, plant species are nonmobile and individuals in plant populations experience exposure at small spatial scales (for example, the root diameter of the individual plant). Populations of plants can cover broader areas (for example, a few to thousands of square kilometers or acres). Animal species may be characterized in terms of breeding areas, foraging areas, territories, spatial extent of local populations, and spatial extent of metapopulations. The region occupied by animals is often stated in terms of a home range. Habitats are also often characterized in terms of their size. Because there may be limited data at the screening-level stage of an analysis and because there could be substantial heterogeneity in exposure, it is common to use the maximum concentration of a chemical for screening media.

X4.4.7.3 Spatial scales are frequently described in terms related to the physical dimensions of the exposed areas (for example, square kilometers or acres of habitat or territory, or kilometres of shoreline or stream bed) and the percent of a particular habitat, territory, or area occupied by local populations. These scales give different perspectives on the nature of exposure. For example, small areas based on physical dimensions (that is, kilometres or acres) can be ecologically important if they are a critical habitat for reproduction and foraging of animals. Expressing exposure as incremental impacts (that is, percentages) of these habitats can provide insight into the magnitude of the spatial extent of exposure for such areas. This is especially useful when the habitat or area is critical to a particular biological function for the population (for example, breeding or foraging) or when the habitat has been given special status by natural resource agencies.

X4.4.7.4 Ecological risks to ecological receptors are often evaluated at the population level, although the supporting information is often developed for individuals. Local populations of fish and wildlife consist of individual organisms distributed throughout their habitats. The spatial distribution of these individuals reflects the nature of the habitats and the behavior of the species. It follows that the greater the exposed habitat, the more likely that individuals in the population may experience exposure. The exceptions to population level assessments include threatened or endangered species, or both. Risks to individuals of threatened or endangered species are generally considered to pose risks to the populations of these animals or plants.

X4.4.7.5 The areas occupied by individual organisms and populations of organisms vary among species. Therefore, when considering the spatial extent of exposure for species, it is important to know how that species makes use of the environment. Examples of species-specific information related to spatial scales include foraging areas, breeding areas, areas where individuals may congregate, and areas over which local populations are distributed. Some of this information is available in literature reviews such as U.S. EPA's Wildlife Exposure Factors Handbook (**18**). Knowledge of the aerial distributions of individual wildlife species provides insight into spatial scales for characterizing exposures. Examples of spatial scales that might be important for assessing risk to ecological receptors are listed in Table X4.4. Care must be taken in identifying spatial scales relevant to the site because the spatial scale information presented in the table and supporting text implies that certain small areas of habitat do not support local populations of wildlife. While such areas individually may be unable to support a population, several together (especially if linked by corridors) can support a population. Too often, the small-area argument is used as an excuse to ignore habitat. This rationalization, is misapplied, could lead to loss of habitat through cumulative impact. The spatial scale issue and the habitat quality issue need to be considered in the context of the surrounding landscape.

TABLE X4.4 Example of Spatial Scales

Spatial Scale	Description
Small areas (< 2 acres (0.809 hectares) or < 100 yd (91.44 m))	May contain individual foraging and breeding areas of small mammals, birds, herpetofauna, and fish; however, this spatial scale usually does not support local populations of wildlife. There may be small areas that are special habitats, for example vernal pools or areas that support specific species. These would need to be identified when making judgements about scale.
Moderate areas (2 to 20 acres (0.809 to 8.093 hectares) or 0.06 to 0.5 miles (0.096 to 0.804 km))	In addition to the description for the small areas, this spatial scale may contain individual foraging and breeding areas for medium-sized mammals and birds. This scale is also large enough to include local populations of small mammals, birds, fish, and herpetofauna.
Large areas (20 to 200 acres (8.093 to 80.93 hectares) or 0.5 to 5 miles (0.804 to 8.04 km))	In addition to the description for the moderate areas, this spatial scale may contain individual foraging and breeding areas for medium-sized mammals and birds; these scales are also large enough to include local populations of small mammals, birds, fish, amphibian, and reptile species.
Larger areas (200 to 2000 acres (8.09 to 80.93 hectares) or 5 to 50 miles (8.04 to 80.4 km))	In addition to the description for the large areas, this spatial scale may contain individual foraging and breeding areas for larger wildlife and birds of prey; these scales are also large enough to include local populations of medium-sized mammals and birds.
>2000 acres (80.93 hectares) or >50 miles (80.4 km)	This spatial scales often contain smaller ecosystems, landscapes, and local populations of larger wildlife species.

X4.4.7.6 Some states have used size as a screening criterion for terrestrial habitats early in the assessment process. Size is also an important consideration for wetland and aquatic habitats, but is typically not identified as a screening criterion. For such habitats, size of the exposed area is a consideration when evaluating risks during the tiered assessment process. The reason for this is twofold: (*1*) wetland and aquatic habitats are often identified as areas of concern for which it may not be appropriate to specify a particular size, and (*2*) releases to aquatic or wetland environments have a greater potential for spreading and affecting larger areas than is the case for a release to surface soils. When size is used as a criterion, it should be coupled with other criteria to insure that a sensitive or critical habitat is not being affected. It is also important to consider site setting when applying the criterion of site or release size.

X4.4.7.7 With regard to terrestrial (that is, soil) environments, habitat areas of less than 2 acres (0.809 hectares) are commonly considered small. Some states (for example, Massachusetts, Pennsylvania, and Washington) have suggested areas of about this size as a screening criterion when there are no areas of special concern. It is important to determine if the state or region has specified any screening criteria related to size or nature of habitats.

X4.4.7.8 Temporal scales are also important components of assessing ecological risk, because they are directly related to the potential duration of ecological exposures. Considerations of temporal scale may prove to be valuable for planning response actions or they may serve as a basis for determining if further assessment is appropriate for the site. Temporal scale can be useful as a screening criterion in conjunction with other considerations, such as the valued ecological resources that may be present at the site, the likelihood for contaminant migration from the site, the proximity to a valued or sensitive ecological habitats, spatial scale, and land use. There may be considerable uncertainty associated with judging persistence of released chemicals in the environment. Therefore, use of a criterion based on persistence should take into account this uncertainty in order to insure that it is adequately conservative for screening purposes.

X4.4.7.9 Temporal scales can vary from short term to long term, and are related to the following: (*1*) the nature of the chemical contaminants, (*2*) the manner in which the release occurred, (*3*) the physical characteristics of the environment, and (*4*) the biology of receptors that may be affected by the release. Although both short-term (that is, acute to subchronic) and long-term (that is, chronic) exposures can be harmful to ecological receptors and habitat, shorter exposure durations generally result in lower risks. Further, exposed receptors and habitats often recover more quickly from a short-term exposure than from a long-term one. This is because long-term exposure is more likely to affect sensitive life stages; the exposure could be present through one or more generations. It should be noted that short-term exposures could also occur during a sensitive life stage. The examples given in Table X4.5 provide a framework for considering exposure duration for exposure to chemical contaminants. They are based on time scales at which effects may be manifested at individual and population levels as well as potential for recovery of systems. Note that recovery could involve either structural or functional elements of the system, or both. Further, species differ in generation times and recruitment, dispersal, and immigration rates. Thus, durations of exposure can affect populations of species differently. The example ranges given above should be viewed only as a general scheme for considering temporal scales. If an assessment is focusing on a species or type of receptor, then information on the population characteristics of that species or receptor should be considered when evaluating exposure durations.

TABLE X4.5 Examples of Temporal Scales

Temporal Scale	Description
Short-term exposure (< 1 month)	This duration is long enough to produce acute effects but shorter than the generation times or growing seasons of many fish and wildlife species. Note: Short-term exposures during critical life stages can have long-term consequences on the individual and population.
Short-to-moderate-term exposure (1 month to 1 year)	This duration is long enough to produce acute effects and is also at a temporal scale that could be disruptive to reproductive success and growth of one or a few generations of fish and wildlife species. Note: Short-term exposures during critical life stages can have long-term consequences on the individual and population.
Moderate to long-term exposure (1 to 5 years)	This duration is long enough to produce acute effects and is also at a temporal scale that may include several generations of fish and wildlife species.
Long-term exposure (> 5 years)	This duration is long enough to include several generations of many fish and wildlife species and also generation times of species with longer reproductive periods (for example, larger wildlife).

X4.4.7.10 Continuous or intermittent releases can result in increased duration of exposure in comparison to a single release event of the same type of material. Therefore, a continuous release of a relatively nonpersistent material (for example, gasoline) could give rise to long-term exposure because the material is continually being supplied. A simple scheme for considering the relationship between manner of release and persistence is given in Table X4.6. Information presented in the table could be used to develop screening criteria that are based on the duration of exposure. Small highly toxic sites could also be a problem if animals are attracted to them. Care must be taken not to screen out small sites that may attract and expose individual animals to toxic chemicals.

X4.5 Ecotoxicological Screening Benchmarks

X4.5.1 Analytical data for site media may be compared to conservative ecotoxicological benchmarks in order to distinguish sites for which no further action is required from those that may require further investigation, assessment, or interim remedial action. Identifying the appropriate ecotoxicological screening benchmarks is an important part of the tiered approach to ERA. Appendix X5 of this standard address what ecotoxicological benchmarks are, what they are not, and where they can be found. Site concentration comparisons to benchmarks is also often necessary for documentation of the final remedy for corrective action sites.

X4.5.2 Care should be taken not to misuse or misapply benchmarks, as when someone applies human health criteria to ecological receptors, or sediments to soils. Some regulators wish to see an ecological evaluation conducted (preferably by a trained ecologist), a preliminary conceptual model put forth, and candidate assessment endpoints identified prior to applying benchmarks. They caution that the assessment of ecological risks involves more than just matching numbers.

TABLE X4.6 Examples of Exposure Durations

Chemical Characteristics	Continuous Release	Discrete Release
Persistent Compound	High potential for long-term exposure	Low-to-high potential for long-term exposure
Nonpersistent Compounds	Moderate-to-high potential for long-term exposure	Low potential for long-term exposure (that is, short-term exposure)

X4.6 Physical Barriers

X4.6.1 Physical barriers (walls, foundations, depth below the soil surface, and presence of blacktop) can be important in limiting exposure. Some states have considered the presence of such barriers as screening criteria (effectiveness of the barrier as a control should also be considered).

