RISK-BASED MANAGEMENT PRINCIPLES FOR EVALUATING SEDIMENT MANAGEMENT OPTIONS

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EXECUTIVE SUMMARY

This paper presents a tiered approach to risk assessment and risk management as an appropriate and efficient process for addressing human and ecological health concerns surrounding sediment contamination. Risk management input is critical to framing risk assessment issues and defining the types of risks that must be evaluated and solicited early in the assessment process. In particular, the selection of relevant human and ecological receptor groups, development of exposure scenarios, and specification of assessment endpoints for ecological receptors require discussions between risk managers and risk assessors. Contaminated sediment risk assessments and risk management decisions usually require consideration of both human health and ecological concerns due to the close links between many ecological processes and sources of food and drinking water for human receptor groups.

Decision Framework Overview

The risk assessment decision framework is presented in Figure B-1 in the paper and includes parallel evaluations for both human and ecological receptors. The decision framework highlights the importance of considering both direct toxicity to exposed receptors and bioaccumulative effects of COCs in sediments. Based on sound science and consistency with regulatory guidance, there are a number of places to exit the decision path. Specific steps at each level are discussed in more detail in the paper that follows. It is important to specify the considerations appropriate for evaluating each site as the specific deliberations are somewhat different for human and ecological assessments. For human health risk assessments, it is important to specify the appropriate receptor group(s) and exposure scenario(s). For ecological risk assessments, it is essential to agree on the relevant receptors and exposure scenarios and appropriate assessment endpoints for the ecological receptors at a particular site.

Selecting human and ecological receptors and scenarios involves a significant amount of discussion between risk assessors and risk managers. In particular, human health risk assessments focus on individuals among local populations or at-risk subpopulations within the local community. Ecological risk assessments focus on sustaining populations or communities within the local ecosystem except when it is necessary to protect individuals among rare or threatened species that have been identified as relevant receptors. Once receptors are defined, assessments of their exposure and potential resulting effects are used to estimate the severity, magnitude, and duration of potential risks. These estimates usually are conducted in a tiered manner, moving from generalized assumptions and conservative estimates of exposure and effects to more site-specific, refined estimates. Using this approach minimizes the risk assessment effort, yet provides risk assessment resources commensurate with the magnitude of issues and scale of remedial options. There are various decision points in the process to evaluate the most appropriate subsequent path. At each decision point there are three potential outcomes:

- Risk estimations demonstrate that no further action is required.
- Risk estimations developed suggest that additional characterization or risk analysis is needed to better define risk estimations, determine if remedial action is appropriate, and, if so, determine the nature of the effort.

- Risk estimations demonstrate the need to develop RAOs to reduce risks to acceptable levels, and efforts to further refine the risk estimates are not cost effective in the overall decision process.

The evaluations can be performed on several levels, first as a quick screening assessment and then, if warranted, as a more quantitative and site-specific assessment. The decision process described in the paper that follows relies on a considerable amount of technical and regulatory literature for guidance. The approaches described in these guidance documents must be combined with sound science to ensure that the potential risks estimated for a site are representative of reasonable risk scenarios. It also is necessary to develop the risk assessment to the extent that risk managers understand the levels of uncertainty associated with any decision to expend remedial resources.

The components of the risk-based decision framework depicted in Figure B-1 in the paper are outlined below. The paper provides more detailed discussions of these steps.

Initial Collection of Site Information and Definition of Receptors

The first step in the risk-based decision framework is to collect site information and define receptors. For this step, it is necessary to build a conceptual model, identify relevant receptors and exposure pathways, compare COC levels to background levels, and make a first decision as to whether relevant human and ecological receptors are present at the site. The decision process at this stage requires discussions between risk managers and risk assessors and involves the following four questions:

- Are potentially exposed, relevant receptors present at the site, and do conditions exceed background exposures?
- Is a no natural recovery option appropriate?
- Are there sufficient uncertainties to warrant a Tier 1 risk assessment?
- Can RAOs be developed to guide remedial option development?

The answers to these questions require discussions between risk managers and risk assessors, considering all of the technical, scientific, political, social, economic, and policy aspects of a risk management decision.

