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Standard Guide for Risk-Based Corrective Action for Contaminated Sediment Sites[1]

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INTRODUCTION

This guide provides a framework for the development of a Risk-Based Corrective Action (RBCA) process for contaminated sediment sites (Sediment-RBCA) that integrates ecological and human health risk-based decision making into the corrective action process. Sediment-RBCA guide parallels the RBCA frameworks in Guides E2081 and E2205/E2205M with respect to the tiered approach for data gathering, evaluation and decision-making, and should, when possible, be conducted concurrent with broader RBCA activities. Sediment-RBCA provides a flexible, technically defensible framework for corrective action that can be applied to a wide range of sites and chemicals of concern. The framework incorporates a tiered technical approach, using increasingly complex levels of data collection and analysis as the user proceeds through the process.

This guide is intended to be used in conjunction with E3163 – Standard Guide for Selection and Application of Analytical Methods and Procedures Used during Sediment Corrective Action and E3164 – Standard Guide for Sediment Corrective Action – Monitoring. Successful implementation of the Sediment-RBCA process requires that the user identifies the technical policy decisions (TPDs) that are critical to the risk management process and identify these TPDs prior to beginning the process (see 5.5.3). There are numerous TPDs that must be made to implement the RBCA process, for example, defining data quality objectives (DQOs), identify relevant receptors, defining background and site exposure and toxicity data/inputs for risk evaluation, determining target risk levels, addressing resource protection, and implementing risk management. It is not the intent of this guide to define appropriate TPDs.

The Sediment-RBCA encourages broad stakeholder involvement in both the development of the TPDs and progression through the tiered analysis. This guide recognizes the diversity of sites and provides supporting appendices for additional information, with the intent of sharing industry best practices.

1. Scope

1.1 Sediment-RBCA is based on protecting human health and the environment. The guide supplements the RBCA (Guide E2081) and Eco-RBCA (Guide E2205/E2205M) processes and provides a decision-making process for the management of contaminated sediment. Contaminated sediment sites vary greatly in terms of setting, usage, spatial and temporal complexity, and physical and chemical characteristics; and, therefore, they also vary greatly in terms of the risk that they may pose to human health and the environment. The Sediment-RBCA recognizes this diversity by using a tiered approach for gathering and evaluating data to determine the need for additional evaluation or risk management tailored to site-specific conditions and risks.

1.2 This guide is intended to help direct and streamline the corrective action process and to complement (but not supersede) jurisdiction-specific guidance and regulations. It can be employed where jurisdiction-specific guidance is absent or insufficiently detailed; it can also assist to unify guidance when overlapping jurisdictions apply. It is compatible with a variety of programmatic guidelines for risk assessment and guidance from US Environmental Protection Agency (USEPA), Environment Canada, European, US states, that share the underlying risk assessment approach. In all applications, regulatory agencies should be consulted, as appropriate. Sediment-RBCA is not intended to apply to current permitted releases or permit applications.

[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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1.3 There are numerous TPDs related to the Sediment-RBCA process. Common examples are defining DQOs, identifying relevant receptors, defining toxicity values for risk evaluation, determining target risk levels, specifying the appropriate statistics and sample sizes, determining exposure assumptions, determining when and how to account for cumulative risks and additive effects among chemical(s) of concern, addressing resource protection, along with remedial action constraints (RACs). It is not the intent of this guide to define appropriate TPDs. Users should be aware of jurisdiction-specific guidance and should seek approvals and/or technical policy input as applicable.

1.4 The general performance standard for this guide requires that:

1.4.1 TPDs will be identified early in the Sediment-RBCA process and reevaluated throughout the process (at each tier),

1.4.2 Data and information compiled during the Sediment-RBCA process, including historical data and new data collected during the site assessment, will be relevant to and of sufficient quantity and quality to answer the questions and support the decisions made at each tier of investigation,

1.4.3 Actions taken during the risk-based decision-making process will be protective of human health and the environment, consistent with current scientific principles and practices, and in accordance with jurisdiction-specific requirements (for example, regulations, policies, and guidance), and

1.4.4 Remedial actions implemented consistent with TPDs and the Sediment-RBCA process will not result in greater long-term risks than existed before taking actions.

1.5 There are basic elements common to all RBCA guides:

1.5.1 site assessment;

1.5.2 tiered evaluations of exposure, effects, and risk;

1.5.3 risk-based decision making;

1.5.4 remedial action, and

1.5.5 monitoring.

1.6 This Sediment-RBCA focuses on releases of chemicals from sediment and is intended to be a companion to Guides E1739, E2081, and E2205/E2205M. Risks to human health from contaminated sites are discussed in Guides E1739 and E2081, while risks to ecological receptors are discussed in Guide E2205/E2205M and Guide E2020.

1.7 Both human health and ecological resource risks from contaminated sediment are addressed in this guide. Guidance on conducting human health and ecological risk assessments is available, including from various regulatory agencies, published literature, and scientific associations (see Appendix X1 to Appendix X7, Guide E2205/E2205M, and Guide E2020).

1.8 For sites that warrant remedial action, guidance is provided on developing remedial Action Objectives (RAOs) (Appendix X7) that support a remedial action plan.

1.9 This guide is organized as follows:

1.9.1 Section 2 lists referenced ASTM documents;

1.9.2 Section 3 defines terminology used in this guide;

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

1.9.4 Section 5 describes the tiered approach to the Sediment-RBCA process;

1.9.5 Sections 6 and 7 present Sediment-RBCA procedures in a step-by-step process; and

1.9.6 The reference section lists documents cited in this guide.

1.10 This guide also includes the following appendices, which are provided as supplemental information:

1.10.1 Appendix X1: Considerations for Design and Execution of Weight of Evidence (WOE) Approaches in Sediment Risk Assessment;

1.10.2 Appendix X2: Use of Sediment Quality Guideline Values (SQGs) in Screening Level Ecological Risk Assessments (SLERAs);

1.10.3 Appendix X3: Derivation and Use of Site-specific Ecological Criteria (SSEC) in Ecological Risk Assessments;

1.10.4 Appendix X4: Uncertainty in Risk Evaluation;

1.10.5 Appendix X5: Application of Reference Area Data in Sediment Ecological Risk Assessment;

1.10.6 Appendix X6: Biological Test Methods, and

1.10.7 Appendix X7: Guidance for Developing RAOs.

1.11 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.12 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E1689 Guide for Developing Conceptual Site Models for Contaminated Sites

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

E1848 Guide for Selecting and Using Ecological Endpoints for Contaminated Sites

E2020 Guide for Data and Information Options for Conducting an Ecological Risk Assessment at Contaminated Sites

E2081 Guide for Risk-Based Corrective Action

E2205/E2205M Guide for Risk-Based Corrective Action for Protection of Ecological Resources

E2876 Guide for Integrating Sustainable Objectives into Cleanup

E2893 Guide for Greener Cleanups

E3163 Guide for Selection and Application of Analytical Methods and Procedures Used during Sediment Corrective Action

E3164 Guide for Sediment Corrective Action – Monitoring

[2] 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.

2.2 *EPA Documents:*[3]

USEPA (2006) Guidance on Systematic Planning Using the Data Quality Objective Process: EPA QA/G-4. EPA/240/B-06/001

USEPA (2015) Determination of the Biologically Relevant Sampling Depth for Terrestrial and Aquatic Ecological Risk Assessments, Ecological Risk Assessment Support Center, Washington, DC

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 definitions within jurisdiction specific guidance that vary from that used in this guide. The following terms are being defined to reflect their specific use in this guide. The definitions presented here are intended to be consistent with those provided in Guides E2081 and E2205/E2205M.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *adaptive management, n*—a structured, iterative process of robust decision making in the face of uncertainty, with the goal of ensuring effectiveness during remedial action.

3.2.2 *assessment endpoint, n*—the explicit expression of the environmental value that is to be protected, operationally defined by an ecological entity and its attributes. The term "ecological entity" in this standard is equivalent to "relevant ecological receptors and habitats." Additional information regarding assessment endpoints can be found in Guide E1848. **E2205/E2205M**

3.2.3 *background conditions (aka reference conditions), n*—substances, conditions, or locations that are not influenced by the releases from a site and are either naturally occurring (consistently present in the environment, but not influenced by human activity) or anthropogenic (influenced by human activity, but not related to specific activities at the site). **E3164**

3.2.4 *bioavailability, n*—the degree to which a contaminant is free to be taken up by an organism.