X4.7 Field Observations and Toxicity Tests as Screening Criteria

X4.7.1 At present, screening criteria based on field observations or toxicity tests do not exist. However, for sites with well-known sets of characteristics, it may eventually be possible to use biological observations or toxicity tests as screening criteria. These types of data are commonly thought of as

TABLE X4.7 Considerations for Evaluating Terrestrial Habitats

Wooded
Percentage of site that is wooded
Dominant vegetation (for example, evergreen, deciduous, mixed)
Predominant tree size at breast height (for example, <6 in. (0.152 m), 6 to 12 in. (0.152 to 0.305 m), >12 in. (0.305 m))
Evidence/observations of macroinvertebrates, reptiles or amphibians, birds, mammals
Scrub/Shrub
Percentage of site that is scrub/shrub
Dominant vegetation
Predominant height of vegetation (for example, <2 ft (0.609 m), 2 to 5 ft (0.609 to 1.52 m), >5 ft (1.52 m))
Characterize density of vegetation (for example, dense, patchy, or sparse)
Evidence/observations of macroinvertebrates, herptiles, birds, mammals
Grass/Forb
Percentage of site that is grass/forb
Dominant vegetation (for example, grasses, agricultural crops)
Predominant height of vegetation (for example, <2 ft (0.609 m), 2 to 5 ft (0.609 to 1.52 m), >5 ft (1.52 m))
Characterize density of vegetation (for example, dense, patchy, or sparse)
Evidence/observations of macroinvertebrates, herptiles, birds, mammals

TABLE X4.8 Considerations For Evaluating Aquatic Habitats

Nonflowing (Lentic)
Type of water body (for example, pond, lake)
Natural or man-made (for example, lagoon, reservoir, canal, impoundment)
Size, depth, trophic status of water body
Uses of water body (for example, recreation, flood control, drinking water)
Source water (for example, river, stream, groundwater, industrial discharge, surface water runoff)
Known/suspected chemical inputs to water body
Discharge of water to river, stream, creek, groundwater, wetlands impoundment
Nature of bottom (for example, muddy, rocky, sand, concrete)
Vegetation present (for example, submerged, emergent, floating)
Evidence/observations of benthic macroinvertebrates, fish, herptiles, birds, mammals
Obvious wetlands present
Flowing (Lotic)
Type of water body (for example, river, stream, brook, creek, intermittent stream, dry wash, arroyo)
Natural or man-made (for example, ditch or other channeled waterway)
Size, depth, flow rate of water body
Bank environment (for example, vegetated or bare, steep or gradual grade, height)
Tidal influence
Uses of water body (for example, recreation, flood control, drinking water)
Source water (for example, river, stream, groundwater, industrial discharge, surface water runoff)
Known/suspected chemical inputs to water body
Discharge of water to river, stream, creek, groundwater, wetlands impoundment
Nature of bottom (for example, muddy, rocky, sand, concrete)
Vegetation present (for example, submerged, emergent, floating)
Evidence/observations of benthic macroinvertebrates, fish, herptiles, birds, mammals
Obvious wetlands present

TABLE X4.9 Considerations For Evaluating Known or Suspected Wetland Habitats

Obvious or designated wetlands present
Wetlands suspected (for example, site adjacent to water body; in floodplain; standing water present; dark, wet soils; mud cracks; debris line; water marks)
Vegetation present at suspected wetlands (for example, submerged, emergent, scrub/shrub, wooded)
Size and depth of suspected wetlands
Source water at suspected wetlands (for example, river, stream, creek, lake, pond, groundwater, industrial discharge, surface water runoff)
Known/suspected chemical inputs to suspected wetlands
Discharge of water to river, stream, creek, estuary, groundwater, impoundment
Tidal influence
Observed biota (for example, waterfowl, deer, rodents)

higher-tier activities within Eco-RBCA. However, they have been used as tools for rapidly judging environmental quality at sites and, therefore, are discussed here. Examples include the rapid bioassessment protocols used for aquatic environments (**19**). Biosurvey techniques, such as the rapid bioassessment protocols, are best used for detecting impairments and assessing their relative severity. In using such protocols for aquatic environments, (**19**) note that once an impairment is detected, additional chemical and biological (toxicity) testing is usually necessary to identify the causative agent and its source. In suggesting this type of approach for terrestrial environments, it is suggested that the investigator initially combine chemical measurements with field observations. Bioassay methods are typically considered Tier 3 evaluation tools.

X4.8 Site Visits for Screening

X4.8.1 Site visits can provide information useful for screening and are recommended for situations where there is uncertainty concerning the need for further ecological assessment. Much of the information that can be gathered during a site visit is described above. Additional observations that are useful are provided in Tables X4.7-X4.9. An example of a checklist for

conducting a site walkover is provided in Fig. X4.1. The checklist was developed for petroleum release sites, but could be modified to apply to other sites. The EPA also provides a helpful checklist in its 1997 guidance (**17**).

Site Description

Site Name_____

Location _____

_____

County_____ City_____ State_____

Site Coordinates

Latitude_____ Longitude _____

Regional Climate Characteristics

Wind speed and direction (please specify units for wind speed) _____
Attach wind rose if available

Average temperature (specify °F or °C) _____

Average precipitation (in inches)_____
(Please specify whether this is a monthly or yearly average)

Other comments about climate (e.g, length of growing season):

Approximate area of the site (please specify units)_____

Is this the first site visit? ☐ yes ☐no (**If no**, locate any reports of previous site visits.)

Date(s) of previous visit(s): _____
References for any reports: _____

The present land use on the site is:
(Check all that apply)

FIG. X4.1 Checklist for a Site Walkover at Petroleum Release Sites

☐ Urban
☐ Rural
☐ Residential
☐ Recreational
☐ Undisturbed
☐ Industrial ☐ light ☐ heavy
☐ Agricultural Crops: _____
☐ Other _____

Please describe present land use at the site, including typical human activities:

The area surrounding the site is:
(Check all that apply)

Please specify distance from the site (and units of distance) _____

☐ Urban
☐ Rural
☐ Residential
☐ Recreational
☐ Undisturbed
☐ Industrial ☐ light ☐ heavy
☐ Agricultural
Crops: _____
☐ Other _____

Please describe land use surrounding the site: _____

The past land use on the site was:
(Check all that apply)

☐ Urban
☐ Rural
☐ Residential
☐ Recreational
☐ Undisturbed
☐ Industrial ☐ light ☐ heavy
☐ Agricultural Crops: _____
☐ Other _____

Please describe past land use at the site, including activities that might/did result in petroleum releases to the environment:

FIG. X4.1 Checklist for a Site Walkover at Petroleum Release Sites *(continued)*

Do any potentially sensitive environmental areas exist adjacent to or in proximity of the site?

Ecological:

- ☐ Freshwater or marine wetlands (at or within approximately ¼ mile)
- ☐ Aquatic habitats (at or within approximately ¼ mile)
- ☐ Federal and State parks
- ☐ Grassland habitats (at or within approximately 500 feet)
- ☐ Forested habitats (at or within approximately 500 feet)
- ☐ Prairie potholes
- ☐ Salt marsh
- ☐ Critical habitats for threatened or endangered species
- ☐ Other (including on-site habitats that could attract wildlife species)

Please specify: _____

Human:

- ☐ School
- ☐ Daycare
- ☐ Nursing home
- ☐ Hospital
- ☐ Other

Please specify: _____

Please provide the source(s) of information used to identify these sensitive areas, indicate their general location on a site map, and specify their distance (and the units of distance) from the release site.

What is the source of the petroleum release?
(Check all that apply)

- ☐ pipelines
- ☐ underground storage tank
- ☐ aboveground storage tank
- ☐ pump stations
- ☐ tank farm
- ☐ Other

Please specify: _____

What is/are the suspected petroleum product(s) of concern?
(Check all that apply)

- ☐ fuel oil
- ☐ gasoline
- ☐ diesel
- ☐ kerosene
- ☐ jet fuel

FIG. X4.1 Checklist for a Site Walkover at Petroleum Release Sites *(continued)*

☐ Product, if known
Please specify: _____

How did the release(s) occur?

When did the release(s) occur?

Is there any product visible on the site? ☐ yes ☐ no

If yes, please describe:

Is there NAPL on the site? ☐ yes ☐ no

If yes, is the NAPL migrating toward receptors or habitats? ☐ yes ☐ no

Is there potential for NAPL migration in the **future?** ☐ yes ☐ no

Is there any indication of the degree of weathering of the petroleum product? ☐ **yes** ☐ **no**

If yes, please explain below:

What type of soil is generally found at the site?

☐ Sand ☐ Clay ☐ Silt

☐ Other
Please specify: _____

Is the site vegetated? ☐ yes ☐ no

If yes, please list the type of vegetation present (for example, terrestrial or aquatic) as well as more specific information (if available):

FIG. X4.1 Checklist for a Site Walkover at Petroleum Release Sites *(continued)*

Check any potential routes of off-site migration of contaminants observed at the site:

☐ Swales ☐ Storm drains ☐ Overland Runoff

☐ Other (specify)_____

If known, what is the approximate depth to the water table? _____
(Please specify units)

Have contaminants leached to groundwater? ☐ **yes** ☐ **no**

May contaminants leach to groundwater in the future? ☐ **yes** ☐ **no**

Does groundwater discharge to habitats? ☐ yes ☐ no

Is the direction of surface runoff apparent from site observations? ☐ yes ☐ no

If yes, to which of the following does surface water runoff discharge?
(Indicate all that apply)

☐ Surface water ☐ Groundwater ☐ Sewer ☐ Collection impoundment

☐ Other
Please specify:_____

Is there a navigable waterbody or tributary to a navigable waterbody? ☐ yes ☐ no

Is there a waterbody (potential aquatic habitat) on or in the vicinity of the site?

☐ yes ☐ no

If yes, specify the distance from the release site (and units of distance)_____

FIG. X4.1 Checklist for a Site Walkover at Petroleum Release Sites *(continued)*

Is there evidence of flooding? ☐ yes ☐ no

If yes, this may indicate the presence of a wetland. Specify the distance from the release site (and units of distance)_____

Is there evidence of petroleum in a water body or wetland? ☐ yes ☐ no

Summary of Observations and Site Setting

Field Sketch (optional)

Completed By_____ **Job Title** _____

Affiliation _____

Date_____

FIG. X4.1 Checklist for a Site Walkover at Petroleum Release Sites *(continued)*

X5. SELECTION AND USE OF ECOTOXICOLOGICAL BENCHMARKS

X5.1 Introduction

X5.1.1 This document is intended to assist users of risk-based corrective action for the protection of ecological resources (Eco-RBCA) in the selection and use of ecological benchmarks. An ecotoxicological benchmark (benchmark) is defined as a concentration of a chemical that is not likely to pose unacceptable adverse risks to applicable biota. Benchmarks are used in site investigations to identify chemicals that are present at concentrations that justify further risk evaluation, and to eliminate chemicals from further evaluation if they represent insignificant hazards. Eco-RBCA does not require the use of benchmarks where other information is available to evaluate the ability of a site to support the recovery and maintenance of healthy local populations and communities of biota. However, for many sites, benchmarks are useful and valuable tools for ecological risk assessment (ERA) because their use can narrow the evaluation to chemicals of significant potential ecological concern, thus saving time and resources and helping to guide the decision-making process.

X5.1.2 Benchmarks can be used in several ways in Eco-RBCA. In Tier 1, benchmarks can be used as relevant ecological screening criteria (RESC) where conservative benchmark values can be compared to site chemical constituent concentrations to establish whether or not individual constituents warrant further evaluation. Chemicals that are present at concentrations that exceed the screening benchmark values are identified as chemicals of potential concern (COPCs) and are retained for further Eco-RBCA evaluation. It is important to note that if the chemical concentration in site media (for example, soil, sediment, or water) is greater than the benchmark, it does not mean that an adverse biological effect is likely, but rather that further Eco-RBCA evaluation may be warranted.

X5.1.3 During later tiers of Eco-RBCA, site-specific benchmarks can be developed for COPCs and used as site-specific ecological criteria (SSEC). These site-specific benchmarks can be compared to site chemical concentrations to determine whether or not the individual chemical constituent poses unacceptable risk under the specific conditions that exist at the site. Because site information is used to derive the site-specific benchmark levels, the assumptions associated with them are typically less conservative and the uncertainty is typically less than with screening-level benchmarks.

X5.2 Objectives and Use of Appendix

X5.2.1 This appendix is intended to provide the user with an overview of ecotoxicological benchmarks. Based on this appendix, the user should gain an understanding of:

X5.2.1.1 What ecotoxicological benchmarks are,

X5.2.1.2 How ecotoxicological benchmarks are obtained and derived,

X5.2.1.3 Where to find published ecotoxicological benchmarks,

X5.2.1.4 How to effectively use benchmarks to facilitate Eco-RBCA,

X5.2.1.5 The potential limitations of ecotoxicological benchmarks, and

X5.2.1.6 How to derive screening-level (Tier 1) and site-specific (Tier 2) benchmarks.

X5.3 Intended Audience and Usage

X5.3.1 This appendix is intended for those parties that are using Guide E2205. It is envisioned that users of this appendix will include responsible parties and their consultants, regulatory personnel, project managers, and other stakeholders. This appendix may also be used by persons wanting to gain an understanding of benchmarks and their role in Eco-RBCA and ERA.

X5.3.2 Benchmark values are not included in this document. Instead, sources of published benchmarks are identified as examples of those benchmarks that are currently available for use (see section X5.12). Benchmark values are often revised and updated as additional information becomes available; therefore, users of this appendix should seek the appropriate benchmarks to meet their needs. The inclusion of benchmark sources in section X5.12 should not be construed as an endorsement as to the appropriateness of these values. In addition, steps that may be used to derive screening-level and site-specific benchmarks are included in this appendix (see sections X5.10 and X5.11, respectively). Applicable benchmarks for chemicals of interest will vary, based on site-specific factors including technical policy decisions, regulator's and other stakeholder's acceptance, ecological receptors, media of interest, and site conditions.