Tier 1 Risk Assessment

If the decision is made to proceed with a Tier 1 screening level risk assessment, additional effort may be needed to define the dominant physical, chemical, and biological characteristics. This effort can range from better organizing and sorting existing information to collecting additional data. Regardless, the goal is to develop a conceptual model that allows better definition of relevant receptors at the site and characterizations of their exposure pathways using conservative exposure assumptions. During a Tier 1 risk assessment, the following activities occur: depicting relevant receptors, selecting screening level benchmarks, developing screening values, and determining the relationship between the benchmark screening and the RAOs. The decision process at this step requires additional discussions between risk managers and risk assessors and involves the following five questions:

- Are potentially exposed, relevant receptors present at the site, and do conditions exceed background exposures?
- If risks do not exceed screening criteria, is a natural recovery option appropriate?
- Are there sufficient uncertainties to warrant a Tier 2 risk assessment?
- Are the risks sufficiently defined to support development of RAOs to guide remedial option development?

- Will remedial option risks be less than those of current conditions? (If not, the situation warrants further consideration of no further action.)

If the decision is made to proceed with additional effort and refine the risk estimates in terms of site-specific conditions and receptor attributes, the efforts can be organized in several ways. One approach is to collect specific information to address areas where assumptions in the previous efforts have been most unrealistic. Another is to address the greatest uncertainties, focusing specifically on exposure or hazard estimates for the receptors of concern. The exact sequence of analyses necessary to reach a decision as to whether the risks need mitigation and, if so, to what extent, depends on factors such as the magnitude of preceding efforts, the nature of the receptor groups at risk, resources devoted to the assessment program. At less complex sites, a more streamlined approach using a qualitative risk assessment may be employed, avoiding the need to calculate site risk numbers. At other sites, a more detailed quantitation risk assessment may be necessary. In this situation, efforts proceed in an incremental fashion until the risk manager is comfortable with the risk estimations; the remedial options are presented; and the technical, policy, and social relevancy issues are addressed. The underlying theme of these higher tier efforts is to allow more accurate and quantitative characterizations of exposure pathways and understanding the dynamic nature of the system. With new data, the decision process can return to earlier discussions regarding factors such as exposure pathways and background comparisons and can reevaluate the relevancy of these decisions. The basic activities performed in these higher tier assessments are similar for human health and ecological risk assessments and are as follows: refine target receptor groups, develop enhanced exposure estimates, and evaluate hazard data used in the risk assessment.

The decision process at higher tiers should incorporate a path that parallels earlier discussions between risk manager and risk assessor. Decision-makers should ask the following questions, based on this new information:

- Are potentially exposed, relevant receptors present at the site, and do conditions exceed background exposures?
- If risks do not exceed site-specific criteria, can a no further action option be defended?
- Are there sufficient uncertainties to warrant an additional tier of risk assessment?
- Are the risks sufficiently defined to support development of RAOs to guide remedial option development?
- Will remedial option risks be less than those of current conditions? (If not, the situation warrants further consideration of no further action.)

Conclusions and Recommended Applications

The decision framework is aligned more closely with the emerging American Society for Testing Materials (ASTM) guidance for risk-based corrective action than existing risk assessment guidance from regulatory agencies. More importantly, the framework presents a strong focus on up-front identification of relevant human receptors and ecological assessment endpoints that should be used as the basis for all subsequent evaluations. Typically, risk assessments evaluate many or all of the human receptors and assessment endpoints presented in the decision trees without seeking risk manager/risk assessor discussion as to what issues are at the crux of remedial decisions.

