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

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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 E 2081 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 E 2081 for development and implementation of a corrective action program. This guide supplements Guide E 2081 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 3.1.44, needs to be familiar with Guide E 2081 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

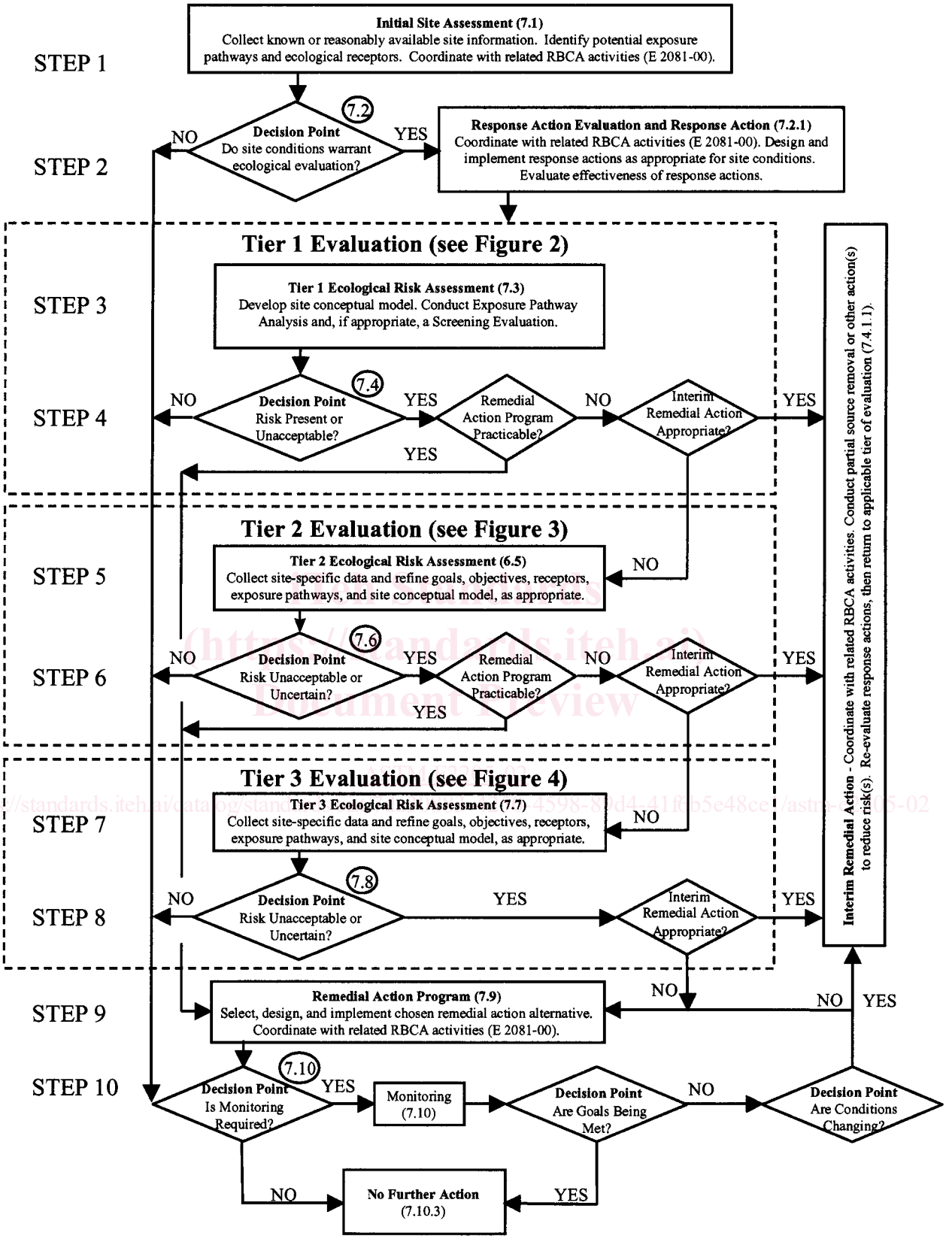

FIG. 1 Eco-RBCA Process Flowchart—Adapted from the RBCA Flowchart (Guide E 2081)