X5.4 Benchmark Definition

X5.4.1 For the purpose of Eco-RBCA, a benchmark is defined as the concentration of a chemical in ambient media (for example, soil, water, sediment, and foods) that is believed to result in a safe dose for selected ecological receptors, therefore representing an acceptable exposure concentration with respect to these ecological receptors.

X5.4.2 Benchmark levels are lower than the threshold concentration for toxic effects. Thus, in situations where the benchmark concentrations are not exceeded, further evaluation of that chemical for impact to biota is typically not warranted.

X5.4.3 Benchmarks are tools that facilitate the decision-making process in Eco-RBCA. For Eco-RBCA, benchmarks allow for Tier 1 screening of chemicals. Ambient chemical concentrations that exceed benchmark levels are identified as COPCs and may warrant further assessment to determine whether they do in fact pose significant unacceptable risks to valued ecological resources. Alternatively, chemicals of which concentrations are less than or equal to benchmark values can be eliminated from further investigation.

X5.4.4 In general, benchmarks are conservative, since they are intended to minimize the likelihood of inappropriately screening out contaminant concentrations that may be hazardous to biota.

X5.5 Role and Rationale for Use of Benchmarks in Eco-RBCA and ERA

X5.5.1 Screening-level benchmarks can be used during Tier 1 Eco-RBCA. Benchmarks are useful in a preliminary, screening-level approach where a large number of chemical constituents may be present. Individual chemical constituents present at a site may be eliminated from further investigation and action by comparison of each site-specific constituent concentration to appropriate benchmark values. The use of published screening-level benchmarks (sometimes referred to as generic benchmarks) during Tier 1 assessments can save considerable time and effort that would otherwise be required to develop equivalent values for individual sites.

X5.5.2 During Eco-RBCA Tier 2 assessments, site information (for example, site chemistry, bioavailability, or toxicity test results) can by used to establish site-specific benchmarks or refine generic benchmarks. Site-specific benchmarks are typically less conservative than screening benchmarks since there is a greater reliance on site-specific information, and therefore, less uncertainty associated with the benchmark values.

X5.5.3 *Inappropriate Applications of Benchmarks*

X5.5.3.1 Screening benchmarks are not appropriate to be used as site-specific cleanup standards, triggers for remediation, or definitive indicators of level or type of risk. The inappropriate application of screening benchmarks as site-specific cleanup standards or triggers for remediation may result in expenditure of effort and resources beyond that necessary to protect valued ecological resources. Due to the conservative nature of screening benchmarks, their application as remedial goals could stipulate cleanup of trivial risks and potentially result in additional, unnecessary environmental damage and liability. However, in lieu of deriving a site-specific cleanup level, the responsible party may elect to use benchmark values as the cleanup level even though these values may require remediation beyond that needed to be protective of ecological receptors.

X5.6 Types of Benchmarks

X5.6.1 In Eco-RBCA, benchmarks are categorized as either screening-level or site-specific benchmarks. The screening benchmarks are generic in the sense that they are broadly applicable to many sites within media and receptor groups. In contrast, site-specific benchmarks are applicable to a much narrower range of conditions associated with a specific site and are applied to Tier 2 or Tier 3 Eco-RBCA.

X5.6.2 Published compilations of screening benchmarks are available for a variety of chemicals. Screening benchmarks are typically grouped based on either exposure route (for example, dermal or diet) or ambient media (for example, surface water, sediment, or soil) or on ecological receptor group (for example, plants, fish, birds, or mammals). For example, benchmarks have been developed by **(20)** for sediment-associated biota. Some currently available compilations of published screening benchmarks are identified in section X5.12.

X5.6.3 Regulatory criteria are a type of generic benchmark that are sometimes used as screening-level benchmarks. Regulatory benchmarks are numerical values used in various federal and state regulatory programs that are typically intended to be protective of a diverse range of ecological receptors, sensitive life stages, and species of varying sensitivity. Typically, regulatory benchmarks cover a broad range of exposure conditions for a given medium. For example, the Environmental Protection Agency's National Recommended Water Quality Criteria (NRWQC) are regulatory criteria that can be applied as benchmarks for surface waters for the protection of aquatic life. A strength of regulatory benchmarks is that they are readily and broadly accepted by regulatory agencies. However, regulatory benchmarks may also have potential limitations. For instance, because they are intended to be broadly protective, they may be too conservative or overly protective in specific applications. Alternatively, they may be underprotective of unusually sensitive species, and they do not account for additive effects of similarly acting chemicals in mixture or bioaccumulation in most cases.

X5.6.4 In general, regulatory benchmarks are not appropriate in higher Eco-RBCA tiers, where risk-based exposure limits are derived for specific ecological receptors. An exposure concentration that exceeds a regulatory benchmark does not necessarily indicate imminent threat or unacceptable risks. Other factors, such as temporal/spatial scale and site-specific conditions, should be considered to assess site risks. In addition, regulatory benchmarks are available for a limited number of chemicals, most of which address aquatic biota only. The user of Eco-RBCA should determine the regulatory status and acceptability of whichever benchmarks are selected to facilitate decision making.

X5.6.5 Ecotoxicological benchmarks are a type of benchmark that represents a safe or tolerated exposure or dose for a particular species of concern (in contrast, regulatory benchmarks apply to specific groups of ecological receptors). They are species specific, can address a certain life stage, can be tailored to site-specific conditions, and can reflect stakeholder input. Some ecotoxicological benchmarks are appropriate for screening (Tier 1), while others are better suited for use during Tier 2 (or higher tiers) of the Eco-RBCA process. Ecotoxicological benchmarks should be linked to survival, growth, or reproduction endpoints indicative of population effects. Limitations of ecotoxicological benchmarks include a lack of consensus on the type of data used to derive the benchmark and the selection of appropriate endpoints and test species. Another potential limitation is that benchmarks typically do not consider the biomagnification potential of a chemical; therefore, potential risks to higher trophic organisms may not be sufficiently addressed with benchmarks for some chemicals.

X5.7 How Benchmarks Are Established

X5.7.1 No consistent or standardized approach is used to develop benchmarks. In general, published benchmark compilations include information as to how the values were derived. However, this is not always the case. Care should be taken when considering benchmarks if the methodology on which they are based is unclear. Without an understanding of how the benchmarks were derived, the user cannot be assured that they

are appropriate for a particular site and has no way to assess the uncertainty associated with their application.

X5.7.2 A variety of measurement endpoints are used to derive benchmarks. Benchmarks may be based on acute or chronic responses, or combinations of both. Appropriate endpoints for screening benchmarks include those that measure effects that are important at population, community, or ecosystem levels such as survival, growth, and reproduction. The value of these endpoints is that they are potentially ecologically significant at the level of the population or higher, and they are commonly measured and reported in toxicological studies. Suborganism level effects, such as enzyme induction or blood chemistry, may not be appropriate as endpoints for screening benchmarks.

X5.7.3 Benchmarks may be based on a particular endpoint effect, no-effect or lowest-effect concentration, or dose for a particular species (for example, no observed effect concentration (NOEC) for a particular fish species; lowest chronic value for an aquatic invertebrate species; acute values; or apparent effects threshold or AET (**21**) for a benthic invertebrate). Many of the benchmarks for wildlife are based on no observed adverse effect levels (NOAELs) or lowest observed adverse effect levels (LOAELs). Some benchmarks may incorporate an application or safety factor (frequently a factor of 5, 10, or 100) into the benchmark to account for uncertainties and limitations of the data set.

X5.7.4 Benchmarks may also be based on statistical evaluations of toxicological data. The effects range-low (ER-L), effects range-median (ER-M), threshold effect level (TEL), and probable effect level (PEL) for sediments are all based on specific percentiles of the relevant toxicological data. The ER-L and ER-M are the 10th and 50th percentiles, respectively, of media concentrations in sediment reported to be associated with some level of toxic effects (**22**). The TEL is the geometric mean of the 15th percentile of effects data and 50th percentile of no-effects data, whereas the PEL is the geometric mean of the 85th percentile of effects data and 50th percentile of no-effects data (**23**).

X5.8 Potential Limitations of Benchmarks

X5.8.1 The potential limitations of benchmarks should be recognized by the user in order to effectively use benchmarks for Eco-RBCA and to avoid the misuse of benchmarks. Potential limitations include:

X5.8.1.1 No consistent or standardized approach for deriving benchmarks;

X5.8.1.2 Lack of consensus of use of benchmarks;

X5.8.1.3 Quality and accuracy of data used to derive benchmarks varies;

X5.8.1.4 Degree of conservatism and assumptions varies;

X5.8.1.5 Inconsistent use of uncertainty factors;

X5.8.1.6 Effects of data extrapolation techniques are unknown;

X5.8.1.7 Not applicable to mixtures of chemicals;

X5.8.1.8 Benchmarks may not be appropriate for the purpose of assessing baseline ecological risks or for establishing remedial goals;

X5.8.1.9 Site-specific conditions are typically not considered;

X5.8.1.10 Benchmarks not available for many receptors, media, and chemicals;

X5.8.1.11 Limited availability of regulatory-approved benchmarks;

X5.8.1.12 Benchmarks are limited to conditions of the test regimes chosen by the scientist; and

X5.8.1.13 Inadequate documentation as to how the benchmarks were derived or how they are intended to be used.

X5.9 Consideration for Selecting and Using Benchmarks in Eco-RBCA

X5.9.1 There are a variety of considerations for the selection and use of benchmarks for a site. Typically, the most important considerations include background concentrations of chemical constituents, ecological relevance, data quality of benchmarks, and applicability to the site.

X5.9.2 In assessing ecological risk posed by COPCs, all sources of the chemicals in the environment should be considered in the evaluation. Potential exposures to chemicals from both the site (area of interest) and surrounding (background) areas should be considered. The background concentration of the chemical of interest refers to the level of the chemical that exists at the site and surrounding areas that is not the result of contributions from the site under investigation or activities conducted at the site.

X5.9.3 Screening benchmarks must be clearly related to the ecological attribute of the assessment endpoint. Appropriate ecological attributes are dependent on the level of organization for the endpoint of interest (for example, individual, population, or community level). Screening benchmarks for individual-level assessment endpoints should be based on measures of individual growth and survival. For population-level assessment endpoints, benchmarks should address effects that have population-level implications (for example, individual-level survival, growth, and reproduction). Community-level assessment endpoints should be evaluated using effects data expressed in terms of abundance and density, richness, evenness, and diversity. The use of sub-organism level effects (for example, enzyme induction, organ weight, or blood chemistry) as screening benchmarks should be avoided because they generally cannot be clearly related to effects at higher levels of biological organization (for example, individual, population, or community level) and therefore are unlikely to support the decision process.

X5.9.4 The quality of the data used to derive benchmarks is an important consideration when selecting benchmarks. Data quality is defined based on the validity and certainty of those toxicological test results providing the basis for a particular benchmark. However, no consistent standards currently exist for evaluating the data quality of toxicological studies specifically for use in deriving benchmarks. Consequently, data quality is unknown for many benchmarks currently used or being developed. Data quality may be addressed by using standards established by the scientific and regulatory community for toxicological testing (for example, following standard

test protocols and acceptability criteria published by USEPA (**21**,**24**,**25**), NOAA (**26**), ASTM (**27**) and OECD (**28**)).

X5.9.5 Some important considerations for assessing benchmark data quality include the following:

X5.9.5.1 *Test Protocol*—Toxicity tests should be conducted using standardized test guidelines that have been documented as providing consistently reliable test results (for example, ASTM, USEPA, and OECD guidelines).

X5.9.5.2 *Purity and Stability of Test Compound*—The purity and stability of test compound can be critical to interpreting test results for benchmark development.