INTRODUCTION

Human health and ecological risk assessments evaluate whether harm to human beings or to nonhuman living things may result from exposure to chemicals in the environment. Risk assessments evaluate the likelihood, magnitude, and severity of this potential harm in a multistep and interdisciplinary scientific process [National Research Council (NRC) 1983, 1994 and U.S. Environmental Protection Agency (USEPA) 1998a]. Risk management is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and ecosystems while taking into account social, political, economic, and practical components of a decision [Presidential/Congressional Commission on Risk Assessment and Risk Management (PCCRARM) 1997]. When the risk assessment paradigm was first developed, a great deal of emphasis was placed upon separating risk assessment from the risk management aspects of the process (NRC 1983). With the passage of time and the maturation of risk assessment as a discipline in its own right, the roles of risk managers and risk assessors are better defined, and the need for specific interactions on various topics has been identified (Pittinger et al. 1998 and PCCRARM 1997). In fact, more recent USEPA guidelines and policies (USEPA 1997a and 1998a) concerning the performance of ecological risk assessment call for the active participation of risk managers in the problem formulation process. The American Society for Testing and Materials (ASTM) is drafting guidance on risk-based corrective action (ASTM 1999) that identifies critical management decision points that are integral to the analysis and remedial decision process.

The objective of this paper is to outline a sound technical process whereby site conditions and remedial actions can be evaluated based on risks posed to human and ecological receptors, providing the foundation for a risk-based approach. Thus, a tiered approach to risk assessment and risk management is presented as an appropriate and efficient process for addressing human and ecological health concerns surrounding sediment contamination. Risk management input is critical for framing risk assessment issues and defining the types of risks that must be evaluated. Hence, the input of risk managers must be solicited early in the assessment process. Discussions between risk managers and risk assessors are needed to select relevant human and ecological receptor groups, their exposure scenarios, and specific ecological risk assessment endpoints.. For example, deciding whether a human health risk assessment should focus on a general population or on a subpopulation of subsistence anglers in a local community is a risk management decision. Similarly, deciding whether the structure of a benthic community (i.e., its diversity) is an assessment endpoint or whether the focus should be on a higher trophic level supported by the benthic community (e.g., fish populations in an area) is an assessment endpoint decision which should be made with risk manager input. Contaminated sediment risk assessments and risk management decisions usually require consideration of both human health and ecological concerns due to the close links between many ecological processes and sources of food and drinking water for human receptor groups.

RISK-BASED DECISION MAKING

Effective risk-based decision making requires construction of a conceptual model that, at a minimum:

- Considers the dominant physical, chemical, and biological characteristics of a system.
- Identifies relevant receptors (both human and ecological).
- Identifies potentially complete pathways by which relevant receptors can be exposed.
- Identifies ecological assessment endpoints.

Additional information such as identifying or estimating COC concentrations and their spatial extent in sediments, their bioavailability, mode of exposure of primary concern (bioaccumulative or directly toxic), or the mechanisms by which they may change in the future can assist in defining the nature and scope of a contaminated sediment issue. However, this information is not needed in all instances or at all levels of effort to reach an efficient risk management decision.

Identifying receptors that serve as the basis for management decisions significantly impacts subsequent risk management considerations. Selecting human receptors and ecological assessment endpoints is a critical component of the risk-based decision framework when developing a contaminated sediment management strategy (PCCRARM 1997, Menzie 1997, and Chapman et al. 1997). It is through this step of evaluating several groups or types of relevant receptors that one identifies what needs protection and determines the level of protection that is desirable.. This identification and determination is achieved by moving from a preliminary consideration of the full range of potential human receptors and ecological assessment endpoints to those of greatest concern, value, and relevance during conceptual model development. This step is particularly important at the screening level risk assessment phase when conservative assumptions of exposure and effects help focus assessment efforts on receptors that may be most at risk. Indeed, it should be necessary to assess the risks to only a few receptor groups to capture the salient risks at a particular site. It is important to note that the conceptual model used in the decision making must encompass all significant risk issues for a site, including risks driven by stresses other than COCs.

The responsibility for communicating the technical basis for the number and types of receptor groups deemed relevant and important to the risk management decision ultimately lies with the risk manager, who is responsible for the course of action(s) taken at a site (Pittinger et al. 1998). For example, the risk management/risk assessment team may decide that the potential risk to a population of sport fish is more ecologically and socially relevant than a potential risk to a ubiquitous benthic macroinvertebrate common in a fishery food web. Thus, the ecological assessment endpoints may focus on an evaluation to ensure sustainability of the fish population. In such a setting, it is understood that the overall health of the ecosystem will be acceptable when risks to the fish population are acceptable. Similarly, evaluating exposures to local anglers with a high avidity for consuming the fish that they catch may be the overriding risk issue for human health considerations. Steps taken to ensure that exposures are at an acceptable level for this subgroup will concomitantly meet any risk reduction necessary to satisfy desired risk levels for other populations of potential human receptors.