3.2.5 *biologically active zone (aka biotic zone), n*—the zone of greatest organism-substrate interaction. **USEPA (2015)**

3.2.6 *chemical(s) of concern (COCs), n*—COCs are chemical or constituents that are identified as posing a risk based on the tiered assessment that warrant remedial action; the COCs are a subset of chemicals of potential concern (COPCs).

3.2.7 *chemical(s) of potential concern (COPCs), n*—the specific compounds and their breakdown products, along with mixtures and other constituents, that are identified for evaluation in the Sediment-RBCA process. Identification can be based on chemicals' historical and current use at a site, detected concentrations in environmental media or their mobility, toxicity, and persistence in the environment. Because COPCs may be identified at many points in the RBCA process, including before any determination that they pose an unacceptable risk to human health or the environment, the term should not automatically be construed to be associated with increased or unacceptable risk. **E2081**

3.2.8 *conceptual site model (CSM), n*—a written description, visual representation, or both, of predicted relationships between relevant ecological receptors and habitats and/or relevant human receptors, and the COCs to which they may be exposed. CSMs describe predicted relationships among COCs in environmental media (water, sediment, biological tissue, etc.) via fate and transport pathways, exposure pathways, and relevant receptors. The CSM should include both the current understanding of the site and the understanding of the potential future conditions and uses for the site. **E2205/E2205M**

3.2.9 *contaminant, n*—a hazardous substance as defined by federal, state/provincial, or international regulation, petroleum product, or other chemical that may pose a threat to human health or the environment when present in environmental media. **E2893**

3.2.10 *corrective action, n*—the sequence of actions that may include site assessment and investigation, risk assessment, evaluations of potential remedial action alternatives, interim remedial action, remedial action, operation and maintenance of the remedy, monitoring of progress, making "No Further Action" determinations, and completion of the remedial action.

3.2.11 *data quality objectives (DQOs), n*—the systematic process to develop performance and acceptability criteria by defining study objectives and the type, quality, and quantity of data needed for site decisions. **USEPA (2006)**

3.2.12 *ecological risk, n*—the potential for or probability of an adverse effect on a relevant ecological receptor or habitat (including populations or communities). These risks may be expressed qualitatively or quantitatively.

3.2.13 *evaluation criteria, n*—the criteria by which remedial technologies and remedial actions are evaluated in remedial decision making.

3.2.14 *human health risk, n*—the potential for or probability of an adverse effect on a human receptor. These risks may be expressed qualitatively or quantitatively.

3.2.15 *industrial sites, n*—sites where there were or are industrial facilities that discharged or currently discharge COCs into a contiguous area in a water body.

3.2.16 *initial site assessment, n*—an initial assessment of a sediment site that relies on readily available information for determining whether a risk assessment might be appropriate, whether a response action is appropriate to mitigate an immediate threat, or a no further action determination is warranted.

3.2.17 *institutional controls, n*—a legal or administrative restriction on the use of, or access to a site or facility to eliminate or minimize potential exposure to a COC(s) (restrictive covenants, restrictive zoning, access restrictions, fish consumption advisories, etc.). **E2081**

3.2.18 *interim remedial action, n*—the course of action, prior to final remedial action, taken to reduce transport of a COC(s) in sediment or water, or to reduce the concentration of

[3] Available from United States Environmental Protection Agency (EPA), William Jefferson Clinton Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460, http://www.epa.gov.

a COC(s) at a source area(s). These include remedial actions that are taken to address imminent risks to human health and the environment.

3.2.19 *measure of effect, n*—a change in an attribute of an assessment endpoint or its surrogate in response to a stressor to which it is exposed. Measures of effect are also referred to as measurement endpoints. **E2205/E2205M**

3.2.20 *non-urban sites, n*—sites where there were few former industrial, public, or commercial facilities and where there are limited point-source and non-point-source discharges. Sites may include residential properties or agricultural properties.

3.2.21 *reasonably anticipated future use, n*—current and likely future use of a site or facility which can be predicted with a reasonably high degree of certainty.

3.2.22 *relevant ecological receptors and habitats, n*—the ecological resources that are valued at the site. Because of the variety of ecological resources that may be present, focusing upon those relevant to a site is an important part of the problem formulation. Identification of relevant ecological receptors and habitats is dependent upon site-specific factors and TPDs.

3.2.23 *relevant human receptor, n*—human receptor that may be reasonably expected to be exposed to COCs in environmental media (water, sediment, biological tissue, etc.) given current and foreseeable uses of the waterway. These may include human receptors such as recreational users (boating, wading, swimming, fishing, crabbing), tribes (subsistence fishing), construction workers, those working on the waterway, or other site-specific receptors.

3.2.24 *remedial action, n*—activities conducted to reduce or eliminate current or potential future exposures to receptors or relevant ecological receptors and habitats. These activities include monitoring, implementing activity and use limitations and designing and operating cleanup equipment. Remedial action includes activities that are conducted to reduce sources of exposure to meet RAOs, or sever exposure pathways to meet RAOs.

3.2.25 *remedial action objectives (RAO), n*—stated objectives that describe what the remedial action for a site is expected to accomplish, based on the CSM and the exposure pathways that may pose an unacceptable risk as determined in a risk assessment. RAOs are specific and achievable goals for reducing risk to human health and the environment.

3.2.26 *risk assessment, n*—an analysis of the potential for adverse effects on relevant human or ecological receptors caused by a COC from a site. The risk assessment results support a decision on whether interim remedial actions, remedial action or a combination of actions are required, and form the primary basis for the development of RAOs.

3.2.27 *risk-based screening level (RBSL), n*—a chemical concentration or dose that is deemed to be protective for a given pathway and receptor (ecological or human). Covers a wide range of similar terms coined by jurisdiction-specific guidance manuals or other ASTM guides, including relevant ecological screening criteria, SQGs, SSECs, site-specific target levels (SSTLs), toxicity reference values (TRVs). RBSLs vary depending on the tier of the Sediment-RBCA and range from generic RBSLs used for the initial screening steps, to literature-based RBSLs typically used in Tier 1 or 2, to detailed, site-specific RBSLs derived from Tier 3 investigations.

3.2.28 *risk characterization, n*—the integration of the results of the exposure and effects analysis to evaluate the likelihood of adverse human health and/or ecological effects associated with exposure to COCs.

3.2.29 *risk management, n*—the consideration of scientific factors, economic factors, legal decisions, social factors, and technological factors to develop a response to identified risks.

3.2.30 *sediment, n*—a matrix of pore water and particles including gravel, sand, silt, clay, and other natural and anthropogenic substances that have settled at the bottom of a body of water. **E3163**

3.2.31 *sediment site, n*—the area(s) defined by the likely physical distribution of the COC(s) from a source area and the adjacent areas required to implement the corrective action. A site could be an entire water body or a defined portion of a water body.

3.2.32 *site assessment, n*—a characterization of a site through an evaluation of its physical and environmental context (for example, subsurface geology, sediment properties and structures, hydrology, and surface characteristics) to determine if a release has occurred. The characterization may identify the concentration and distribution of COCs. Information collected during the site assessment may include data on sediment, groundwater, and surface water quality, land and resource use, and potential human and ecological receptors. This information is used to develop a CSM and support risk-based decision making. **E2205/E2205M**

3.2.33 *site-specific, n*—activities, information, and data unique to a particular site. **E2081**

3.2.34 *stakeholders, n*—individuals, organizations or other entities that affect or are affected by the site conditions, the corrective action, or both. Stakeholders might include, but are not limited to, Potentially Responsible Parties (PRPs), owners, buyers, developers, lenders, insurers, government agencies, Tribes, community members, indigenous authorities, natural-resource trustees, and non-governmental or local community organizations. **E2205/E2205M**

3.2.35 *stressor, n*—a chemical, physical, or biological agent or condition that causes stress to an organism.

3.2.36 *sustainability, n*—the selection of remedial action decisions that balance community goals, economic impacts, and environmental effects.

3.2.37 *sustainable objective, n*—the overarching ideas and themes used to guide the implementation of sustainability for a project. These ideas and themes generally arise from outside of the specific project (state/provincial or federal regulations or guidance, municipal planning goals, corporate sustainable objectives, etc.) and are not developed exclusively for the specific project. **E2876**

3.2.38 *technical policy decisions (TPDs), n*—the choices specific to the user that are necessary to implement the RBCA framework described in this guide at a particular site. **E2081**

3.2.39 *tier 1 evaluation, n*—a screening-level assessment that uses existing information, nonsite-specific screening criteria, and protective assumptions to ensure that risks are not underestimated.

3.2.40 *tier 2 evaluation, n*—a risk-based analysis that involves an incremental refinement of the Tier 1 methodology to develop site-specific screening criteria.