X5.9.5.3 *Exposure and Dosing System*—The testing system should be clearly and completely described with respect to dose or exposure concentration, administration route, exposure and dosing schedule, and exposure and dose duration.

X5.9.5.4 *Test Subjects*—Characteristics of test subjects, such as body weight or length, age or life stage, reproductive condition, and gender should be recorded because differing characteristics could invalidate test results.

X5.9.5.5 *Controls*—Control media should be identical to the test media in all respects except the treatment variable.

X5.9.5.6 *Test Environment*—Chemical and physical parameters of the testing environment should be completely described and should adhere to required testing conditions.

X5.9.5.7 *Statistical Design*—The study should employ an appropriate number of samples and replicates, randomize treatments, ensure independence of observations, and use appropriate statistical models (**29**).

X5.9.6 It is important to understand the applicability of a specific benchmark to a particular site or situation. In order for benchmarks to be used effectively, they must be appropriate for the specific application. For small sites with only a single impacted medium, comparison to one benchmark value may be appropriate. For larger, ecologically diverse sites, more benchmark comparisons may be required. The use of inappropriate benchmarks or the inappropriate use of benchmarks can result in misguided management decisions and actions.

X5.9.7 Benchmarks are often revised based on the acquisition of additional or higher quality toxicological data. The user should make sure that the selected benchmarks are current and appropriate.

X5.10 Derivation of Screening Benchmarks for Tier 1 Eco-RBCA

X5.10.1 Screening-level benchmarks for Tier 1 Eco-RBCA are most easily obtained from published sources of benchmarks such as those identified in X5.12. However, in many instances, appropriate benchmarks for a specific chemical, media, or biological organism will not exist in the published literature. Alternatively, if published benchmarks are available, there may be sufficient uncertainty associated with the benchmarks that they cannot be assumed reliable for the intended use. In either case, it may be necessary or desirable for the user to derive or develop benchmarks for Tier 1 use.

X5.10.2 Two approaches are commonly used to derive screening benchmarks. The first and generally simplest approach is to select from published ecotoxicological studies the data that fits or qualifies for the intended use, and from this data calculate benchmarks. Possible steps for this approach as described below. For the second approach, ecotoxicological studies are conducted specifically for the purpose of generating data for the derivation of screening-level benchmarks. The second approach is less commonly used for deriving benchmarks for Tier 1 assessments, since such studies can be time and resource consuming; this level of effort is typically limited to the derivation of site-specific or Tier 2 benchmarks.

X5.10.3 *Steps for Deriving Screening Benchmarks from Published Data*—The following process may be used to derive screening benchmarks. The user should establish the appropriateness and the acceptability of whatever approach is used to derive benchmarks for the site of interest.

X5.10.3.1 *Conduct Literature Search*—A literature search is conducted to identify available ecotoxicological studies for the chemical, ecological receptors, and media of interest. A variety of literature databases, such as those identified in section X5.12.7, are available and can be used to facilitate the search. Careful planning will be required for effectively conducting a literature search. In most instances, the literature search will need to be limited by specifying (*1*) the media of interest (for example, aquatic, soil, or sediment), (*2*) species or taxa of interest, (*3*) the chemical species of ecological concern (for example, copper, copper sulfate, or copper acetate), and (*4*) toxicity endpoint of interest (for example, mortality, or reproduction).

X5.10.3.2 *Screen Literature for Acceptability*—Published studies identified in the literature search will need to be screened for acceptability for inclusion into the database. The purpose of the literature screen is to ensure that the study's data meet the minimum quality standards that are acceptable to the user. The issue of data quality is of paramount importance to the derivation of benchmarks. Examples of criteria for literature acceptability may include:

X5.10.3.2.1 Study must specify exposure as from a single chemical or potential mixture.

X5.10.3.2.2 Study must include negative controls with analysis reported.

X5.10.3.2.3 Study must include at least minimal media characterization, including pH and organic matter content.

X5.10.3.2.4 Duration of exposure must be reported.

X5.10.3.2.5 Chemical form and concentration must be reported.

X5.10.3.2.6 Ecologically relevant endpoints must be reported.

X5.10.3.3 *Compile Database*—Compile an ecotoxicological database for literature that meets the acceptance criteria. The database should containing the following kinds of information:

X5.10.3.3.1 Chemical species/form,

X5.10.3.3.2 CAS number,

X5.10.3.3.3 Exposure concentrations (mg chemical/kg soil),

X5.10.3.3.4 Metal or salt,

X5.10.3.3.5 Soil concentration measured,

X5.10.3.3.6 Laboratory or field study,

X5.10.3.3.7 Single chemical or mixture,

X5.10.3.3.8 Biological species,

X5.10.3.3.9 Life stage,

X5.10.3.3.10 Exposure duration,

X5.10.3.3.11 Measurement endpoint (for example, growth, fecundity, or mortality),

X5.10.3.3.12 Toxicity parameters (for example, NOEC or LOEC),

X5.10.3.3.13 Toxicity results (measurement), and

X5.10.3.3.14 Media characterization data (for example, texture, percent sand, silt, and clay, or pH).

X5.10.3.4 *Calculate Benchmark*—Various approaches can be used to calculate screening-level benchmarks. One approach is to calculate the benchmark as the geometric mean of the acceptable data. Section X5.7 describes the more commonly used approaches for deriving screening-level benchmarks.

X5.11 Tier 2—Derivation of Site-Specific Benchmarks

X5.11.1 Site-specific benchmarks can be derived to support Tier 2 and Tier 3 assessments. A decision should be made as to the appropriateness of developing site-specific benchmarks in cases where site chemical constituent concentration exceeds the appropriate screening-level benchmark or in instances where appropriate screening-level benchmarks are not available.

X5.11.2 The following are the steps for development of site-specific benchmarks:

X5.11.2.1 Identify relevant, site-specific species and appropriate measurable endpoints.

X5.11.2.2 Identify an appropriate dose-response test that mimics or provides information on selected endpoint. The designed experiment should isolate the effect of the compound(s) of interest and be as free as possible from confounding effects; controls should be included with all tests.

X5.11.2.3 Select an appropriate benchmark effect level.

X5.11.2.4 Conduct the study and delineate the benchmark value.

X5.11.3 Site-specific benchmarks for ecosystem function or other large-scale or interrelated endpoints, or both, are more difficult to establish. In this case, specific, measurable endpoints that may be representative of the overall ecosystem condition must still be identified. Field data rather than laboratory data may be used to derive site-specific benchmark values.

X5.12 Sources for Benchmarks and Ecotoxicological Data

X5.12.1 Currently, there are no standard nationally or internationally recognized benchmarks for all media of concern. However, a variety of readily available benchmark compilations that are commonly used for screening purposes are identified below. Additional benchmarks and compilations of benchmarks are being developed on an ongoing basis by a variety of groups. For example, the USEPA is currently leading a stakeholder-participation effort to develop benchmarks and guidelines for chemicals of concern in soil for plants, soil invertebrates, birds, and mammals.

X5.12.2 *Benchmarks for Aquatic Biota*—There are more benchmarks available for aquatic biota than for other biota, due to the large body of available data for aquatic ecotoxicity. Sources of benchmarks for aquatic biota include:

X5.12.2.1 National Recommended Water Quality Criteria (NRWQC) (**30**). Commonly use as screening benchmarks for aqueous chemical constituents. The NRWQC were not developed as benchmarks; instead they are regulatory values developed to protect most aquatic species most of the time with reasonable confidence. NRWQC are suitable as Tier 1 benchmarks in Eco-RBCA because are conservative, generic (that is, non–site-specific) concentrations below which effects are unlikely;

X5.12.2.2 Oak Ridge National Laboratory (ORNL) (**31**,**32**);

X5.12.2.3 USEPA (**33**) ;

X5.12.2.4 USEPA Hazardous Waste Identification Rule, Proposed Rule (HWIR; 1999)(see X5.14.12); and

X5.12.2.5 CCME (**34**).

X5.12.3 *Benchmarks for Sediment-Associated Biota*—Sources of benchmarks for sediment-associated biota include:

X5.12.3.1 Ontario Ministry of the Environment;

X5.12.3.2 National Sediment Quality Criteria (EPASQC1);

X5.12.3.3 USEPA Ecotox thresholds (**35**);

X5.12.3.4 Oak Ridge National Laboratory (ORNL) (Hull and Suter 1994)(see X5.14.13);

X5.12.3.5 National Ocean and Atmospheric Administration (NOAA) (**22**);

X5.12.3.6 Florida Department of Environmental Protection (**36**);

X5.12.3.7 Smith et al (**23**) ; and

X5.12.3.8 MacDonald et al (**37**).

X5.12.4 *Benchmarks for Soil Invertebrates*—Sources of benchmarks for soil invertebrates include:

X5.12.4.1 Canadian Council of Ministers of the Environment (**34**); and

X5.12.4.2 Oak Ridge National Laboratory (ORNL) (**38**,**39**).

X5.12.5 *Benchmarks for Wildlife*—Sources of benchmarks for wildlife include:

X5.12.5.1 Canadian Council of Ministers of the Environment (**34**);

X5.12.5.2 Oak Ridge National Laboratory (ORNL) (**40**,**41**); and

X5.12.5.3 USEPA (**42**).

X5.12.6 *Benchmarks for Plants*—Sources of benchmarks for plants include:

X5.12.6.1 Oak Ridge National Laboratory (ORNL) (**43**,**44**).

X5.12.7 *Benchmarks for Soil Microbial Processes*—Sources of benchmarks for soil microbial processes include:

X5.12.7.1 Oak Ridge National Laboratory (ORNL) (**44**,**39**).

X5.12.8 *Published Data and Data Bases*—Data for benchmark derivation may be acquired from the following sources:

X5.12.8.1 AQUIRE (**45**) ;

X5.12.8.2 ATSDR (Agency for Toxic Substance and Disease Registry) Toxicological Profiles;

X5.12.8.3 BIOSIS (Biological Abstracts, Inc.);

X5.12.8.4 TERRETOX (ATSDR);

X5.12.8.5 IRIS (Integrated Risk Information System, USEPA);

X5.12.8.6 National Academy of Science reports;

X5.12.8.7 PHYTOTOX (USEPA);

X5.12.8.8 POLTOX;

X5.12.8.9 RTECS (Registry of Toxic Effects of Chemical Substances, National Institute for Occupational Safety and Health);

X5.12.8.10 Current contents;

X5.12.8.11 U.S. Department of the Interior Fish and Wildlife Service Synoptic Review Series; and

X5.12.8.12 World Health Organization Environmental Criteria Reports.

X5.13 Terminology

X5.13.1 *adverse effect levels (AELs)*—chemical concentrations that result in ecologically significant impacts relevant to the maintenance or sustainability of populations (for example, fecundity, growth, or mortality).

X5.13.2 *ambient concentrations*—the measured concentration of the chemical of concern at the location of interest, resulting from the addition of an incremental concentration to a background concentration.

X5.13.3 *background concentration*—the concentration (mg/kg) of the chemical of interest in locations not impacted by chemicals from the area of interest. Pristine background concentrations are those that do not contain the chemical of interest originating from any anthropologic source.

X5.13.4 EC_{20} —a statistically or graphically estimated concentration that is expected to cause one or more specified effects (for example, decreased growth or reproduction) in 20 % of a group of organisms under specified conditions.

X5.13.5 *endpoint*—the response of the receptor.

X5.13.6 *ER-L (effects range low)*—a sediment concentration associated with an effect in 10 % of the data evaluated.

X5.13.7 *hazard quotient (HQ)*—ambient concentration or dose divided by benchmark.

X5.13.8 *LOEC*—the lowest concentration in a toxicity test that has a statistically significant adverse effect on the exposed population of test organisms as compared with the controls.

X5.13.9 *NOEC*—the highest concentration in a toxicity test that has no statistically significant adverse effect on the exposed population of test organisms as compared with the controls.

X5.13.10 *reference site*—a relatively noncontaminated site used for comparison to the area of interest.