RISK-BASED DECISION FRAMEWORK

The risk-based decision framework is presented in Figure B-1 and addresses both human and ecological receptors exposed to COCs in sediments. In addition, the framework identifies the types of considerations needed to evaluate potential direct toxicity to exposed receptors and the considerations necessary to evaluate potential bioaccumulative and bioavailability issues associated with the COCs in sediments. The framework is presented as a decision model that flows through sequential considerations on parallel paths for human and ecological receptors. An overview of the model is presented, followed by a description of the specific decision path within the overall framework.

Decision Framework Overview

A parallel process for both human and ecological receptors with specific steps at each level is discussed in more detail below. It is important to specify the considerations appropriate for evaluating each site, as the specific deliberations are somewhat different for human and ecological assessments. For human health risk assessments, it is important to specify the appropriate receptor group(s) and exposure scenario(s). For ecological risk assessments, it is essential to agree on the relevant receptors and exposure scenarios and appropriate assessment endpoints for the ecological receptors at a particular site. Based on sound science and consistency with regulatory guidance, there are a number of places to exit the decision path.

As discussed below, selecting human and ecological receptors and scenarios involves a significant amount of discussion between risk assessors and risk managers. In particular, human health risk assessments focus on individuals representing various segments of the general or local population or more highly exposed (or more sensitive) subpopulations within the local community. Ecological risk assessments focus on sustaining populations or communities within the local ecosystem except when it is necessary to protect individuals of rare or threatened species that have been identified as relevant receptors. Once receptors are defined, assessments of their exposure and potential resulting effects are used to estimate the severity, magnitude, and duration of risks. These estimates usually are conducted in a tiered manner, moving from generic assumptions and conservative estimates of exposure and effects to more site-specific, refined estimates. Using this approach minimizes the time and effort needed to define risks and provides a means to invest risk assessment resources to an extent commensurate with the magnitude of the COC issues and scale of potential remedial options.

As the risk assessor and risk manager work through the tiers, there are various decision points in the process to evaluate the most appropriate subsequent path. At each decision point, there are several potential outcomes:

- Exposure analysis indicates no potentially complete pathways to relevant receptors of concern.
- Risk estimates demonstrate that no further action is required.
- Risk estimates suggest that additional characterization or risk analysis is needed to better define potential risks, determine if remedial action is appropriate, and, if so, determine the nature of the effort.
- Risk estimates demonstrate the need to develop remedial action objectives (RAOs) to reduce risks to acceptable levels, and efforts to further refine the risk estimates are not cost effective in the overall decision process. The decision to develop RAOs may be made early in the tiered process if risk managers determine that the benefits of undertaking a remedial action are greater than the possible benefits arising from conducting additional studies to further refine potential risks or RAOs.