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

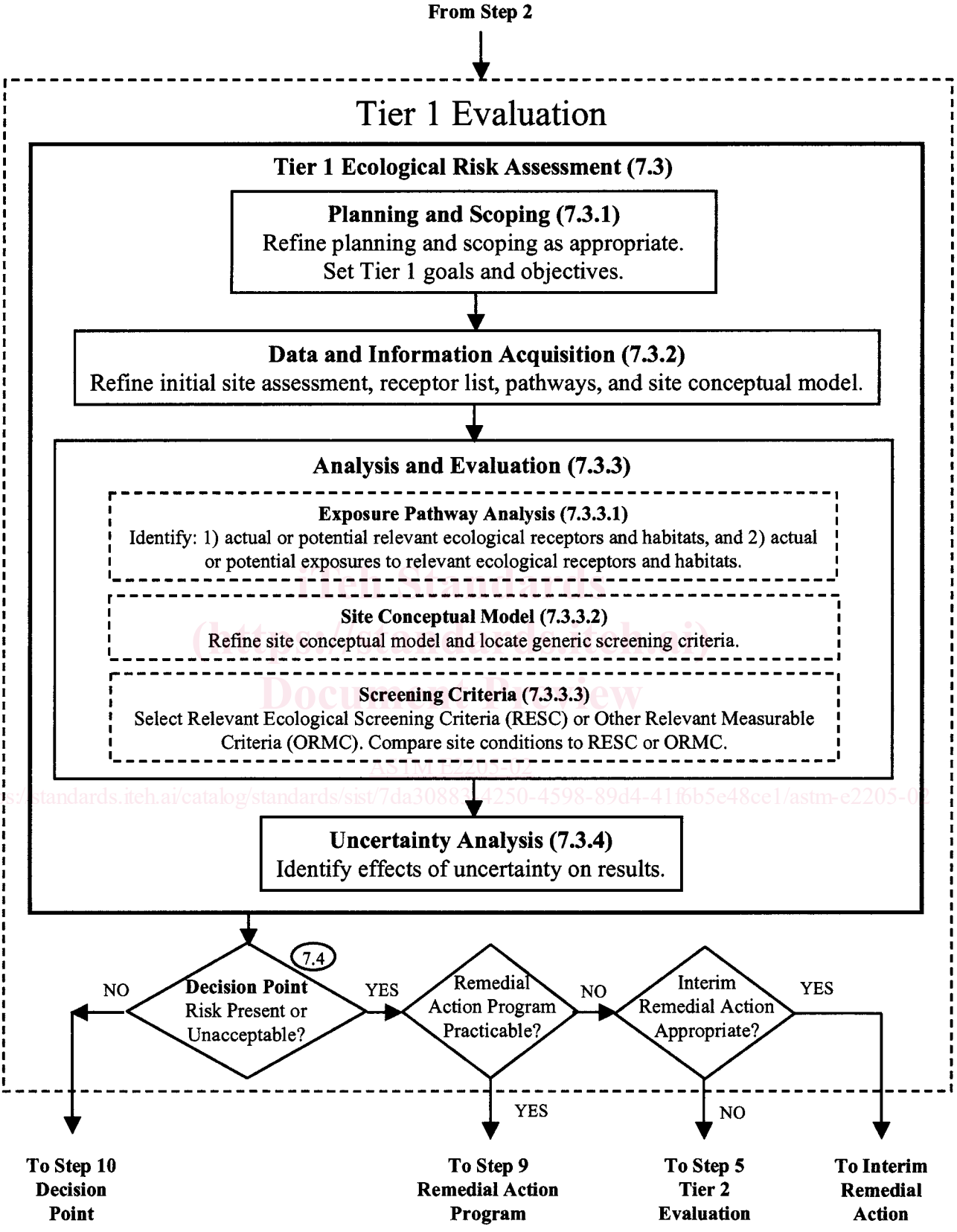

FIG. 2 Tier 1 Evaluation Flowchart

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

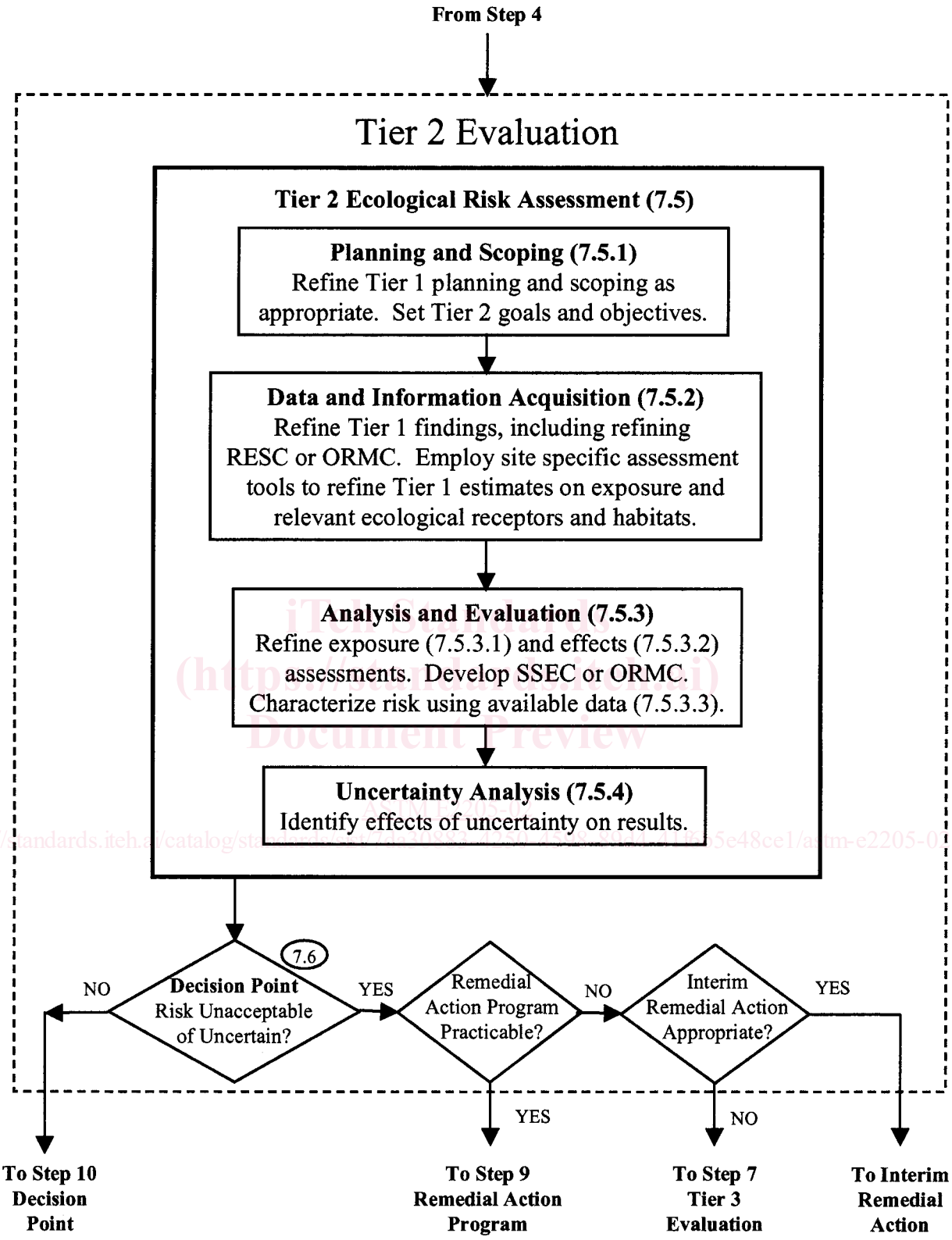

FIG. 3 Tier 2 Evaluation Flowchart

[1] This guide is under the jurisdiction of ASTM Committee E50 on Environmental Assessment and is the direct responsibility of Subcommittee E50.04 on Performance Standards Related to Environmental Regulatory Programs.