X5.13.11 *regulatory benchmarks*—national or regional benchmarks that are intended to protect a diverse range of receptors, sensitive life stages, and species of varying sensitivity, as well as to cover a broad range of exposure conditions (for example, the USEPA) National Recommended Water Quality Criteria (NRWQC). Regulatory benchmarks are typically most applicable in Eco-RBCA to early risk-screening efforts (that is, Tier 1).

X5.13.12 *safety factor*—a multiplier applied to an observed or derived concentration to arrive at a value that is considered safe. Sometimes referred to as the uncertainty or application factor.

X5.13.13 *Tier 1*—the initial stage of an environmental evaluation for ecological impacts. In this stage, screening is conducted to determine whether the site warrants further evaluation.

X5.13.14 *Tier 2*—the second stage of an environmental evaluation for ecological impacts, for use in evaluations that do not meet the Tier 1 screening criteria. At this stage, more site-specific information is used for evaluation.

X5.13.15 *toxicological benchmarks*—toxicological benchmarks are concentrations of chemicals in ambient media that are believed to represent acceptable concentrations with respect to selected ecological receptors (**46**). They represent a safe or tolerated exposure or dose for a particular species of concern. They are species- and medium-specific, can address a certain life stage, if necessary, can be tailored to site-specific conditions (for example, an EC_{20} from a site-specific toxicity study), and can reflect stakeholder input.

X5.14 Additional Suggested Literature

X5.14.1 "Development and Application of Benchmarks in Ecological Risk Assessment," Issue Brief #46, American Industrial Health Council, 1998.

X5.14.2 "Contaminants of Concern for Effects on Sediment-Associated Biota," ES/ER/TM-95/R1, Oak Ridge National Laboratory, 1994 revision.

X5.14.3 Jones, D. S., Suter, II, G. W., and Hull, R. N., "Toxicological Benchmarks for Screening Contaminants of Potential Concern for Effects on Sediment-Associated Biota," ES/ER/TM-95/R4, Oak Ridge National Laboratory, 1997 revision.

X5.14.4 Long, E. R., MacDonald, D. D., Smith, S. L., and Calder, F. D., "Incidence of Adverse Biological Effects within Ranges of Chemical Concentrations in Marine and Estuarine Sediments," *Environmental Management*, 19(1), 1995, pp. 81-97.

X5.14.5 Shacklette, H. T., and Boerngen, J. G., "Element Concentrations in Soils and Other Surficial Materials of the Conterminous United States," *U.S. Geological Survey Professional Paper 1270*, 1984.

X5.14.6 Suter II, G. W., "Guide for Performing Screening Ecological Risk Assessments at DOE facilities," ES/ER/TM-153, Oak Ridge National Laboratory, 1995.

X5.14.7 Suter II, G.W., Will, M. E., and Evans, C., "Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Terrestrial Plants," ES/ER/TM-85, Oak Ridge National Laboratory, 1993.

X5.14.8 Suter II, G. W., Futrell, M. A., and Kerchner, J. A., "Toxicological Benchmarks for Screening of Potential Contaminants of Concern for Effects on Aquatic Biota on the Oak Ridge Reservation," ORNL/ER-139, Oak Ridge National Laboratory, 1992.

X5.14.9 Suter II, G. W., and Tsao, C. L., "Toxicological Benchmarks for Screening of Potential Contaminants of Concern for Effects on Aquatic Biota," ES/Er/TM-96/R2. Oak Ridge National Laboratory, 1996 revision.

X5.14.10 "Criteria and Related Information for Toxic Pollutants," U.S. Environmental Protection Agency (USEPA), Waste Management Division–Region IV, 1992, p. 304(a).

X5.14.11 "Reference Dose (RfD): Description and Use in Health Risk Assessments," *Background Document 1A, Integrated Risk Information System*, U.S. Environmental Protection Agency (USEPA), 1993.

X5.14.12 *Supplemental Technical Support Document for the Hazardous Waste Identification Rule: Risk Assessment for Human and Ecological Receptors*, Vol 1, U.S. Environmental Protection Agency (USEPA), 1995a.

X5.14.13 "Ecological Screening Values," *Ecological Risk Assessment Bulletin No. 2*, Waste Management Division, U.S. Environmental Protection Agency Region IV, 1995c.

X5.14.14 "Calculation and Evaluation of Sediment Effect Concentrations for the Amphipod *Hyalella azteca* and the Midge *Chironomus riparius*," EPA 905/R96/008, U.S. Environmental Protection Agency (USEPA), Great Lakes National Program Office, 1996b.

X6. CASE STUDIES

INTRODUCTION

The purpose of this appendix is to provide examples of how the Eco-RBCA process can be applied to a variety of different sites. The case studies provided are hypothetical situations designed to highlight various aspects of the Eco-RBCA framework. While they may be useful for illustrating the manner in which the steps and decision points can be applied, they should not be considered templates for addressing similar issues at actual sites being evaluated.

Case Study Number 1: Former Chemical Manufacturing Site

X6.1 *Background Information*—The owners of a former chemical manufacturing facility are evaluating options for redevelopment. Previous investigations have identified contaminants, specifically ChemX and ChemY, in surface soils. Therefore, an ecological evaluation was requested by applicable regulatory agencies to determine the need for remedial action. Human health risks at the site were addressed separately based on the Standard for Risk Based Corrective Action (see Guide E2081).

X6.2 *Step 1: Initial Site Assessment*—The initial site assessment was based on a preliminary review of available site data, as well as a site visit, to evaluate current site use and conditions. A checklist was completed (see X2.1) that helped organize information on the description of the site, identify potential chemicals of concern, and evaluate the potential for complete exposure pathways to ecological receptors and habitats. In addition, the appropriate stakeholders were identified and contacted, the relevant regulatory guidance applicable to the site was reviewed and land use plans were considered. Documents describing historical activities were also reviewed. Screening criteria were also defined through discussions with the applicable regulatory agencies and stakeholders.

X6.2.1 *Preliminary Site Description*—The site is approximately 32 375 m^2 in size. The manufacturing facility was operational for about 16 years; however, it has not been active for more than a year and the entire property is enclosed by a fence and locked gate.

X6.2.1.1 Approximately half of the site is occupied by buildings associated with the manufacturing operation, as well as a former unlined lagoon previously used for liquid waste treatment and disposal. The remainder was used for drum storage and is currently characterized by piles of empty drums and abandoned equipment. The habitat in the area is dominated by a variety of shrubs and grasses typically considered early successional pioneering species, including staghorn sumac (*Rhus typhina*). The area surrounding the site, previously industrial, is in transition to residential and commercial development. The facility is bordered to the north, south, and east by commercial and residential areas, while the area to the west is undeveloped and characterized by a successional field and a small forested area. This forested area is vegetated by older, second-growth trees, including species such as pin oak (*Quercus palustris*), European white birch (*Betula alba*), black locust (*Robinia pseudoacacia*), black cherry (*Prunus serotina*), and red maple (*Acer rubrum*).

X6.2.1.2 The site is topographically flat, as are most of the surrounding areas. Regionally, the area is underlain by a sequence of sediments and sedimentary rocks resting on a basement of igneous and metamorphic rocks. The surficial material at the site consists of a sandy clay or silt, or both. The thickness of these deposits in the area of the site typically range from 100 to 300 ft (30.48 to 91.44 m). The aquifer underlying the site is an unconfined one, and groundwater is encountered 18 to 24 ft (5.486 to 7.315 m) below the ground surface.

X6.2.2 *Identification of Potential Chemicals of Concern*—Historically, the facility disposed liquid wastes contaminated with ChemX and ChemY in an on-site unlined lagoon. This activity resulted in elevated levels of these chemicals in surface soils on the site and potentially throughout a 10-acre (4.047 hectare) area in the vicinity of the site, including the unoccupied area to the west of the facility. These chemicals are persistent, bioaccumulative compounds known to be transferred through the food chain. They have been associated with reproductive impairment in mammals and predatory birds.

X6.2.3 *Preliminary Assessment of Exposure Pathways*—Based on the initial site visit, there are existing habitats on-site as well as in the off-site areas impacted by the facility that could support terrestrial ecological communities, such as small mammals, insectivorous birds, and predatory birds as described above. These communities could be exposed to ChemX and ChemY in soil through direct contact as well as through food chain transfers. Therefore, it was determined that potentially complete exposure pathways do exist at the site.

X6.3 *Step 2: Decision Point*—Based on the information obtained in the initial site assessment, there is potential for exposure to ecological receptors at the site. Based on a review of previous investigations, concentrations of ChemX and ChemY are present in soils at levels above the screening criteria agreed to with the appropriate regulatory agencies during the initial site assessment. However, exposures to ChemX and ChemY appear to occur only through exposure to surface soils; there is no evidence of existing chemical spills and the lagoon is no longer in use. Therefore, following discussions with the appropriate regulatory agencies, responsible parties, and other stakeholders, an interim remedial action was deemed unnecessary. Agreement was also reached during these discussions that the initial site assessment provided sufficient justification to require an Eco-RBCA Tier 1 evaluation of potential exposures to ChemX and ChemY in surface soil.

X6.4 *Step 3: Tier 1 Evaluation*—The purpose of the Tier 1 evaluation is to provide a screening-level evaluation of the risk at the site. This step relies primarily on existing data and conservative assumptions; however, limited additional data may be collected to fill identified data gaps.

X6.4.1 *Site Characterization*—A more extensive site visit was conducted to more accurately characterize existing ecological communities at the site. As discussed in the initial site assessment, potential habitats were found to be limited to grassland and scrub brush communities, comprised predominantly of introduced European annual grasses and forbs. The majority of these areas are fragmented by roads or other man-made structures. Based on the vegetation, it is possible that the area could support mammalian species such as white-footed mice (*Peromyscus leucopus*) or eastern cottontail (*Sylvilagus floridanus*). Avian species such as field sparrow (*Spizella pusilla*), chipping sparrow (*Spizella passerina*), and white-throated sparrow (*Zonotrichia albicollis*) may also be present. In addition, red-tailed hawks (*Buteo jamaicensis*) have been observed in the vicinity of the site. In the off-site areas, available ecological habitats are limited to the area west of the facility, which is dominated by a successional field, fringed by an upland hardwood forest. This area occupies about 15 acres (6.07 hectares) and would provide habitat for several species of mammals, including eastern fox squirrels (*Sciurus niger*), eastern chipmunks (*Tamias striatus*), raccoons (*Procyon lotor*), eastern striped skunks (*Mephitis mephitis*), and white-footed mice. Avian species that may be present include the black-capped chickadee (*Parus atricapillus*), tufted titmous (*Parus bicolor*), northern cardinal (*Cardinalis cardinalis*), woodpeckers (Family Picidae), wrens (Family Troglodytidae), nuthatches (Family Sittidae), warblers (Family Parulidae), and sparrows (Family Fringillidae).

X6.4.1.1 The preliminary data quality objectives were evaluated and refined based on the results of the initial site assessment. After completion and approval of a workplan, additional soil sampling was conducted to further delineate the extent of ChemX and ChemY contamination in surficial soils. Samples were collected from several representative locations on-site near the former lagoon and throughout the drum storage area. Off-site, samples were collected in a transect across the successional field to the west of the facility, as well as along the edge of the forested area.

X6.4.2 *Conceptual Site Model and Exposure Pathway Analysis*—On-site, detected concentrations of ChemX and ChemY were primarily limited to the area surrounding the former lagoon. Neither chemical was detected in the upland forest area; however, both were detected in surface soils throughout the adjacent successional field. Based on observations made during the site visit, this area supports a variety of small mammals such as mice, shrews, voles, rabbits, and squirrels, as well as several insectivorous songbird species. In addition, raptors such as red-tailed hawk have been observed in the vicinity of the site. No threatened or endangered species have been observed at the site or in the surrounding areas, and consultation with local, state, and regional agencies confirmed that none are expected to be present. Therefore, the assessment endpoints selected for the site are the population health of insectivorous and granivorous mammals (for example, shrew and deer mouse, respectively), herbivorous mammals (for example, vole and rabbit), insectivorous birds (for example, robin), and carnivorous birds (for example, red-tailed hawk) as measured through potential reproductive success.