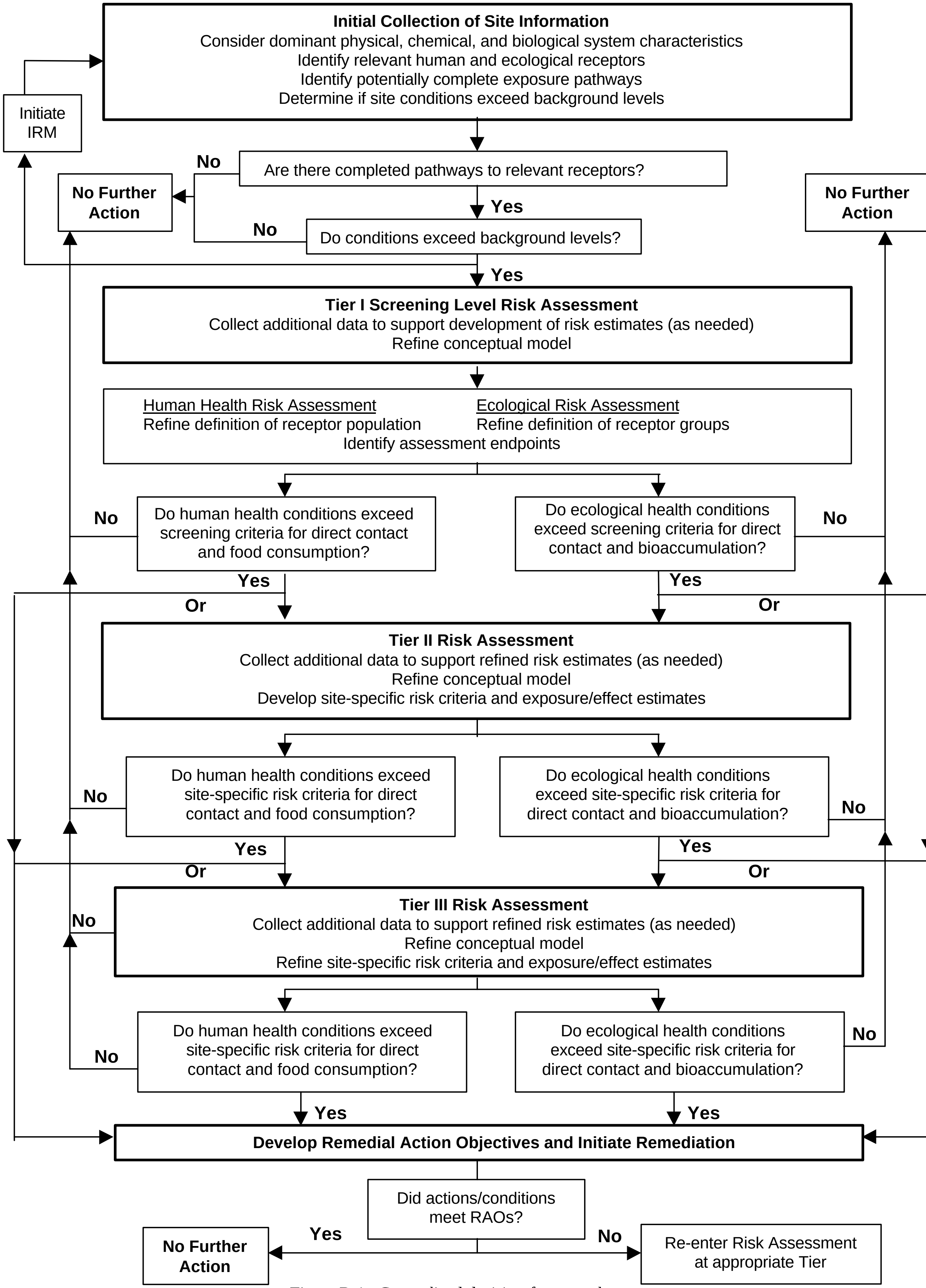

Figure B-1. Generalized decision framework.

The evaluations presented in the decision framework are performed as a quick screening assessment and then, if warranted, as a more quantitative and site-specific assessment. The framework described herein relies on the available literature for guidance as to how to conduct appropriate risk assessments at each step in the process. The human health risk assessments guidance documents include, but are not limited to, the following:

- *Risk Assessment in the Federal Government: Managing the Process* (NRC 1983)
- *Superfund Public Health Evaluation Manual* (USEPA 1986)
- *Risk Assessment Guidance for Superfund. Volume I: Human Health Evaluation Manual. Part A*. (Interim Final; USEPA 1989)
- *Final Guidelines for Exposure Assessment* (USEPA 1992b)
- *Proposed Guidelines for Carcinogen Risk Assessment* (USEPA 1996b)
- *Policy for use of Probabilistic Analysis in Risk Assessment at the EPA, Office of Research and Development* (USEPA 1997b)
- *Guiding Principles for Monte Carlo Analysis* (USEPA 1997c)
- *Exposure Factors Handbook* (USEPA 1998b)
- *Guidance for Risk Characterization* (USEPA 1995a)
- *Standard Guide for Risk-Based Corrective Action* (ASTM 1999)