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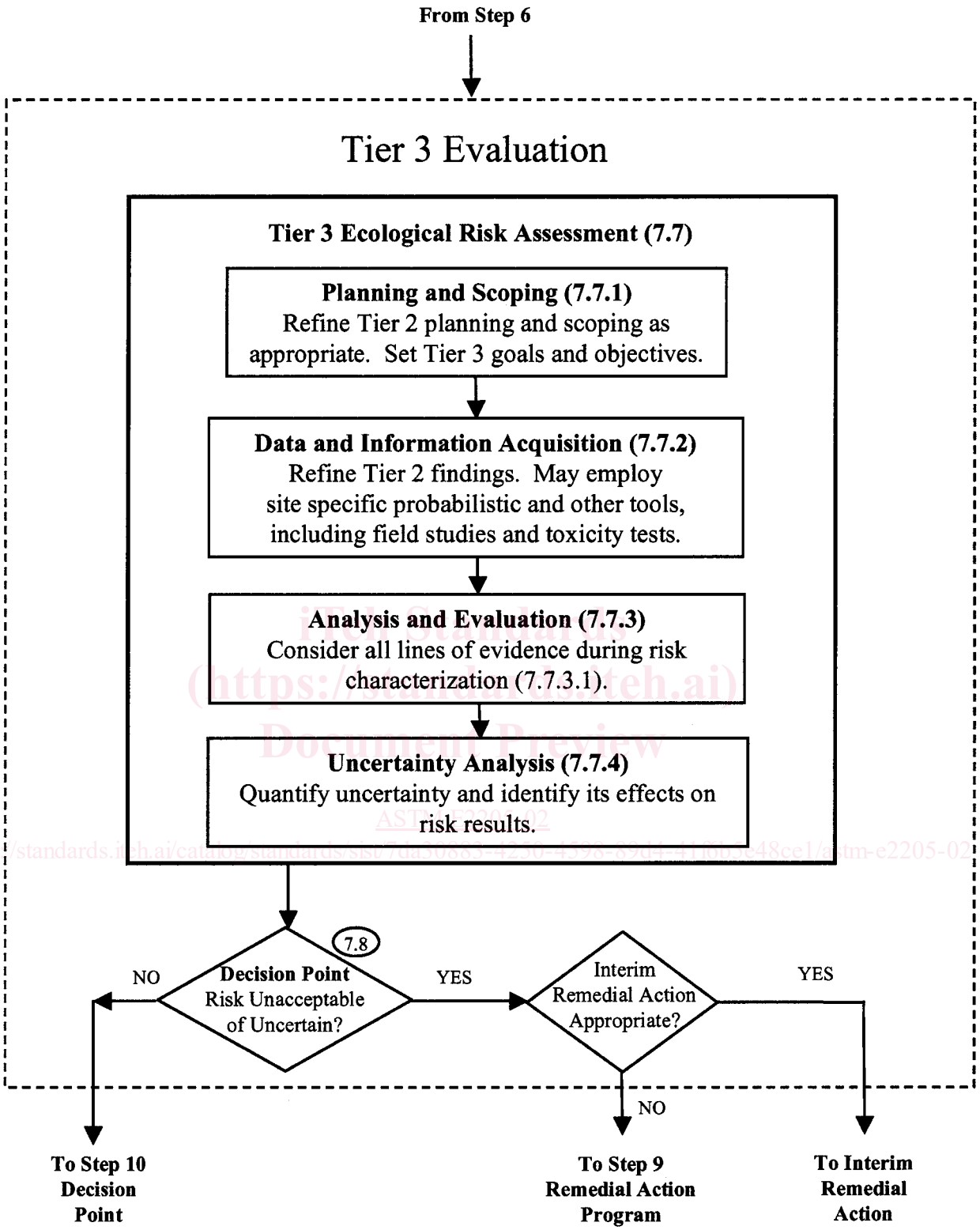

FIG. 4 Tier 3 Evaluation Flowchart

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 E 2081 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. Scope

1.1 This is a guide to risk-based corrective action for the protection of ecological resources and supplements the RBCA process (Guide E 2081). 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 E 2081).

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 E 2081, 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 E 2081 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 E 2081), as appropriate;

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

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 E 2081).

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 E 1739 and E 2081). 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).

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.

2. Referenced Documents

2.1 *ASTM Standards:* [3]

E 1739 Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites

E 1848 Guide for Selecting and Using Ecological Endpoints for Contaminated Sites

E 2081 Guide for Risk-Based Corrective Action

3. Terminology

3.1 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 E 2081.

3.1.1 *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.

3.1.2 *assessment endpoint*—the explicit expression of the environmental value that is to be protected, operationally

[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.

defined by an ecological entity and its attributes (**1**). The term in this standard for ecological entity is relevant ecological receptors and habitats (see 3.1.25). Additional information regarding assessment endpoints can be found in Guide E 1848.

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

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

3.1.5 *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.

3.1.6 *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.

3.1.7 *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 3.1.21, 3.1.26, and 3.1.36). 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.

3.1.8 *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**).

3.1.9 *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.

3.1.10 *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.

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

3.1.12 *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.

3.1.13 *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).

3.1.14 *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.

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

3.1.16 *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).

3.1.17 *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.

3.1.18 *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.

3.1.19 *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.

3.1.20 *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).

3.1.21 *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.

3.1.22 *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.

3.1.23 *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.

3.1.24 *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 3.1.2) that will be evaluated in the risk characterization (see 3.1.31) 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.

3.1.25 *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 (3.1.2).

3.1.26 *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).

3.1.27 *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.

3.1.28 *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.

3.1.29 *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.

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

3.1.31 *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.

3.1.32 *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.

3.1.33 *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.

3.1.34 *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.

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

3.1.36 *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.

3.1.37 *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.

3.1.38 *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.

3.1.39 *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.

3.1.40 *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.

3.1.41 *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.

3.1.42 *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.

3.1.43 *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.

3.1.44 *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 3.1.8) 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 E 2081.

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 E 2081) 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 E 2081 [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 3.1.24 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 3.1.7) 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 E 2081) 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 E 2081). 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 3.1.24 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 3.1.24 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