X6.4.2.1 Due to their physicochemical properties, ChemX and ChemY are generally not taken up by most plants, but are readily accumulated by soil macroinvertebrates. Therefore, exposures to herbivorous species (for example, voles and rabbit) would only be expected to occur via direct contact with soil and incidental ingestion. Insectivores (for example, robin and shrews) and carnivores (for example, red-tailed hawk) could, however, also be exposed to ChemX and ChemY through consumption of contaminated prey items. They are known to biomagnify in terrestrial food chains, therefore the ingestion exposure route warranted further evaluation for higher trophic-level organisms (for example, red-tailed hawk) feeding upon potentially contaminated prey.

X6.4.3 *Generic Screening Evaluation*—As an initial evaluation of the risks posed by ChemX and ChemY concentrations at the site, a generic screening evaluation was conducted based on conservative assumptions. Relevant ecological screening criteria (RESC) for soil were identified from appropriate regulatory guidance documents and compared to maximum soil concentrations from each area. The generic RESC concentrations are conservative values intended to be protective of ecological exposures to soil through either direct contact or trophic transfer. Exposures to chemicals below these levels are not believed to result in reproductive impairments. In the absence of RESC values, ChemX and ChemY would have been evaluated qualitatively. Maximum concentrations of ChemX in

the vicinity of the former lagoon and in the successional field exceeded the available RESC. Elsewhere (that is, the former drum storage area), concentrations were below the RESC. Concentrations of ChemY were below RESC at all of the locations evaluated, both on-site and off-site. As a result, ChemY was not evaluated further and the evaluation of ChemX was focused on the former lagoon and the successional field.

X6.5 *Step 4: Decision Point*—Based on the results of the Tier 1 evaluation, complete exposure pathways exist for several receptor groups including insectivorous mammals (for example, shrew), insectivorous birds (for example, robin), and carnivorous birds (for example, red-tailed hawk). The generic screening analysis indicated that on-site ChemX concentrations in soils were below conservative RESC values with the exception of soils collected in the vicinity of the former lagoon. Off-site, however, soils located throughout the successional field were found to exceed the RESC for ChemX. Concentrations of ChemY were below RESC at all locations both on-site and off-site, eliminating it from further consideration.

X6.5.1 Based on the comparison of maximum chemical concentrations to RESC and following discussions with the appropriate regulatory agencies, responsible parties, and stakeholders, it was decided that soils on-site in the vicinity of the former lagoon would be removed and stored in an upland disposal facility. Concentrations detected elsewhere were below applicable RESC, therefore, additional on-site ecological investigations were determined to be unnecessary. Thus, the focus of the Tier 2 evaluation was on ChemX concentrations in the successional field located to the west of the facility.

X6.6 *Step 5: Tier 2 Evaluation*—In Tier 2, additional information on exposure and toxicity is gathered to refine the screening analysis conducted in Tier 1 or to initiate a risk assessment process. The purpose of this step is to continue reducing the uncertainty associated with the assessment through either additional data collection or more realistic or site-specific exposure assumptions.

X6.6.1 *Planning*—Based on the results of the Tier 1 evaluation, the focus of the Tier 2 evaluation was on ChemX concentrations in the successional field located to the west of the facility. Following discussions with the regulatory agencies, it was determined that the best approach for evaluating this areas was to conduct an ecological risk assessment focusing on both exposures to insectivorous mammals (for example, shrews), insectivorous birds (for example, robin), and carnivorous birds (for example, red-tailed hawk). Therefore, a work plan summarizing the methodologies to be used, refined data quality objectives, and relevant criteria was submitted to and approved by the appropriate regulatory agencies and stakeholders prior to initiating the Tier 2 evaluation.

X6.6.2 *Refinement of Exposure Assessment*—As previously discussed, the primary relevant ecological receptors associated with the successional field are insectivorous mammals (for example, shrews), insectivorous birds (for example, robin), and carnivorous birds (for example, red-tailed hawk). Values for each of the exposure parameters identified below were determined based on a review of the available literature as well as site-specific data where possible. The proposed exposure parameter values were summarized in the work plan. Based on the approach presented in the approved work plan, a reasonable maximum exposure (for example, 95 % upper confidence limit) was used to estimate risk in Tier 2.

X6.6.3 *Insectivorous Birds and Mammals*—The primary route of exposure for insectivorous birds and small mammals is through the consumption of insects, soil invertebrates (for example, earthworms), and other prey items. However, incidental exposures via ingestion of contaminated soils may occur and was therefore also included. Dermal exposures via direct contact were assumed to be negligible based on the chemical and physical properties of ChemX that make it unlikely to be absorbed through the skin. Therefore, estimated intakes associated with these exposure pathways were defined using standard daily intake equations. The concentration of ChemX in the food items (that is, insects and soil invertebrates) of these receptors was determined by applying a conservative bioaccumulation factor to the measured soil concentrations.

X6.6.4 *Carnivorous Birds*—Exposures to red-tailed hawk, used as a representative carnivorous bird, were determined to be limited to consumption of prey items such as small mammals and insectivorous birds. Exposures via dermal contact and incidental ingestion of soil were determined to be negligible. Therefore, estimated intakes associated with these exposure pathways were defined using standard exposure equations. The concentration of ChemX in the food items (that is, small mammals and birds) of the red-tailed hawk was determined by applying literature-based trophic transfer factors to the concentrations previously estimated for the food items of these species. The trophic transfer factors used were proposed and summarized in the approved work plan.

X6.6.5 *Ecological Effects Evaluation*—To evaluate the potential for effects of site-related ChemX on reproductive impairment in mammals and predatory birds, a toxicity reference value (TRV) was derived for each of the receptors evaluated. The TRV represents the minimum daily intake believed to be associated with adverse reproductive effects. The literature used to develop the TRVs was summarized in the work plan and discussed with the appropriate regulatory agencies and stakeholders.

X6.6.6 *Risk Characterization*—The daily intakes derived in the refined exposure assessment were compared to the TRVs developed for the ecological effects evaluation. Based on this evaluation, daily intakes derived for the small mammal and insectivorous bird (for example, robin) were below the TRVs derived from the literature, implying limited potential for adverse effects to these species. However, daily intakes estimated for the carnivorous bird (for example, red-tailed hawk) exceeded the TRV, indicating the potential for unacceptable risks.

X6.7 *Step 6: Decision Point*—Based on the results of the Tier 2 evaluation, concentrations of ChemX in the successional field do not pose risks to insectivorous birds or to small mammals. Therefore, these species were eliminated from

further consideration. Risks to carnivorous birds, however, were indicated. Therefore, after discussions with the appropriate regulatory agencies, responsible parties, and other stakeholders, it was decided that red-tailed hawks were the relevant ecological receptors and that an additional line of evidence in the form of site-specific bioaccumulation data was needed in Tier 3.

X6.8 *Step 7: Tier 3 Evaluation*—The Tier 3 evaluation should be based on site-specific information to the extent possible, to ensure that uncertainty is further reduced. Therefore, after discussions with the appropriate stakeholders, and further refinement of the data quality objectives, a work plan was submitted and approved for evaluating risks to small mammals from exposure to ChemX-contaminated soils. Included in the work plan was a field sampling plan describing methods to be used to collect prey items of the red-tailed hawk (for example, small mammals) from various locations at the site and analyze their tissues for ChemX. Based on the results of this sampling effort, risk estimates were derived based on the same methodology described in the Tier 2 evaluation but using the maximum, site-specific prey tissue concentrations in place of those estimated using bioaccumulation factors.

X6.8.1 The results of the refined risk evaluation based on the site-specific prey concentrations indicated a low potential for adverse effects associated with the site-specific prey concentrations.

X6.9 *Step 8: Decision Point*—The results of the Tier 3 Evaluation indicated minimal risks to populations of insectivorous mammals (for example, shrews) at the site based on the criteria established in the work plan. Therefore, after discussions with the appropriate regulatory agencies, responsible parties, and other stakeholders, it was decided that remedial action in the off-site area was not warranted.

X6.10 *Step 9: Remedial Action Program (RAP)*—As discussed in the Tier 1 evaluation, it was decided that soils in the vicinity of the former lagoon would be excavated to a concentration protective of small mammals based on conservative exposure assumptions developed in conjunction with the appropriate stakeholders. This RAP was coordinated with other remedial activities at the site identified during the concurrent RBCA human health evaluation. Soils from this area were excavated and transported to an upland, confined disposal facility. The area was then paved in preparation for future commercial land use.

X6.11 *Step 10: Decision Point*—It was determined based on discussions with the appropriate regulatory agencies, responsible parties, and other stakeholders that further action (for example, compliance monitoring) was not required at the site.

Case Study Number 2: Automotive Parts Manufacturer

X6.12 *Background Information*—The site, occupying approximately 6 acres (2.428 hectares), is an active facility producing automotive metal parts (for example, bumpers). During a plant inspection, a large pile of scrap metal was noticed on a concrete slab, adjacent to one of the manufacturing buildings. Staining of the slab was observed underneath the metal pile, which was caused by exposure of the scrap metal to rainfall. Rainfall drains from the site via paved drainage ditches and ultimately into a wetland 2 miles downstream. A sample was taken from the pile and from the stained material for analysis of inorganic constituents. Iron was the only chemical detected. At the request of the plant manager, the Eco-RBCA process was initiated to evaluate potential harm to the environment.

X6.13 *Step 1: Initial Site Assessment*—The initial site assessment was based on a site visit to evaluate current site use and conditions. A checklist was completed (see X2.1) that helped organize information on the description of the site, identify potential chemicals of concern, and evaluate the potential for complete exposure pathways to ecological receptors and habitats. Prior to the site assessment, applicable regulatory agencies were contacted to determine appropriate exclusion criteria for the site and other specific regulatory requirements. In addition, documents describing historical and proposed future site activities, past chemical use and releases, and prior site assessments were obtained from the plant manager.

X6.13.1 *Site Description*—As previously discussed, the 6 acres (2.428 hectares) site is an active manufacturing facility. With the exception of a small landscaped area in front of the main office building, the entire facility is covered with either asphalt or concrete, and there is no exposed soil inside the property boundary. The facility currently has several environmental permits for various activities at the site, including electroplating and sandblasting. The facility has been in operation at the present site for over 25 years. The site is located in an industrialized area and is bordered on all sides by similar industrial facilities.

X6.13.2 *Identification of Relevant Habitats and Ecological Receptors*—Based on the site visit, vegetation at the site is limited to a small area of grass and a few ornamental trees. There is no significant habitat for ecological receptors on or adjacent to the facility. During the site visit, no evidence of ecological receptors (for example, birds or small mammals) was observed. There are no surface water bodies or wetlands on the site and the nearest surface water body is more than 5 miles (8.047 km) from the facility property boundary. A 1-mile (1.61-km) exclusion criterion for nearest surface water body was established for the site with the regulatory agencies prior to the site assessment.

X6.13.3 *Identification of Potential Chemicals of Concern*—Based on a review of the information obtained from the plant manager, there is no evidence that any current or historical releases of chemicals, with the exception of the iron staining attributed to the scrap metal pile, have occurred at the site or at neighboring facilities.

X6.13.4 *Conceptual Site Model*—During the initial site visit it was determined that there are no ecological receptors present at the site or in the immediate vicinity due to the industrialized nature of the area. Even though the iron stain was transported offsite, no surface water bodies are within two miles, and iron

reaching the wetland is expected to be tightly bound to soils and not leached into ground water or bioaccumulated in wetland animals. Based on this information, it was determined that there are no complete or potentially complete exposure pathways at the site.

X6.14 *Step 2: Decision Point*—As an initial response, the plant manager had the scrap metal removed by a general contractor and recycled. Furthermore, an overhang was constructed off of the manufacturing building to protect future scrap metal piles from being exposed to rainfall. Given the apparent lack of ecological receptors or available habitats, it was determined that additional measures were not required. The appropriate regulatory authorities were notified and after discussing the preestablished exclusion criteria and the lack of chemicals of concern, relevant ecological receptors and habitats, and completed exposure pathways, it was agreed that this site did not warrant further action. However, the plant manager elected to implement a monitoring plan to visually observe the storage area for further signs of discoloration to determine the need for any additional modification to daily activities related to storage of scrap metal.