3.2.41 *tier 3 evaluation, n*—a risk-based analysis that involves a significantly advanced incremental effort over the Tier 2 evaluation to assess site-specific risks.

3.2.42 *unacceptable risk, n*—a condition under which the likelihood of adverse effects to relevant human and/or ecological receptors and habitats is not within acceptable limits as defined by TPDs. **E2205/E2205M**

3.2.43 *uncertainty, n*—the lack of knowledge regarding site conditions, the nature of exposure, and effects on relevant human or ecological receptors and habitats. This lack of knowledge is recognized at each tier of evaluation through an uncertainty analysis. **E2205/E2205M**

3.2.44 *urban sites, n*—a site where there are industrial, municipal, commercial, or residential properties with multiple point-source and non-point-source discharges into a contiguous water body.

4. Significance and Use

4.1 This guide provides a consistent and transparent decision-making process for selecting risk-based corrective actions at sediment sites (that is, a Sediment-RBCA). Sediment-RBCA shares the same process as other RBCAs described in E1739, E2081, and E2205/E2205M but with explicit consideration of the constraints on how the available sediment assessment techniques impact decision making. Several factors exist that distinguish sediment sites from upland sites and warrant unique consideration, including background, potential for recontamination, sediment stability, sediment processes, lack of control on exposure and transport, exposure pathways and receptors, and unique site characteristics such as public lands, lack of site control on use and access. The diversity of available assessment techniques for a sediment site is considerably larger than for other media. Guidance on the technical tools themselves are described in other ASTM guides and regulatory guidance manuals.

4.2 Sediment-RBCA incorporates the same paradigm of planning and scoping, problem formulation, exposure and effects assessments, risk characterization, and uncertainty analysis that is common to ecological and human health risk assessment guidance documents. Irrespective of terminology, both Sediment-RBCA and risk assessment share the same science-based process and share the same goal of informing risk management decisions. The specific approach used to develop risk-based human health and ecological criteria and risk-based management plans may vary from site to site based on jurisdictional requirements, site complexity, TPDs, and best professional judgment regarding the appropriate use of different assessment techniques. Some attributes of Sediment-RBCA are:

4.2.1 Description of a tiered approach, including process flow charts, to identify critical steps and provide an overview of the entire RBCA process;

4.2.2 Identification, development, and use of TPDs throughout the Sediment-RBCA process;

4.2.3 Indications of the value and timing of stakeholder involvement, recognizing that some jurisdictions require varying degrees of coordination with a variety of stakeholders;

4.2.4 Identification of situations under which a risk assessment may or may not be necessary;

4.2.5 Identification of decision points where risk assessment results are used as part of the risk management decision making; and

4.2.6 Identification and development of appropriate RAOs to support risk management.

4.3 Activities described in this guide should be conducted by qualified professionals familiar with site characterization, remedial action science and technology, human health and ecological risk assessment methodologies, or related scientific and engineering subject areas, as they relate to complex sediment sites. A defensible application of a RBCA process is often a collaboration of multiple subject matter experts.

4.4 To properly apply the Sediment-RBCA process, the user should AVOID the following:

4.4.1 Using Tier 1 RBSLs as a default remedial action standard without considering if proceeding to develop more refined RBSLs through a Tier 2 or Tier 3 evaluation is appropriate;

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

4.4.3 Failing to document the purpose of the Sediment-RBCA process (that is, defining the management goal per the problem formulation requirement) and connecting that management goal to the specific assessment techniques in a logical and transparent way (that is, developing a clear set of assessment endpoints and measures of effects per risk assessment guidance);

4.4.4 Using unjustified or inappropriate exposure factors, toxicity parameters, or other assumptions required by an assessment technique or applying a model that is not supported by site-specific data;

4.4.5 Developing ecologically-based RBSLs from data that do not exhibit a dose- or concentration-response relationship, or failing to consider cumulative risks or additive effects when required to do so by jurisdiction-specific guidance;

4.4.6 Neglecting aesthetic, narrative, or other constraints when using RBSLs to establish the RAOs for a site;

4.4.7 Initiating remedial action(s) (other than an action taken to address imminent or priority issues) before determining the appropriate RAOs for the site. RAOs must be attainable using existing technology (that is, technically practicable and cost effective) and must reflect the desired long-term outcome for a sediment site in the context of current and realistic future site uses, as well as background concentrations and the potential for recontamination. It is also inappropriate to proceed with remedial action(s) without consideration of site

source-control measures (due to the potential for recontamination from uncontrolled sources).

4.4.8 Limiting remedial action options to a single type of remedial technology, failing to consider options for remedial activity or failing to consider use limitations of remedial technologies. In all cases, a robust remedial options analysis that is not biased towards a particular remedial action option is needed;

4.4.9 Using an interim remedial action to delay the RBCA process rather than to reduce risk;

4.4.10 Failing to consider the impact of a potential remedial action on relevant receptors as part of the selection process;

4.4.11 Failing to consider the long-term effectiveness of a potential remedial action during the selection process, or failing to monitor the effectiveness of the option once selected and implemented; and

4.4.12 Continuing to monitor a site once the RAOs have been achieved (unless the RAOs were explicitly designed to involve such monitoring). (Guide E3164)

5. Tiered Approach to RBCA for Contaminated Sediment Sites

5.1 Sediment-RBCA is the overall process of integrating site assessment, risk assessment, remedial action, and monitoring at sites where a chemical release to sediment has occurred. The decision-making process in Sediment-RBCA integrates both human health and ecological considerations (Guide E2081).

5.2 Sediment-RBCA progresses through one or more tiers until it has proceeded to the point a defensible conclusion about the magnitude of risk can be made, RAOs can be defined, and an appropriate remedial action (which may also include interim remedial actions) can be selected. The tiered process begins with an Initial Site Assessment using available site data and appropriate RBSLs (typically specified by the jurisdiction). If those initial RBSLs are exceeded, Sediment-RBCA guides the user to proceed to subsequent tiers as discussed in Section 6.

5.3 Each tier of Sediment-RBCA involves the same five steps (Fig. 1: Planning and scoping; Data and information acquisition; Analysis and evaluation; Decision-making; and Remedial action) but with increasing realism and complexity in the selected assessment methods with each successive tier.

5.4 Sediment-RBCA emphasizes flexibility in how the evaluation process is tailored to site conditions and requirements. This flexibility is necessary due to the wide variety of methods used to evaluate human health and ecological risk (see Appendix X1 through Appendix X6; E2205/E2205M). The specific methods selected for each tier should focus on providing the quality and quantity of data necessary to support risk-based decision making as defined by DQOs. As noted above, the complexity and sophistication of the methods increase with each tier to reduce the uncertainty in the decision-making process. A corollary is that COPCs, portion(s) of a site, exposure pathways, and/or receptors that can be eliminated at an early tier should not be revisited in subsequent tiers unless new information warrants re-inclusion.

5.5 Sediment-RBCA does not have to be a linear process and should proceed only to the point that a defensible decision can be made. The level of effort at any given tier is ultimately a project-specific decision that can be influenced by one or more of the following factors:

5.5.1 *Timing and Urgency of Response Actions*—Moving directly to Tier 2 or 3 early in Sediment-RBCA process may be appropriate if preliminary information indicates significant human health or ecological risks likely exist. Accelerating Sediment-RBCA may also make sense if there is an opportunity to integrate remedial actions with other site management activities (for example, habitat enhancements, flood mitigation projects, maintenance dredging).

5.5.2 *Stakeholder Feedback*—The nature and frequency of stakeholder engagement depends on jurisdiction- and site-specific requirements. There is no single model for stakeholder engagement and many sites may not require a formal stakeholder process. Further context about stakeholder engagement in RBCA projects can be found in Appendix X1.5 of E2205/E2205M and Appendix X1 of E2081. Stakeholder engagement can influence all parts of the process including the scope and tiering of the Sediment-RBCA process.

5.5.3 *Regulatory Input and TPDs*—Practitioners are cautioned that significant effort may be needed to obtain consensus on how specific TPDs will be applied on a site-specific basis. TPDs specifically for sediment are not available for many of the more complex investigative tools typically used in Tier 3. There is a need to select relevant TPDs for the current tier and appropriately apply them. The three general categories of TPDs are *(1)* those that exist prior to beginning the Sediment-RBCA process and will not change because they are prescribed by regulation or policy, *(2)* those that exist prior to the Sediment-RBCA but can be modified based on site-specific information, and *(3)* those that are developed specifically as part of the site-specific Sediment-RBCA process. Some regulatory agencies may also default (inappropriately) to TPDs that are based on upland considerations, for example using soil standards for the protection of human health to screen sediment data. Guides E2081 (Appendix X1) and E2205/E2205M (Appendix X3) provide additional information on considerations for establishing TPDs. Regulatory engagement is often central to the success of a Sediment-RBCA process, especially those that proceed to higher tiers and incorporate less common assessment tools.