Similar guidance documents for performing ecological risk assessments include, but are not limited to, the following:

- *Framework for Ecological Risk Assessment* (USEPA 1992a)
- *Procedural Guidelines for Ecological Risk Assessments at U.S. Army Sites, Volume I* (Wentsel et al. 1994)
- *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (Interim Final; USEPA 1997a)
- *Guidelines for Ecological Risk Assessment* (USEPA 1998a).
- Standard Guide for Risk-Based Corrective Action (ASTM 1999)

The methods presented in the above guidance documents must be combined with sound science and site-specific information to ensure that the potential risks estimated for a site are representative of reasonable risk scenarios. Risk assessments need to provide risk managers with information on both the levels of uncertainty associated with any decision to expend remedial resources or take no further action and the level of uncertainty that is acceptable and commensurate with the levels of risks quantified.

Decision Framework Components

The first step in the risk-based decision framework is to collect site information, define receptors, and select COCs. If this effort indicates that sufficient uncertainties exist regarding receptors and exposures, then a Tier 1 risk assessment is performed. If, after the Tier1 risk assessment, a decision is made to refine the risk estimates in terms of site-specific conditions and receptor attributes, then a Tier 2 or 3 risk assessment is performed. These three steps are described below.

- *Initial Collection of Site Information, Definition of Receptors, and Selection of COCs*
  The following activities should be considered when performing this step:
  - Build a Conceptual Model
    The first evaluation step (see Figure B-1) is to collect sufficient site information to develop an initial conceptual model of the site, including describing the dominant physical, chemical, and biological features of the site; determining whether relevant human and ecological receptors are present; selecting COCs; and identifying exposure pathways for the COCs and other sources of risk to the receptors at the site (e.g., biological pathogens, habitat losses, temperature extremes). In the conceptual model, COCs are defined as

detected chemicals that are assumed to be related to historic site activities. The conceptual model can be captured in terms of various combinations of words, drawings, flow diagrams, or mathematical/computer models that demonstrate the qualitative or quantitative relationships between both the relevant receptors and exposure pathways/media and the dynamics of their environment. This effort helps put a spatial and temporal scale on contaminated site issues and allows the development of logic paths upon which remedial options can be structured if mitigating risks becomes necessary.

It is important to note that before embarking on a risk assessment that assumes sediments are the source of exposure for human or ecological receptors, it should be confirmed that sediments (and direct releases to surface water) are the source of COCs in biota. The sources, bioavailability, fate and transport, and potential for exposures to COCs in sediments are issues that should be considered during conceptual model development and factored into exposure estimates.

— Identify Relevant Receptors and Exposure Pathways

Although a somewhat cursory selection of relevant receptors is oftentimes adequate at this initial stage of a tiered risk assessment, it nevertheless is important to determine whether human receptor groups and ecological resources are actually present at the site or exposed in some manner. For contaminated sediment sites, the human receptor groups considered for inclusion at this phase tend to be those with direct contact activities, such as local fishermen, residents using local groundwater, or swimmers. Identifying relevant ecological receptors should focus on issues such as the presence of rare or endangered species, fisheries of sport or commercial importance, or habitats used by local wildlife populations (Menzie 1997 and Chapman et al. 1997). In actual practice, the benthic invertebrate community is also often selected as a receptor for evaluation. Evaluation of the benthic community is often based on its structure (i.e., species diversity, presence of pollution intolerant taxa, toxicity to sensitive laboratory test species) and not its function (i.e., ability to serve as a prey base for fish and wildlife). This distinction is important to recognize because the outcome of an ecological risk assessment can be greatly affected by whether the structure or function of the benthic community is appropriate for evaluation.

Discussions between the risk managers and risk assessors about receptor groups at risk set the tone for the scope necessary to address environmental issues at the site. These initial discussions also set the stage for the level of effort required for all subsequent analyses. For sites with limited receptor activities and limited opportunities for exposure due to incomplete pathways, risk issues can be handled expeditiously. Larger or more complex sites involving multiple receptor groups, multiple stressors, and multiple exposure pathways can require considerable effort to understand the risks associated with sediment contamination and to evaluate their incremental significance for human and ecological receptors in the area. In such cases, it is important to understand how receptors relate to the long-term uses and resource management goals of the site. More discussion on this topic is presented below.