X7. SUPPLEMENTAL INFORMATION ON UNCERTAINTY ANALYSIS

X7.1 Purpose

X7.1.1 The purpose of this appendix is to provide the user with a broad understanding of the concepts of uncertainty and variability, and how the analyses of these may change as one progresses through Eco-RBCA tiers.

X7.2 Introduction

X7.2.1 This appendix provide additional information on handling uncertainty in ecological risk assessments. Uncertainty is the lack of knowledge about scenarios, models, parameters and factors used in the ecological risk assessment. Information on uncertainty in the risk assessment is used in making risk technical policy decisions. It is important for the risk assessor to identify what uncertainties exist at each tier of the process and to identify which of the uncertainties matter to the decision makers. Section X7.4 provides suggestions for handling uncertainty in the three-tier assessment process. Section X7.8 provides information on documenting and communicating uncertainty. Terminology related to the uncertainty analysis is presented in section X7.9. Additional references on handling uncertainty in quantitative risk assessment are provided in the text. The discussion in this appendix focuses on ecological risk assessments for chemical stressors.

X7.2.2 *Uncertainty versus Variability*—Uncertainty is the lack of knowledge about scenarios, models, parameters and factors used in the ecological risk assessment. Variability refers to observed differences in values for exposure parameters or populations that can be attributed to true heterogeneity **(47)**. It is inherent to many parameters. Uncertainty can sometimes be reduced and variability characterized more completely by site-specific data collection. Additional sampling and analysis may help characterize variability, but it does not reduce variability (for example, body weights for a population). An effort should be made to collect additional information to reduce uncertainty to the lowest level needed to achieve the data quality objectives developed for each tier of assessment. Any remaining uncertainties should be characterized to identify the source of uncertainty and the magnitude and direction of impact on risk characterization. Cullen and Frey **(48)** provide a recent in-depth discussion of variability and uncertainty in human health risk assessment. Suter et al **(49)** provide a recent review of uncertainty in ecological risk assessment.

X7.3 Uncertainty in the Context of the State of the Science of Ecological Risk Assessment

X7.3.1 *Limitations of Methods and Data Bases*—Uncertainty is inherent to ecological risk assessment, in part because the sciences of ecology and ecotoxicology are relatively young and not yet fully developed. It is important to acknowledge that the methods and databases of ecology and ecotoxicology are not developed to the point that they allow characterizing ecological risks with a high degree of certainty. In addition, risks characterized for any ecosystem are going to be highly uncertain based on the few measures typically included in an ecological risk assessment. Thus, uncertainty analysis, which sheds light on the results of an ecological risk assessment, can sometimes be as important as the assessment itself. It is important to acknowledge the limitations and data gaps in an ecological risk assessment at each tier, so that regulators, risk managers, and risk assessors can identify areas of improvement in subsequent tiers.

X7.3.2 *Limitations in Ecotoxicological Data*—Toxicity data are only available for a limited number of species (most of them laboratory test species) and usually only for a defined set of test conditions (which very likely deviate from natural conditions). In current practice, most of the resources in toxicology are focused toward the study of single chemicals and single species. Lovett Doust et al **(50)** suggested that the study of single chemicals is similar to eating the ingredients of cake individually and expecting to taste cake. Furthermore, simplistic extrapolations from laboratory species to wildlife species and testing conditions to field conditions may not be accurate, and are rarely, if ever, validated against natural conditions **(51)**. Moreover, the toxicological endpoint of endocrine disruption has only recently been identified as significant, and there are very few data except for a few dioxin-like compounds **(52)**. Equally important, there are relatively few studies that actually evaluate the effects of toxicity on predator-prey interactions **(53)**. The lack of data in the literature on the effects of toxicity and other stressors on these interactions emphasizes the value of collecting organisms from a site and using site media in toxicity tests. These site data can be used to develop inferences and reduce uncertainty regarding the potential adverse impacts of site stressors on the predator-prey dynamics that form the basis of food webs typically evaluated in ecological risk assessments.

X7.3.3 *Extrapolation from Individuals to Populations*—Another example of a limitation in ecology with regard to ecological risk assessment is related to the protection of populations. A population is a group of individuals of the same species in the area under study. It has been considered the smallest ecological unit that persists through time (**54**), and the USEPA requires protection of population, communities, and ecosystems (note that protection of individuals is required for a variety of rare, threatened, and endangered species) (**55**,**7**, **56**). However, most ecological risk assessments are based on toxicity benchmarks and exposure parameters focused toward individual organisms. Because it is variable and depends on many factors, ecologists and population biologists have not identified the amount of population decline that any given population can sustain without causing undesirable changes. Thus, attempts to evaluate the ecological significance of risk estimates for individuals on a population are replete with uncertainty. Furthermore, risks estimated toward the individual organism (or even a population of organisms) do not take into account predator-prey interactions, which may result in effects to receptors other than those evaluated in a risk assessment.

X7.3.4 *Determination of an Acceptable Level of Uncertainty*—The degree of uncertainty that can be acceptable for a given site should be addressed at the onset of each tier of Eco-RBCA. In many respects, the degree of uncertainty is set by establishing the data quality objectives for the tier. The overall philosophy for the tiered Eco-RBCA process is that uncertainty decreases as one proceeds to higher tiers. Uncertainty can be reduced and variability characterized more completely by site-specific data collection. Uncertainty and variability are analyzed and reported qualitatively (for example, narrative statements) and quantitatively (statistically). The following two sections briefly describe these approaches.

X7.4 Handling Uncertainty in the Three Eco-RBCA Tiers

X7.4.1 The following sections describe how uncertainty is handled at each tier in the ecological risk assessment process following the initial site assessment. Characterization of uncertainty begins with review of existing site data and assessment objectives for the Tier 1 evaluation. Uncertainty can be reduced by collection of additional site data to fill data gaps identified in this tier and to allow quantitative risk estimation in higher assessment tiers. Uncertainty is next considered in the planning and scoping process for site-specific data collection in Tier 2 and 3 assessments. Uncertainty is further reduced by clear definition of data quality objectives and sampling requirements for developing point estimates of risk (Tiers 2 and 3), and performing probabilistic risk assessments (Tier 3). Characterization of uncertainty in the quantitative analyses leading to Tier 2 and 3 risk estimates further identifies any assessment limitations and their impacts on risk results as a context for risk management decisions. The following sections provide additional information on how uncertainty can be handled within each tier of the assessment process.

X7.5 Tier 1 Assessment

X7.5.1 *Summary of the Tier 1 Assessment*—The Tier 1 qualitative analysis focuses on collection and review of historical and existing data, refinement of potentially complete exposure pathways for current and future conditions identified in the initial site assessment, development of a conceptual model for the site, and identification of potential endpoints and endpoint species for further assessment. Where it is possible to directly measure attributes of an assessment endpoint, extrapolation is unnecessary, thus preventing the introduction of a source of uncertainty. For example, endpoints such as "nesting and feeding conditions" or "endemic plant community diversity," may be directly measurable in the field. Sampling of environmental media and limited habitat and receptor surveys can occur in this tier, as can location of generic screening criteria and generic exposure factors for dietary exposure model calculations. A simple hazard quotient method can be performed using conservative assumptions to determine if risks are unacceptable or uncertain.

X7.5.2 *Uncertainty in the Tier 1 Assessment*—Uncertainty at this level can include incomplete analysis, descriptive errors, and limitations of data and observations (for example, areas of the site not visited during the site reconnaissance) that form the basis of the understanding of site conditions. The following are examples of sources of uncertainty related to a full understanding of the site that can be eliminated or their impacts minimized by additional site investigations or data collection activities in Tier 1.

X7.5.2.1 *Conceptual Site Model Uncertainty*—Poor communication with stakeholders can contribute to failure to consider all relevant sources of contamination or elements of a conceptual site model. Uncertainty (lack of knowledge) in conceptual site models at this assessment level can be due to incomplete and erroneous descriptive data, limited observations (for example, areas of the site not visited during the site reconnaissance and areas without habitat are assumed to have habitat), and historical documents that are not available for review to characterize sources of contamination, exposure pathway, and relevant ecological receptors and habitats. Site boundaries might not be known at the time the Tier 1 qualitative analysis is completed. Site-specific information on future land use might not be available. Therefore, source areas and habitats might not be included in the initial assessment, or contaminated areas from adjacent sites might erroneously be included as exposure areas. Aerial photographs might not be available to identify all habitats and historical sources of contamination on site. Hydrogeological information and current topographic maps might not be available to identify potential soil-to-groundwater, surface-soil-to-surface-water and groundwater-to-surface-water pathways.

X7.5.2.2 *Uncertainty in the Nature and Extent of Contamination*—Uncertainty is often associated with historical site monitoring data that was not collected for the purpose of assessing ecological risks. An adequate description of sample locations might not have been recorded, so there might be uncertainty related to what location is represented by a data record. Chemical analyses of environmental media samples might have been limited, so quantitative information on potential chemicals of concern might not be available to compare to relevant ecological screening criteria (RESC) or other relevant

measurable criteria (ORMC). Data quality and usability concerns can be evaluated by considering published guidance on these topics (for example, **(57)** and **(58)**).

X7.5.2.3 *Uncertainty Due to the Lack of Effects Information on Uncommon Chemicals*—Contamination might include uncommon chemicals for which RESCs and ORMCs are not available and must be developed using the methodologies presented in Appendix X5. Uncertainty in the application of RESC may also result when an RESC for the most toxic form of a chemical is chosen due to the lack of information on the actual form of the chemical present at a site.

X7.5.2.4 *Uncertainty in Exposure Model Assumptions and Parameter Values*—Generic or default exposure factors used in dietary exposure model calculations can be an important source of uncertainty. This can be an important source of uncertainty for threatened and endangered species and groups of animals that have specialized behavior (for example, burrowing animals) or have not been the focus of studies relevant to risk assessment (for example, reptiles and armadillos).

X7.5.2.5 *Options for Addressing Uncertainties in Tier 1 Assessments*—Uncertainties of the types listed for Tier 1 Assessments can be characterized as data gaps to be addressed in planning the subsequent quantitative assessment tiers. Certain exposure pathways, relevant ecological receptors, habitats and chemicals might be carried forward to a Tier 2 analysis or additional Tier 1 data collection and evaluation step to resolve these uncertainties. Uncertainty may also be present due to the lack of RESC for some chemicals or the presence of non-detected values with high detection limits. Treatment of such data is via TPDs (Appendix X2). Due to the uncertainties inherent in Tier 1, often the assessment will need to proceed to Tier 2.

X7.6 Tier 2 Assessment

X7.6.1 *Summary of the Tier 2 Assessment*—The Tier 2 Assessment includes further discussions with stakeholders and regulators to refinement the Assessment objectives. Planning and scoping are formalized, the site conceptual model is refined, and additional screening criteria and site-specific approaches are focused on a single line of evidence. Data gathering is continued in Tier 2, including collection of additional historical data, environmental media sampling, and collection of site-specific toxicity values and exposure factors. A deterministic approach is often followed using refined dietary exposure model calculations and the simple conservative quotient method to determine whether risk is acceptable or, if unacceptable, to develop SSEC (see 3.1.36) protective of assessment endpoints.