5.5.4 *DQOs*—DQOs are developed for all sampling and analytical activities. These DQOs should be reviewed as the assessment progresses from tier to tier. Guide E3163 and USEPA (2006) provide more information about how to establish defensible DQOs for a variety of different sampling and analytical activities. The flexibility of Sediment-RBCA also means that it is relatively common to incorporate more innovative methods into a Tier 3 Sediment-RBCA. These methods may not yet be familiar to all users and may involve different types of DQOs beyond the traditional ones applied to chemical and toxicological analyses. Regardless, all methods must have DQOs in order to determine how much weight the data should receive in terms of making an informed site management decision (see Appendix X1).

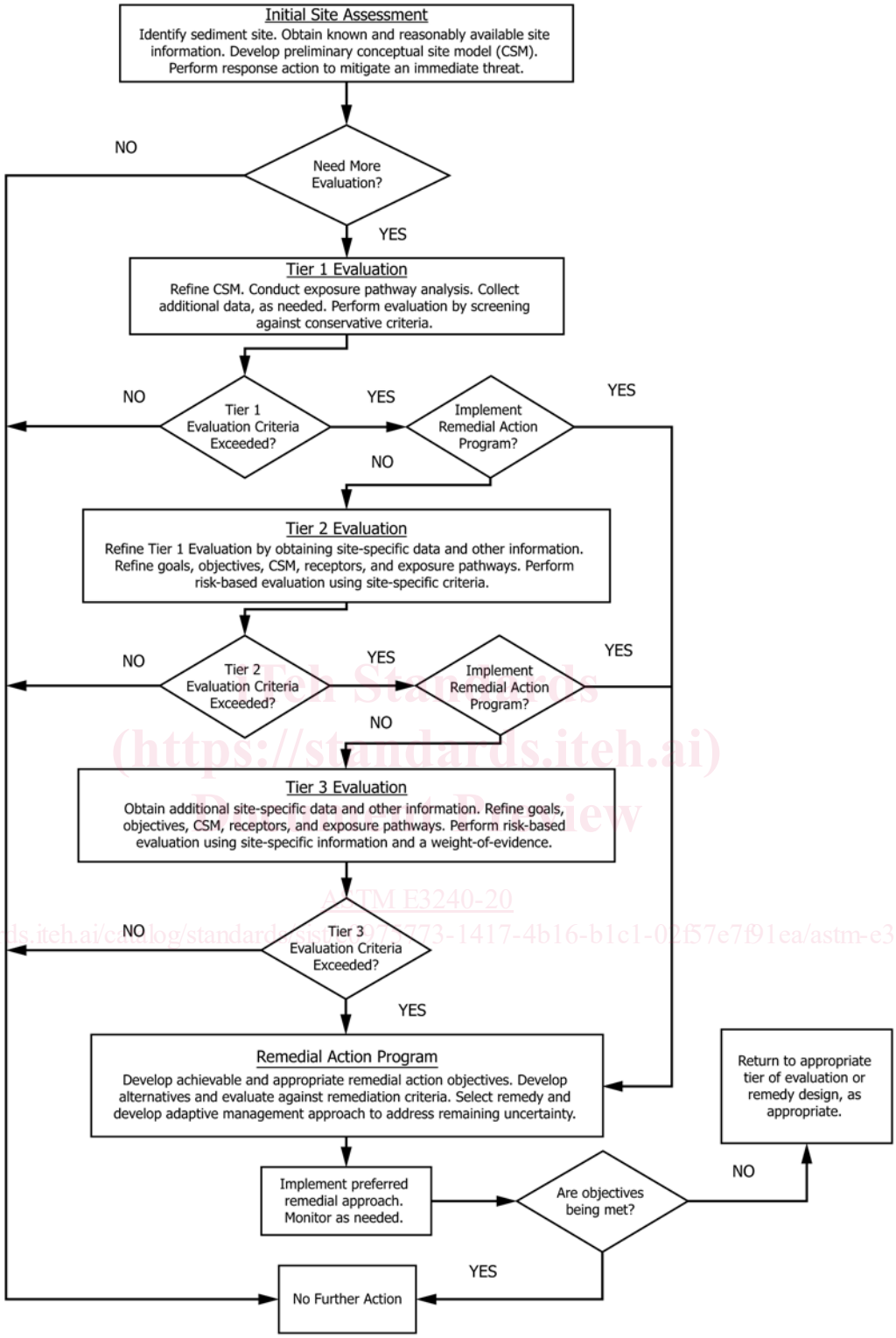


FIG. 1 Sediment-RBCA Process Flowchart

5.5.5 *Degree of Acceptable Uncertainty*—There is always uncertainty in both the site assessment and risk evaluation components at any tier (see Appendix X4). The level of conservatism in each subsequent tier will generally decrease as the uncertainty in the assessment and risk evaluation decreases, but in all respects, the uncertainty should be clearly documented (10.1.1) to show that the information is adequate to make an informed risk management decision. The degree of acceptable uncertainty may also be a TPD that warrants specific dialogue with regulatory agencies and stakeholders.

6. Sediment-RBCA Procedures

6.1 The sequence of principal tasks and decisions associated with the Sediment-RBCA process are outlined in Fig. 1. Each of these actions and decisions is discussed in the following sections. For the purposes of this guide, guidance is provided for the Initial Site Assessment, the Tier 1 evaluation and then the Tier 2+ Sediment-RBCA. The distinction between Tier 2 and Tier 3 evaluations is related to the site characteristics; the difference between Tier 2 and Tier 3 can be loosely defined by increasing complexity of the assessment (see Table 1). As noted in Section 5, the Sediment-RBCA process is intended to be highly flexible allowing for the application of various tools and analytical methods at either tier. Identification of specific tools or analytical methods in the following sections are intended to reflect common approaches and are not intended as prescriptive guidance.

6.2 *Initial Site Assessment (ISA)*—The ISA is performed to review existing information for determining if an initial response action is required to mitigate an immediate threat, further tiered evaluation is required, or if a no further action determination can be made (Fig. 1).

6.2.1 *Objective of the ISA*—The ISA is a planning and scoping activity that develops the CSM based on an initial understanding of the site. This planning and scoping activity is a critical part of implementing the TPDs due to the potential complexity of human and ecological exposure pathways at sediment sites. The ISA incorporates the same main steps as the subsequent tiered evaluations (Sections 6.3 and 6.4) but does not involve any new site-specific sampling.

6.2.2 *Planning and Scoping*—The focus of the planning and scoping effort is establishing a preliminary boundary for the study area, identifying the applicable regulatory TPDs, identifying and engaging stakeholders, and determining if there are appropriate RBSLs available to make an informed decision.

6.2.3 *Data and Information Acquisition*—The data and information acquisition activities for the ISA are limited to existing site reports or other readily available sources of information. This step is often more about compiling the available information and documenting the data gaps to be addressed in Tier I. Data gaps can also include the absence of appropriate TPDs and RBSLs.

6.2.4 *Analysis and Evaluation*—The analysis and evaluation in an ISA consists of two main activities.

6.2.4.1 *Preparation of a Preliminary CSM*—A preliminary CSM is developed during the ISA to facilitate overall understanding of the site, serve as a valuable tool for communicating the understanding of the site to stakeholders, and assisting in the decision-making process. The CSM describes the hypotheses that form the basis of the Sediment-RBCA evaluation by relating the potential chemicals of concern, fate and transport mechanisms, potential exposure pathways, and relevant receptors. Information collected during the ISA may identify incomplete exposure pathways that may eliminate the need for any further evaluation of one or more (or all) exposure pathways or the site as a whole. The CSM will be iteratively revised and updated as additional site information is obtained in subsequent tiers, as needed. In many cases, the data will not be sufficient to determine if exposure pathways are operable or inoperable, or if receptors are present or absent. A CSM for an ISA is typically more about documenting the identified data gaps to help focus future sampling than making a definitive statement about specific contaminants, sources, pathways and receptors, as illustrated in Fig. 2.

6.2.4.2 *Comparison to RBSLs*—It is common to compare any available sediment chemistry data to applicable RBSLs using a hazard quotient approach. It may be necessary to compare sediment chemistry data to RBSLs from a different jurisdiction (which is another TPD that may require early regulatory engagement).