— First Decision Point: Are relevant receptors present and exposure pathways complete?

Once a conceptual model capturing the dominant physical, chemical, and biological aspects of the site is developed, an assessment is conducted of whether relevant human and ecological receptors are present at the site. If receptors are present, the conceptual model is sufficiently detailed to determine if potentially completed pathways exist by which the relevant receptors are exposed.

— Second Decision Point: Are COC concentrations higher or lower than background levels?

If exposed receptors exist at the site, a comparison of COC concentrations in sediments to background levels, defined as the concentration of a COC representative of regional sediment quality that has not been affected by site activities (e.g., a reference area) is conducted. Such comparisons should be based on evaluations of statistical analyses of available information rather than simple documentation of exceedances. If the analyses have proceeded to this point and the COC concentrations are above appropriate local background sediment concentrations, then the evaluation proceeds to the next tier. If relevant receptors and completed pathways exist but COC concentrations are less than or equivalent to local background levels, the risk management decision usually is made that site activities have not contributed incremental risks in the area and that sediments do not require further evaluation or remediation.

If the risks at a site are equivalent to those that exist in the vicinity of the site, attempting to reduce risks within a small area is futile. For example, Massachusetts developed the concept of "local conditions" as distinct from "natural" or "pristine" background [Massachusetts Department of Environmental Protection (MADEP) 1996]. Similarly, Tennessee adopted the concept of "control background" to address areas that have had significant anthropogenic impacts due to historic industrialization [Tennessee Department of Environment and Conservation (TNDEC) 1999]. "Local conditions" and "control background" recognize the impracticality of creating a clean hole in a dirty river. In many instances, sediment transport may cause COC concentrations in the newly remediated sediments to become similar to COC concentrations in the surrounding sediments. Currently, there is no standard consensus methodology to define background (i.e., the location and the number of samples) and the appropriate statistical test for the comparisons. Although methods for determining background conditions are not presented in this paper, useful discussions are provided in Ingersoll, Dillon, and Biddinger (1997); Suter (1993); Calabrese and Baldwin (1993); and specific guidance from various regulatory programs.

Up to this point, the decision process has involved the following four questions:

1. Are potentially exposed, relevant receptors present at the site, and do conditions exceed background exposures?
2. Is a no further action option appropriate?
3. Are there sufficient uncertainties to warrant a Tier 1 risk assessment?
4. Can RAOs be developed to guide remedial option development?

The answers to these questions require discussions between risk managers and risk assessors, considering all of the technical, scientific, political, social, economic, and regulatory/policy aspects of a risk management decision.

- *Tier 1 Risk Assessment*
  If the decision is made to proceed with a Tier 1 screening level risk assessment, additional effort may be needed to define the dominant physical, chemical, and biological characteristics. This effort can range from better organizing and sorting existing information to collecting additional data. Regardless, the goal is to develop a conceptual model that allows better definition of relevant receptors at the site and a characterization of their exposure pathways using conservative exposure assumptions.
  — Identify Relevant Receptors
  The tiered decision process provides a logical framework to evaluate both human health and ecological risks associated with COCs in sediments. Defining and characterizing the human and ecological receptors and the ecological assessment endpoints is completed first to focus subsequent exposure and effects assessments.

Risk managers and assessors can consider many or all of the human and ecological receptors and assessment endpoints presented in Table B-1 for potential relevancy to a site. Chapman et al. (1997) provide an overview of the types of considerations used for selecting appropriate ecological receptors and relevant assessment endpoints. Without sufficient upfront emphasis and discussion between risk managers and risk assessors, there may be a tendency to use any potential receptor (regardless of relevancy and necessity) with little regard for the level of protection conferred upon humans and the environment. For that reason, the receptors shown in Table B-1 are presented in a hierarchy. Selecting receptors listed toward the bottom of a particular column of Table B-1 generally leads to more stringent RAOs than selecting receptors at the top of the column. For example, selecting highly avid sports fishermen leads to a more stringent RAO than selecting an average member of the general population. Similarly, selecting benthic community diversity as an assessment endpoint will generally lead to more stringent RAOs than selecting the benthic community's ability to function as a prey base for terrestrial and aquatic biota.