X7.6.2 *Uncertainty in the Tier 2 Assessment*—Quantitative uncertainty occurs in the assumptions and values of screening-level calculations of risk. Sources of uncertainty at this tier include lack of knowledge about exposure factors, fate and transport models, exposure dose calculations, and effects data. Uncertainty about exposure dose model equations, parameter values for relevant ecological receptors, uncertainty factors used in deriving toxicity reference values, and chemical fate and transport processes are the major sources of uncertainty at this level of analysis. Simplistic fate and transport modeling might be used at this tier, and uncertainties associated with the model and its parameter values and assumptions need to be addressed **(59)**. Uncertainty in this assessment tier can be characterized more easily as causing an overestimate or underestimate of ecological risk than in the Tier 1 assessment. Cullen and Frey **(48)** provide suggestions on handling uncertainty in models used to estimate exposure dose and models that describe chemical fate and transport. One goal of a site-specific quantitative analysis might be to obtain site-specific exposure or toxicity information to reduce uncertainty identified in the screening ecological risk assessment. In the case where it is possible to measure attributes of an assessment endpoint directly, extrapolation is unnecessary and the introduction of one source of uncertainty can be avoided. For example, endpoints such as "nesting and feeding conditions" or "endemic plant community diversity," may be directly measurable in the field. Thus, one option for reducing uncertainty, in some cases, is to rely on direct field measurements rather than relying strictly on assumptions and models.

X7.7 Tier 3 Assessment

X7.7.1 *Summary of the Tier 3 Assessment*—The Tier 3 Assessment includes additional discussion with stakeholders and regulators for development of the Tier 3 assessment objectives. Site-specific approaches are developed to address the objectives for this tier. Additional data are collected using *in situ* studies to support measures of exposure and effect and to provide distributional information for model parameters. Additional deterministic and probabilistic analyses of risk are combined with multiple lines of evidence. Site-specific benchmarks can be developed for specific chemicals. MacIntosh et al **(60)** and Moore et al **(61)** provide examples of what might be considered a Tier 3 assessment.

X7.7.2 *Uncertainty in the Tier 3 Assessment*—Uncertainty can be characterized quantitatively in the Tier 3 assessment. A goal of a Tier 3 analysis is to characterize uncertainty identified in the Tier 2 analysis quantitatively. One way this can be accomplished is by performing a Monte Carlo or similar simulation. Additional literature searches and site-specific data collection activities can also be performed to reduce uncertainty in assumptions regarding probability density functions or distributions used to represent exposure parameters in probabilistic risk assessments. The distribution of available toxicity data can be used to characterize the relative degree to which the toxicity reference values used in screening ecological risk assessments are conservative (see section X.7.8.6 for an example distribution). More and Elliott **(62)**, Suter **(63)**, Suter et al **(49)**, USDOE **(64)** and Warren-Hicks and Moore **(65)** should be consulted for additional details on how to handle uncertainty in a Tier 3 assessment to support decision making.

X7.8 Documenting and Communicating Uncertainty

X7.8.1 Documentation of uncertainties in an ecological risk assessment can be in the form of text, tables, figures, and matrices. The purpose of the documentation is to provide additional information about lack of knowledge for making technical policy and response action decisions.

X7.8.2 *Characterizing the Significance of an Uncertainty and its Impact on Decisions*—The presentation of uncertainties should identify the significance relative to the technical policy decisions that need to be made at the site. This can be described as high, medium, or low; or significant/insignificant. Significance is an indicator of how important lack of information is to a technical policy decision or strategy. If an uncertainty is considered significant to the decision, additional data collection might be warranted. If an uncertainty is considered insignificant, a decision is made without additional data collection. Uncertainties judged to be significant might be handled without collecting data by changing the technical policy decision.

X7.8.3 *Tier 1 Assessment*—Documentation of uncertainty in a qualitative ecological risk assessment usually focuses on uncertainties regarding assumptions about the conceptual site model and potentially complete exposure pathways and identifying needs for additional ecological evaluation that would involve site data collection to be used in a quantitative assessment of ecological risk. Narrative statements are used to characterize uncertainty for the decisions that are made at this stage of the assessment process. The emphasis in this level of assessment is on assumptions about the conceptual site model, exposure pathways, potentially exposed ecological receptors, habitats, and types of adverse effects on receptors based on gaps in available site-specific data and limitations of site-specific observations. Uncertainty in available environmental monitoring data, RESCs, and ORMCs also should be described.

X7.8.4 *Tiers 2 and 3 Assessments*—Quantitative information (statistical parameters) may be presented to describe variability and uncertainty in parameters and input data used to calculate ecological risks, as appropriate. This quantitation may be simplistic (for example, the source and basis of any safety factors used to derive toxicity reference values or standard deviations used to describe data dispersion) or may be complex (for example, Monte Carlo simulation). Quantitative analysis may include distributions, descriptors of central tendency, ranges, and percentiles used to characterize variability and uncertainty. These can be presented by tabular or graphical means. Methods for handling and reporting uncertainty and variability in quantitative risk assessment are available from a variety of sources (for example, **(66)** and **(65)**). Documentation of sources of uncertainty describe uncertainty in parameters and input data used to calculate ecological risks that lead to additional data collection or in documenting final assessment results. The source and basis of any uncertainty factors used to derive toxicity reference values for use in hazard quotients should be identified. Lack of data and information on probability density functions or distributions representing exposure parameters in a probabilistic exposure and risk assessment should be documented.

X7.8.5 *Examples of Documenting and Communicating Uncertainty Qualitatively*—Uncertainty analyses are almost always qualitative, and depend on the complexity of the tier. Narrative statements are typically used to characterize uncertainty in a qualitative ecological exposure assessment. For example, uncertainty based on gaps in available site-specific data and limitations of site-specific observations may be identified. Spatial and temporal variability in habitat characteristics and use of site habitat by receptors may be characterized. Uncertainty in Tier 1 benchmark values may be described if these benchmarks are used. Descriptive errors, incomplete analysis (for example, areas of the site not visited during the site reconnaissance) and errors in professional judgment may also be characterized. Uncertainty and variability regarding exposure dose model equations, parameter values for site-specific receptors, ecological processes and effects, and chemical fate and transport processes are common sources of uncertainty at this level of analysis. Variability can be summarized through qualitative statements about population heterogeneity. The following sections provide brief examples that illustrate the documentation of a variety of uncertainties qualitatively for a site evaluated in Tier 1 or Tier 2.

X7.8.5.1 *Assumptions in the Conceptual Site Model*—The potentially complete exposure pathways shown in the conceptual site model for future conditions at the site are uncertain. The site is located in a rural area on the edge of an urbanized area, and the county planning agency has not yet developed a master plan for the area. The mayor of the adjacent city indicated in a telephone interview that the wooded area that overlaps the site is slated for development as a residential area beginning in the fall. Therefore, the assumption that there will continue to be a potentially complete exposure pathway from the former landfill to upper level predators is uncertain under the future scenario.

X7.8.5.2 *Selection of Chemicals of Concern*—Only chemicals detected in at least one sample were selected as chemicals of concern (COCs). In some cases, the detection limits for many of the COCs were greater than the RESCs and ORMCs used in selecting COCs. If the laboratory analytical detection limits had been lower for these chemicals, they might have been identified as COCs. This represents an uncertainty in the selection of COCs and a potential data gap at this stage in the assessment. Because there is a known source of COCs on site, some of the COCs are bioaccumulative, and the terrestrial food chain is topped by the Bald Eagle, this uncertainty is considered significant and additional soil sampling and analysis with lower detection limits are needed in Tier 3 to finalize risk estimates before clean-up levels can be calculated and a remedial action decision can be made.

X7.8.5.3 *Exposure Estimates*—Only two soil samples were available for estimating exposure concentrations in the upland exposure area. Therefore, a 95th upper confidence level estimate of the mean concentration could not be estimated and the maximum measured concentration was used to estimate exposure to the deer mouse. This represents an uncertainty in the estimated exposure dose for this receptor. The magnitude and direction of the uncertainty is unknown.

X7.8.5.4 *Lack of Chronic Toxicity Information on Site-Specific Relevant Ecological Receptors*—A search of the literature and the AQUIRE data based yielded no chronic toxicity data for amphibians for three COCs detected in stream sediment and surface water. This data gap represents an uncertainty in Tier 2.

X7.8.5.5 *Extrapolation of Laboratory Evaluation of Sediment Toxicity to Site Conditions*—The grain size, total organic carbon content and ammonia levels measured in the river adjacent to the site differed significantly from the values reported for the laboratory toxicity test on which the sediment benchmark value is based. Therefore, the applicability of the literature value for use at this site is highly uncertain.

X7.8.5.6 *Lack of Tissue Data for Prey on Calculated Exposure Dose for Upper Trophic Level Receptors*—The lack of site-specific data on the concentration of one COC in fish required use of literature values on the uptake of this COC from sediment by benthic invertebrates to estimate the exposure dose for blue gill. Therefore, the risk to the great blue heron from consumption of fish and benthic invertebrates living in the stream is uncertain, but the magnitude and direction of the uncertainty cannot be estimated.

X7.8.6 *Example of Documenting and Communicating Uncertainty Quantitatively*—Fig. X7.1 is an example of the presentation of the quantitative uncertainty in a toxicity reference value (TRV) for a Tier 3 probabilistic risk assessment (**67**). It presents the probability density of the TRV values along the range of doses tested. This is a quantitative presentation that includes the values of the best estimate, upper 95 % and lower 5 % confidence limits on the TRV. Similar presentations could be made for other risk assessment variables in a Tier 3 assessment.

X7.9 Terminology

X7.9.1 *Uncertainty*—the lack of knowledge regarding site conditions, the nature of exposure, and effects on relevant ecological receptors and habitats. This lack of knowledge is recognized at each tier of evaluation through an uncertainty analysis (see 3.1.43).

X7.9.2 *Variability*—the observed spatial, temporal, and interindividual heterogeneity in values of a variable, exposure parameter, or population characteristic that can be attributed to true heterogeneity (**47**).

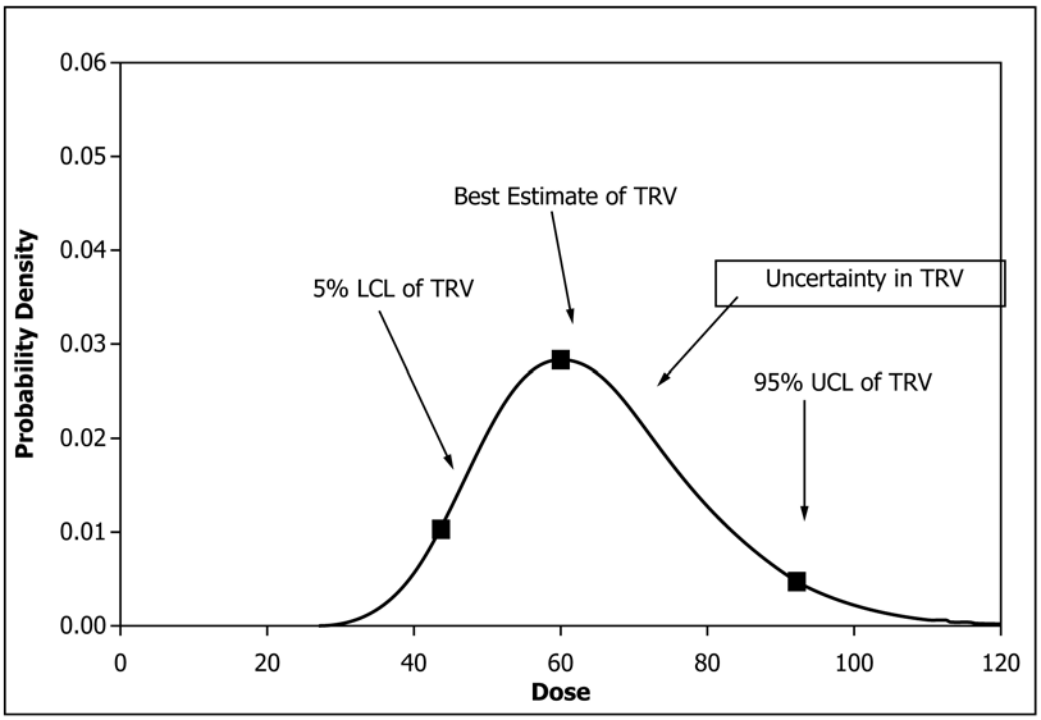

FIG. X7.1 Probability Density Function for a Toxicity Reference Value

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