6.2.5 *Decision Making*—The ability to make a no further action or a response action decision at the completion of the ISA is frequently limited due to the lack of sufficient existing data. If complete or potentially complete exposure pathways are identified after developing the CSM based on available data, then a Tier 1 evaluation should be conducted.

6.2.6 *Remedial Action*—The ISA will lead to a Tier 1 Sediment-RBCA for many sites but can lead to no further action in two specific scenarios.

6.2.6.1 The ISA can conclude that no further action is warranted (that is, stop the Sediment-RBCA process) when there is compelling and sufficient existing site-specific data to demonstrate that all chemical concentrations in site sediments are less than the applicable RBSLs or that there are no completed pathways to receptors at the site. RBSLs in this scenario would be default nonsite-specific, conservative, and chemical-specific values that are associated with a clear TPD that a no further action decision is supported.

6.2.6.2 The ISA can conclude that a response action is appropriate if there is compelling and sufficient site-specific data to demonstrate that there is an imminent and unacceptable risk to priority receptors identified in the CSM. The Sediment-RBCA process continues (after the response action is implemented) to determine the appropriate RAO(s) and final corrective actions (that is, remedial action[s]). A decision to implement a response remedial action based on the ISA typically requires a clear TPD to define what constitutes a priority receptor and what constitutes an imminent unacceptable risk. Human receptors are more likely to be a priority for these early response actions, although some jurisdictions may have legislation that mandates immediate action for certain ecological receptors (for example, prevention of acute lethality to specific, protected species).

6.3 *Tier 1 Evaluation:*

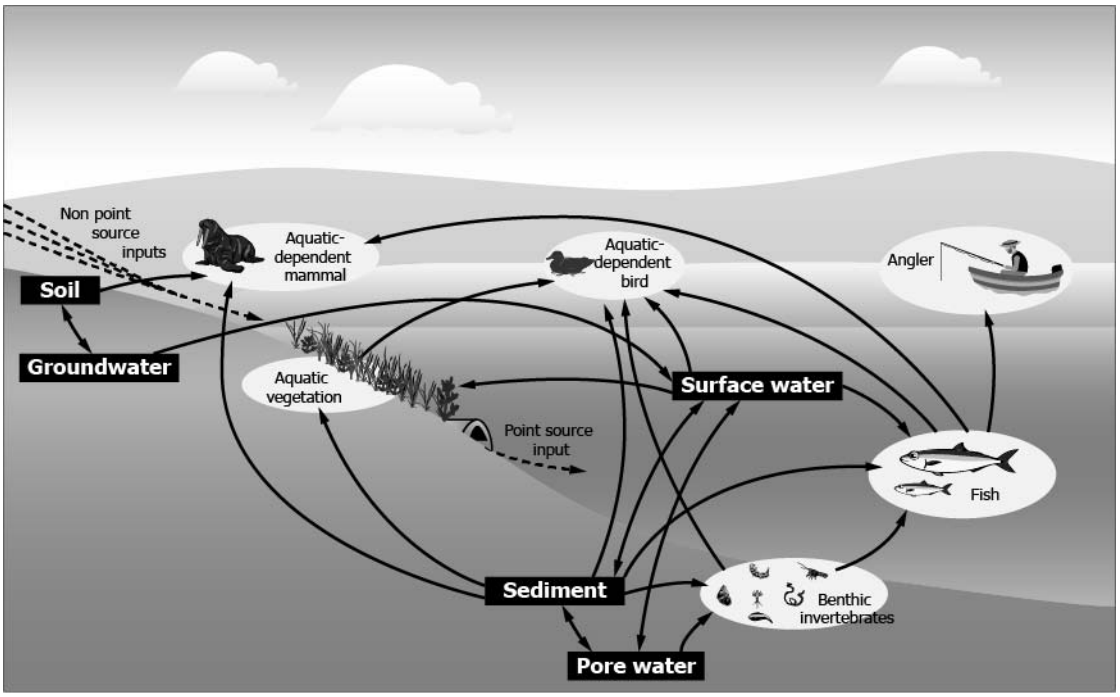
6.3.1 *Objective of the Tier 1 Evaluation*—The Tier 1 evaluation incorporates a screening-level risk assessment. As with all screening-level risk assessments, the level of complexity in the selected assessment methods is intentionally low, and the degree of conservatism is intentionally high. This conservatism extends throughout all aspects of the decision-making process for a Tier 1 evaluation. The Tier 1 evaluation uses the data and information collected for the ISA, as well as any additional data collected specifically for Tier 1.

6.3.2 *Planning and Scoping*—The planning and scoping for a Tier 1 evaluation is typically focused on addressing the major data gaps identified in the ISA. The Tier 1 planning and

TABLE 1 Sediment-RBCA Tier Content Comparison[A]

Sediment-RBCA Component	Initial Site Assessment	Tier 1	Tier 2	Tier 3
Data Compilation	Compile Existing/Historical Data: Obtain existing sediment data and other relevant information acquired from prior reports and site assessments, a site visit, records of historical site activities, or chemical releases or spills; identify meaningful data gaps	Initial Sampling: To fill data gaps previously identified, compile bulk sediment chemistry and TOC data to obtain chemical concentrations in sediments to identify initial COCs and an initial estimate of bioavailability	Site-Specific Sampling: Compile site-specific information to refine exposure estimates and fill data gaps; consider contaminant forms and species, and chemical mixtures	Compile site specific data and other information to perform detailed risk assessment
Site Visit	Conduct an initial site visit to compile information and record observations to inform the initial CSM	Compile source, pathway and receptor data; Collect bulk sediment and TOC data to assess contaminant bioavailability	Collect select site-specific information to refine CSM, including receptor groups and their use of the site	Conduct field study to collect data and other information to fill remaining data gaps for calculating estimates of bioaccumulation, benthic surveys, etc.
Conceptual Site Model (CSM)	Preliminary CSM: include an initial identification of sources, pathways, and receptors	Refine CSM: include exposure pathways, and identify contaminant sources and receptors	Refine CSM: include site specific refinement of exposure pathways and human and ecological receptors	Refine CSM: adjust as necessary, based upon Tier 2 findings and site-specific data collections
Work Plan	Establish Work Plan to fill data gaps with existing information	Develop Work Plan to conduct the screening assessment and perform simple mathematical modeling (EQP/Narcosis, Biotic Ligand, etc.), and an assessment of uncertainty	Develop Work Plan to collect data (for example, porosity) to perform for example relatively simplistic predictive models that are often algebraic and employ semi-analytical expressions; bioavailability testing in sediments (passive sampling, AVS/SEM, porewater sampling, etc.), and uncertainty assessment	Develop Work Plan to collect additional site-specific data, including community or habitat structure and function; population modeling (probabilistic); population or community level effects; site- specific or chemical-specific benchmarks; bioavailability factors; tissue data or other measures of bioaccumulation and biomagnification; toxicity testing, quantitative measures of uncertainty
Stakeholders	Identify appropriate stakeholders and define their involvement in the ISA	Identify, define their involvement, and engage appropriate stakeholders in Tier 1	Identify, define their involvement, and engage appropriate stakeholders in Tier 2	Identify, define their involvement, and engage appropriate stakeholders in Tier 3
Technical Policy Decisions (TPDs)	Identify TPDs and engage stakeholders to develop them	Identify TPDs for screening criteria, including bioavailability	Identify TPDs for site-specific screening criteria, including contaminant species and form, and chemical mixtures	Identify TPDs for site-specific risk assessment to include multiple lines of evidence
Screening Criteria	Compare site data and existing bulk sediment concentration data to generic sediment screening criteria	Compare site data to sediment screening criteria (RBSLs)	Compare site data to site-specific sediment screening criteria (RBSLs)	Compare site data to site-specific criteria, data, and other information using weight of evidence
Uncertainty Analysis	Qualitative; much uncertainty may be present as generic screening criteria and limited data are being used	Qualitative; consider that screening criteria being used are not site-specific	Usually qualitative; more rigorous than Tier 1; consider that site-specific criteria are being used	Rigorous, often quantitative
Remedial Action Objectives (RAO)	Develop achievable and appropriate RAO based on TPDs to mitigate an immediate threat (if needed)	Develop achievable and appropriate RAO based on TPDs	Develop achievable and appropriate RAO based on TPDs	Develop achievable and appropriate RAO to include for example additional considerations such as sustainability
Available Actions	No further action; further tiered evaluation, response action to mitigate an immediate threat	No further action; remedial action, further tiered evaluation	No further action; remedial action, further tiered evaluation	No further action; remedial action, further Tier 3 evaluation
Monitoring	If no further evaluation is needed in Tier 1, monitoring not prescribed under an Initial Site Assessment	Monitor as appropriate after reviewing exiting data for the site	Monitor as appropriate after collecting additional exposure pathway data to plug data gaps remaining from Tier 1	Monitor as appropriate after collecting additional site- specific data to plug data gaps remaining from Tier 2

[A] Each level of tiered evaluation should build upon data from previous tier(s) to ensure increased site specificity.



NOTE: Solid arrows indicate potential exposure routes between media and receptors. Dashed arrows indicate potential sources of contamination.

FIG. 2 Example Preliminary CMS Developed During the Initial Site Assessment for Human and Ecological Receptors when Limited Site Information is Available

scoping effort needs to have clarity about the relevant management goal, assessment endpoints, TPDs, and RBSLs. If regulatory or stakeholder engagement is needed to confirm these points, the Tier 1 planning and scoping effort provides an opportunity to do so. Early agreement with decision-makers that sediment management decisions will be risk-based and involve a tiered approach with an inherent trade-off between effort and uncertainty at each tier is strongly encouraged.

6.3.3 *Data and Information Acquisition:*

6.3.3.1 *Scope of Effort*—There is no prescriptive delineation between the scope of the Tier 1 evaluation and those of subsequent tiers (Table 1), however most Tier 1 evaluations focus on sediment chemistry data for comparison to conservative, non-site-specific RBSLs and leave more sophisticated assessment techniques to Tiers 2 or 3. Data acquisition for a Tier 1 evaluation is often focused on identification of site contamination (COPC concentrations, nature and extent, etc.) through bulk sediment sampling. Other sampling (water, pore water, tissue, etc.) can be considered where appropriate on a site-specific basis. The scope of the Tier 1 evaluation is dependent on the quality and quantity of data from the ISA (6.2).

6.3.3.2 *Planning Documentation*—The specific planning documentation required for field activities varies by jurisdiction but should always include a rationale for the level of effort (for example, a study design), a description of planned activities (work methods, specific work instructions, etc.), a definition of what constitutes reliable data (for example, DQOs) and a statement about how the data will be evaluated (for example, decision criteria). For a Tier 1 evaluation, planning documentation may be relatively straight-forward to prepare because there are standardized methods available for sediment sample collection, processing, transport, and analysis. DQOs for sediment chemistry are straight-forward and described by the standardized analytical protocols (Guide E3163).

6.3.3.3 *Other Activities that may be a Part of the Tier 1 Evaluation*—Some Tier 1 evaluations incorporate a desktop evaluation of possible hazards to higher trophic levels by predicting tissue concentrations using biota-sediment accumulation factors (or using site-specific data, if available).

6.3.4 *Analysis and Evaluation*—Analysis and evaluation at Tier 1 focuses on refining the CSM and exposure pathway analysis by comparing the available data to the Tier 1 RBSLs using a hazard quotient approach. Evaluation of multiple types of data using a WOE assessment (Appendix X1) are commonly deferred to Tiers 2 or 3.

6.3.4.1 *Refinement of the CSM*—The Tier 1 evaluation should refine the CSM to determine if exposure pathways are complete, potentially complete, or incomplete. (Note that other terms such as “operable” or “viable” pathways are also commonly used instead of “complete” but are synonymous). Refinement of the CSM at Tier 1 is largely based on the spatial extent of contamination (relative to the Tier 1 RBSLs). In addition, refinement of the CSM can be based on field observations regarding potential point and non-point sources, observations about relevant human health and ecological receptors and habitat (considering current and reasonable future uses of the study area), and consideration of significant fate and transport mechanisms for each COPC (in light of the identified human health and ecological receptors and habitats).

6.3.4.2 *Selection of RBSLs*—Chemistry data collected during a Tier 1 evaluation are compared to highly conservative RBSLs typically mandated by the jurisdiction. Some jurisdictions specify a hierarchy of published sources (Appendix X2)

in lieu of deriving their own RBSLs. Some jurisdictions permit adjustment of a RBSL to account for site-specific factors such as grain size or organic carbon content.

6.3.4.3 *Deriving a New RBSL*—In the absence of an approved RBSL, the user can develop a RBSL in consultation with the appropriate regulatory agencies, as appropriate. It may also be feasible to establish a Tier 1 RBSL for upper trophic level receptors based on simple calculations (see Appendix X2 and Appendix X3). The decision to derive a new RBSL at Tier 1 is ultimately a TPD and is frequently deferred to the Tier 2 evaluation.

6.3.4.4 *Comparisons to RBSLs*—It is common to refine the selection of COPCs by comparing the maximum chemical concentrations found in sediment to the Tier 1 RBSLs; if the maximum concentration of a COPC does not exceed a Tier 1 RBSL, then it can be excluded from further consideration (in Tiers 2 and 3). Some jurisdictions may allow further refinement by making comparisons using a statistically derived point-estimate (for example, 95 % upper confidence limit of the mean) instead of using the maximum concentration. In some cases where there is an understanding that background and site conditions are similar, the Tier 1 evaluation can include comparison to background concentrations. The final decision about using a point-estimate or a background concentration to refine the Tier 1 RBSL is ultimately a TPD and is frequently deferred to the Tier 2 evaluation.

6.3.4.5 *Uncertainty Analysis*—Uncertainty is discussed in greater detail in Appendix X4. The Tier 1 evaluation is intentionally protective, and therefore, the uncertainty analysis is typically focused on those aspects that might contribute to the over-estimation of potential risk. It is important to avoid an erroneous conclusion that the estimated risk is acceptable, when in fact the risk is unacceptable; the use of overly conservative, non-site-specific Tier 1 RBSLs has a high potential to cause such an erroneous conclusion. The uncertainty analysis at Tier 1 will continue to identify data gaps. These data gaps may still involve the exposure assessment (that is, the vertical or horizontal extent of sediment contamination may still be unclear), but the Tier 1 uncertainty analysis will likely identify data gaps associated with the effects assessment (that is, lines of evidence that quantify the magnitude of biological impacts). In all instances, the goal of the uncertainty analysis is to document the assumptions being employed and the degree to which the results of the Tier 1 evaluation can be used to make an informed management decision.

6.3.5 *Tier 1 Decision Making*—From a narrative perspective, a Tier 1 RBSL is intended to provide a conservative value below which there is no potential for unacceptable risk to relevant human health or ecological receptors or habitat. Exceedance of a Tier 1 RBSL does not mean that an unacceptable risk exists. An exceedance of a Tier 1 RBSL only indicates that there is a potential for risk that warrants further evaluation. Not all contaminants will have a Tier 1 RBSL available. If a Tier 1 RBSL is available, it may not be applicable to all relevant receptors or exposure pathways identified in the CSM. It is frequently necessary to defer the evaluation of biomagnifying COCs to the Tier 2 evaluation because many Tier 1 sediment RBSLs are based on toxicity to a single organism rather than long-term bioaccumulation and biomagnification at higher trophic levels. One of three decisions are possible based on the Tier 1 evaluation:

6.3.5.1 RBSLs are not exceeded and no further action is warranted. This decision is typically linked to a TPD and assumes that the chemistry data is sufficiently robust and representative to allow this conclusion.

6.3.5.2 RBSLs are exceeded and warrant further evaluation in subsequent tiers (see 6.4). This is the most likely outcome of most Tier 1 evaluations.

6.3.5.3 RBSLs are exceeded and of a sufficient magnitude to warrant an immediate remedial action (or even an interim remedial action) per Section 7. This decision is like that described in 6.2.4.2 for the ISA. The decision about what constitutes a "sufficient magnitude" is a TPD. In most cases, the remedial action or interim remedial action would be focused on a specific COC or portion of the site area, and the evaluation of the remainder of the COCs and site area would continue forward within the Sediment-RBCA process (that is, Tiers 2 and 3).

6.4 *Tier 2 and 3 Evaluations:*

6.4.1 *Objective of the Tier 2 or 3 Evaluations*—Each successive tier of the Sediment-RBCA process will incorporate increasingly complex field assessment methods, more sampling effort, and more sophisticated analytical or statistical approaches (Table 1). Narratively, the intent is to replace conservatism with realism, and generic with site-specific. As noted in 6.1, the decision about which assessment methods belong to a given tier is site-specific, and in all cases, the intent is that the Sediment-RBCA process be applied in a flexible way that reflects site-specific conditions. There is no requirement to use three tiers: one can proceed directly from Tier 1 to Tier 3, or alternatively, end the evaluations at Tier 1 or Tier 2. This is ultimately a benefit-cost tradeoff between proceeding with remedial action and risk management as opposed to continuing with further data collection and risk assessment. Guidance is provided in the following sections about which methods tend to be applied in Tier 2 versus Tier 3 and are not intended as prescriptive guidance as how to structure the tiers. Consistent with other RBCA standards, Tier 2 primarily focuses on chemistry-related data while Tier 3 typically focuses on biological analyses. As the process progresses additional data is collected where the costs/level of effort associated with the additional data are less than the value of the data to support a decision. The goal is to increase site-specific knowledge and reduce uncertainty to support the most appropriate decision.

6.4.2 *Planning and Scoping*—Each tier expands on the data previously collected and provides an opportunity to refine any of the decisions previously made considering new information. This refinement can cover all aspects of the Sediment-RBCA process.

6.4.2.1 *CSM*—Iterative refinement of the CSM continues throughout the Sediment-RBCA process to provide clarity about the status of difference sources, COCs, exposure pathways and receptors. There may still be gaps to address in a Tier 2 evaluation, but by Tier 3, the data should be sufficient to determine which pathways are complete versus incomplete.

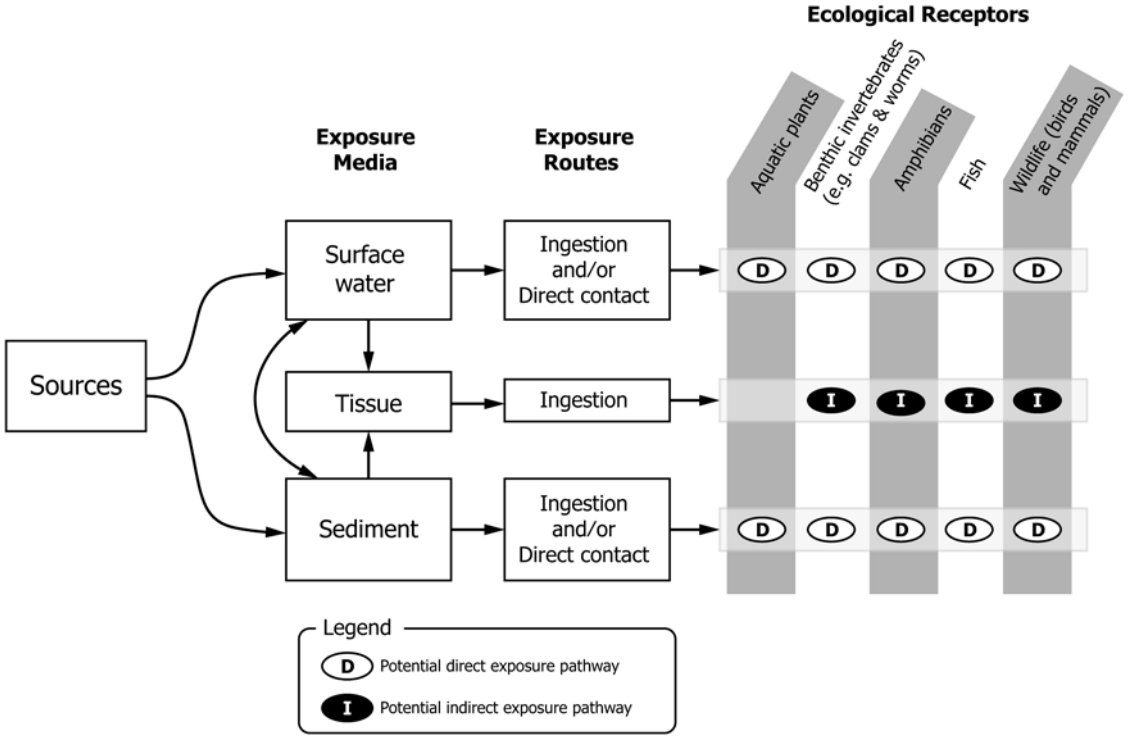


FIG. 3 Example of a refined CSM developed for ecological receptors that builds on the CSM developed in the Initial Site Assessment

6.4.2.2 *Definition of Appropriate RBSLs*—Tier 2 and 3 evaluations will incorporate more than sediment chemistry, and therefore, there will need to be decision criteria (collectively, RBSLs, selected or derived) to evaluate those additional data. These RBSLs may involve the evaluation of toxicity data from the literature, the use of predictive models, and other approaches. Many Tier 2 and 3 RBSLs will be dose- or concentration-based (see Appendix X2 and Appendix X3) but could also be a TPD to be applied to the site-specific data. For example, it is relatively common to evaluate site-specific toxicity data against a RBSL that a reduction of less than 20 % in test endpoint performance relative to a reference site does not constitute an adverse effect. This RBSL is based primarily on common practice and may not necessarily reflect a jurisdiction-specific TPD. Users are cautioned that it can require considerable effort to provide a robust technical rationale to support selected RBSLs, especially at Tiers 2 and 3. Relying on a RBSL from the literature without demonstrating that it is applicable and appropriate for use at a particular site is not an acceptable practice for Tier 2 or 3 evaluations.

6.4.2.3 *Confirmation of TPDs and Stakeholder Engagement*—There are multiple TPDs that need articulation or clarification as the Sediment-RBCA process progresses. Best professional judgement becomes increasingly necessary when less commonly-used methods are incorporated into the assessment. The availability of multiple lines of evidence means that WOE approaches will be used (Appendix X1) which in turn requires more TPDs. Often, it becomes necessary to outline the hierarchy of assessment and evaluation methods (that is, communicate the entirety of the Sediment-RBCA process) early in the process, acknowledging that the decision-making in later tiers will be influenced by the findings of the current tier. Regulatory engagement (and frequently, some form of stakeholder consultation) becomes increasingly important as the Sediment-RBCA process progresses. There is a high probability that the risk assessment will not be sufficient to support risk management planning if stakeholder engagement is not considered.

6.4.2.4 *Planning Documentation*—The same requirements apply to the later stages of the Sediment-RBCA process (5.5.4) but the level of documentation increases with the sophistication of the methods being proposed. Planning documents are often formal, stand-alone deliverables that articulate a formal study design (for example, impact-reference versus gradient designs), formulate specific hypotheses, consider statistical power and spatial coverage to establish the appropriate sampling effort, and describe the quality assurance plan for the work. This may require collaboration by multiple subject matter experts to describe the rationale and technical background for a particular method, and the involvement of risk assessment specialists to describe how the technical work by different subject matter experts will be integrated into an overall risk conclusion. Appendix X1 provides more information about the importance of robust planning on a successful WOE evaluation. Users should not underestimate the level of effort needed to develop work plans for many Tier 3 investigations.

6.4.3 *Data and Information Acquisition*—The Tier 2 data and information acquisition will be more site-specific than those in Tier 1, and will depend on the objectives, assessment endpoints and measures of effect, and the approach identified during planning and scoping (6.4.2). Data may be collected to fill data gaps identified during Tier 2 planning and scoping. Specific data collection activities may include the following:

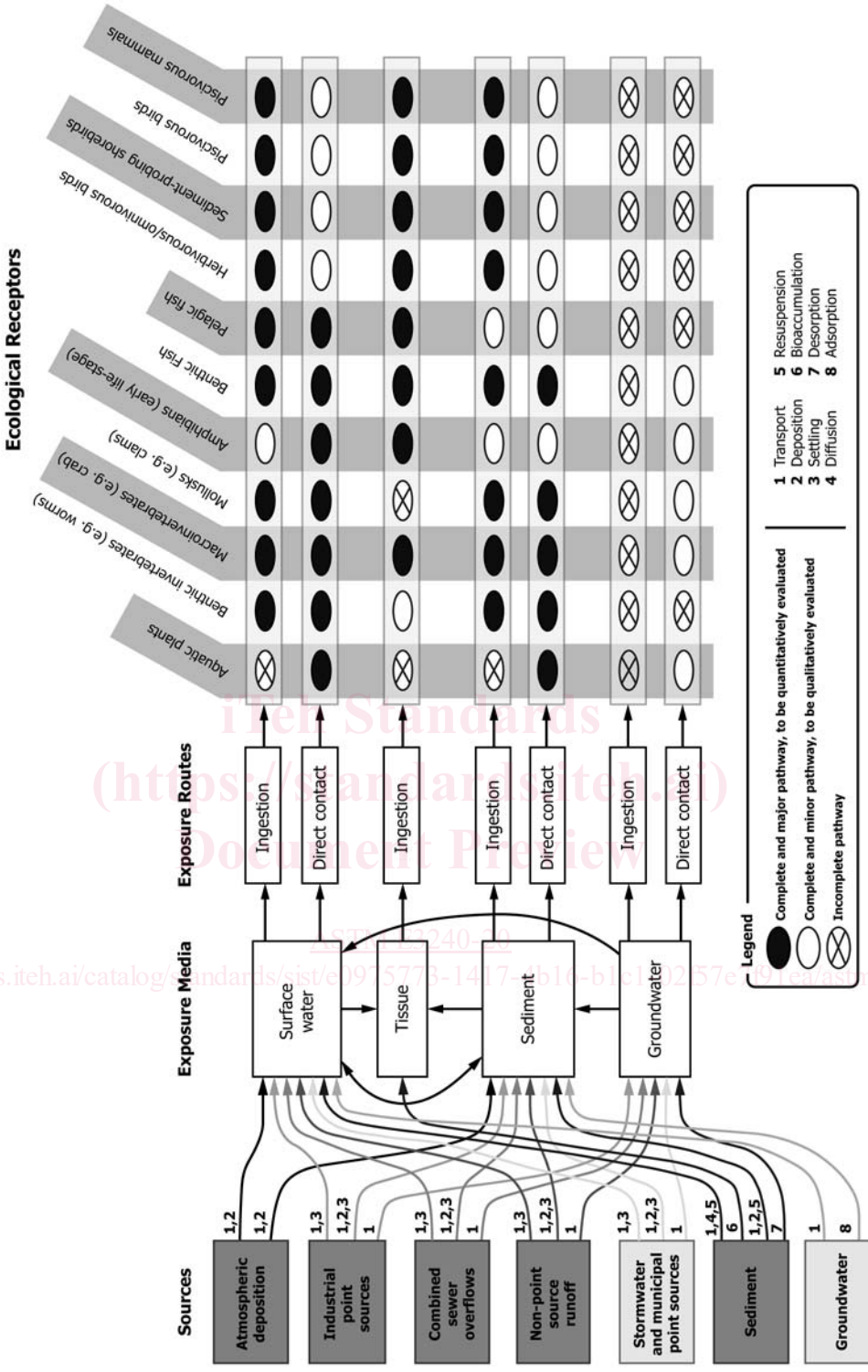


FIG. 4 Example of a highly refined CSM showing more sophisticated understanding of site-specific ecological receptors

6.4.3.1 *Differentiation between Tiers 2 and 3*—There is no prescriptive definition of what constitutes a Tier 2 versus a Tier 3 evaluation. If a Tier 1 evaluation can be operationally defined as a screening level analysis based on bulk sediment chemistry, then a Tier 2 evaluation expands on the initial site chemistry with data collected to understand site-specific bioavailability (for example, porewater analyses, AVS/SEM, etc.). The Tier 3 evaluation expands the Tier 2 data set to include biological testing (tissue testing, Triad-related analyses – chemistry, benthic community, toxicity) to support a more complete site-specific understanding to determine if and what remedial action would be appropriate. Additional elements of Tier 3 may include more sophisticated modeling, specialized analytical techniques, or anything else that requires the risk assessor to

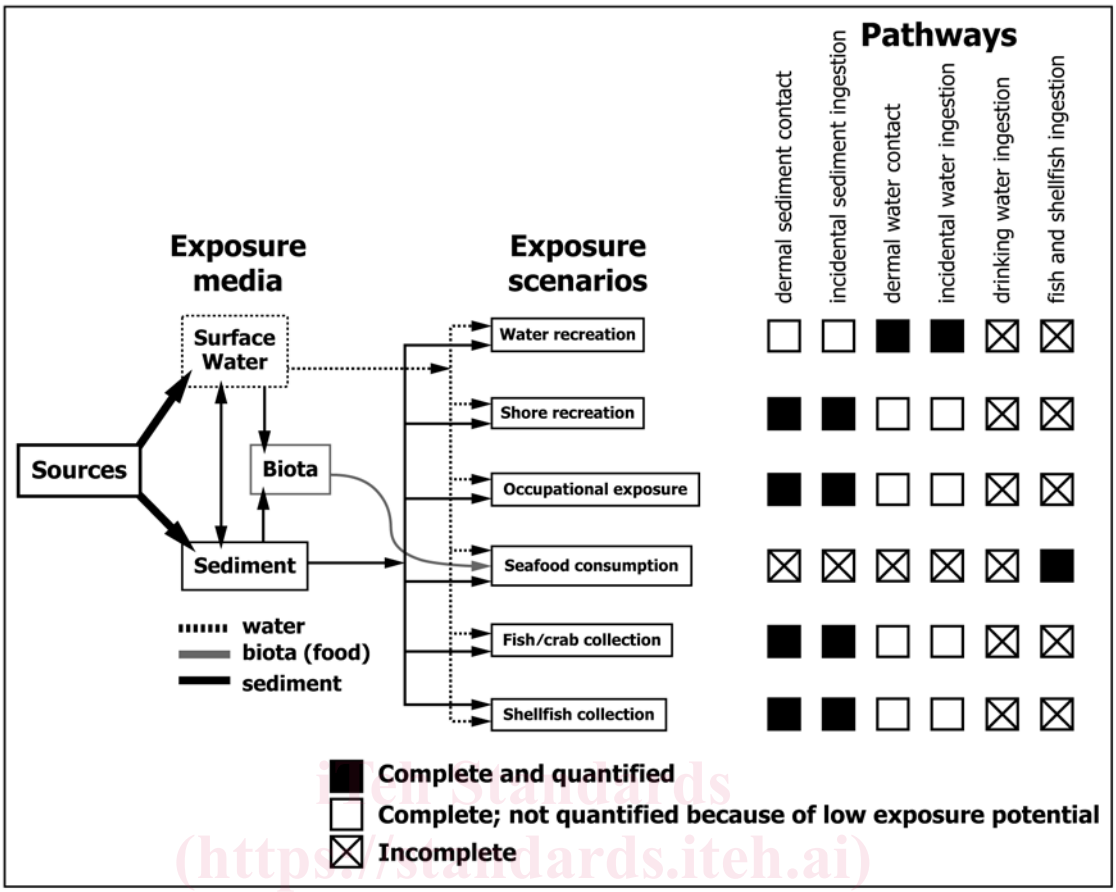


FIG. 5 Example of a highly refined CSM showing more sophisticated understanding of site-specific human receptors and exposure scenarios

consider WOE integration without the clearly articulated TPDs that are commonly available for a classic triad analysis.

6.4.3.2 *Acquire Information on Relevant Receptors*—Field observations or biological survey data at Tier 1 are generally used to refine the CSM by documenting what receptors are present or expected to be present at or near the site. The Tier 1 evaluation may have assumed that particularly sensitive, guilds (that is, groups of species that feed in similar ways) were present as a surrogate for other species to ensure adequate protection of all species. Site-specific information collected in Tiers 2 and 3 can be used to determine whether the underlying technical justification for using this generic assumption (that is, presence of sensitive guilds) is appropriate. Biological survey data may also be used as a line of evidence, for example by providing direct, quantitative information about individual organisms, species, or ecosystem components; as noted above, measurement of benthic community structure is a frequently used method. For example, sediment profile imaging is a tool that can be used in conjunction with classic benthic taxonomy surveys to help refine a Tier 3 study design (or to act as additional lines of evidence). Tier 3 evaluation could also include other types of information on receptor populations (creel surveys, fish tracking, etc.) that are used as their own lines of evidence or help to refine other assessment methods (site-specific information about feeding habits, habitat use to refine food chain modeling, etc.).

6.4.3.3 *Acquire Information on Exposure (Chemistry Data)*—Tier 2 and 3 evaluations continue to improve the exposure information by measuring the concentrations of COCs along gradients, by calculating area-weighted averages, and/or by measuring other media such as porewater or overlying water instead of relying on bulk sediment alone. Chemical measurements that provide information about contaminant bioavailability (AVS-SEM, passive sampling, organic carbon normalization, etc.) become increasingly common at Tiers 2 and 3. Data evaluation may include: *(a)* statistical evaluation of the chemistry data to determine a reasonable worst-case concentration in lieu of using the maximum concentration; *(b)* using a model to predict an exposure concentration assuming steady-state or equilibrium conditions (for example, predicting porewater concentrations from sediment concentrations based on K_{ow}); or *(c)*, extrapolation of exposure concentrations along gradients using simplistic transport models. At Tier 2, there may still be limited site-specific data, and therefore, some degree of conservative assumptions to manage uncertainty are still needed.

6.4.3.4 *Acquire Information on Exposure (Chemical Form)*—Toxicity of a COC may vary dramatically, depending