The central point of Table B-1 is that selecting receptors and assessment endpoints is as much a risk management decision as it is a risk assessment decision. Once receptors and assessment endpoints are selected, they limit the universe of possible RAOs at a site. Thus, decisions about which receptor groups and assessment endpoints are appropriate need to be made as early in the process as possible, recognizing they affect the ultimate outcome of the risk assessment. These decisions are made with the understanding that achieving target risk levels for the selected receptor groups often leads to sufficient protection of many other potential receptors.

Table B-1
Range of Receptor Groups for Risk Assessments and Exposure Scenario Development

Target Receptors and Assessment Endpoints	Human Health Receptors	Ecological Receptors	
		Terrestrial and Aquatic Vertebrates	Benthic Invertebrates
Regional population ↓ Local population ↓ Average Individual ↓ Highly exposed individual ↓ Highly sensitive individual	Average individual of the general population ↓ Average individual of the local population ↓ Highly exposed individual of the general or local population ↓ Average or highly exposed individual of a local highly exposed subpopulation (i.e., highly avid sports fisherman)	Regional population ↓ Local population ↓ Local subpopulation ↓ Average individual ↓ Highly exposed individual ↓ Individual of a threatened or endangered species	Community function (i.e, prey base, nutrient cycling) ↓ Community structure (i.e., species diversity, absence of pollution intolerant species) ↓ Toxicity to moderately sensitive individuals (i.e., chironomids) ↓ Toxicity to highly sensitive individuals (i.e., amphipods)

— Select Screening Level Benchmarks and Develop Screening Values
Screening level values commonly represent hazard or adverse effect thresholds and often are developed with generalized assumptions containing maximum exposure estimates and benchmarks for effects in vulnerable test subjects (Calabrese and Baldwin 1993, Suter 1993, and Clark et al. 1999). Depending on the nature of the COCs, screening values may need to be considered for effects due to direct exposures or effects due to indirect exposures brought about by COCs that have bioaccumulated in tissues or food items. If a COC poses both a bioaccumulation risk and a direct exposure risk, then RAOs for both types of risk are

considered. Specific discussions about screening value selection and screening level human health and ecological risk assessments are presented in Boxes B-1 and B-2, respectively.

Box B-1
Specific Considerations in Screening Level Comparisons for Tier 1 Human Health Risks

Approaches and Considerations for Indirect Exposures (Bioaccumulative Chemicals)
Develop an exposure estimate based on indirect exposure pathways and an appropriate representation of COC concentrations [either the average, upper 95th percent confidence limit of the mean (95% UCL), or maximum] for comparison to screening effects levels used to set thresholds for toxic effects. The screening level values (encompassing both indirect exposure and effects) used or developed as part of this effort are likely based on highly conservative exposure and effects assumptions. Typically, the conservative assumptions include a high rate of use of a water body and its resources by a specified subpopulation as well as an efficient transfer of COCs from sediments to biota in the food chain. Although there has been considerable effort in developing screening values for some bioaccumulative COCs, additional COCs may need screening value development either because values do not exist or values currently proposed by various research organizations or agencies may need to be updated or reevaluated for applicability [Integrated Risk Information Service (IRIS) 1999 and USEPA 1993, 1995b, 1995c, and 1997d).

Approaches and Considerations for Direct Exposures
Develop an exposure estimate based on direct exposure pathways and an appropriate representation of COC concentrations (either the mean, 95% UCL of the mean, or maximum) for comparison to screening effects levels used to set thresholds for toxic effects. The screening level values (encompassing both direct exposure and effects) used or developed as part of this effort are likely to be based on the same highly conservative exposure and effects assumptions used in developing screening values for bioaccumulative COCs. Screening values for direct exposures can be found in a variety of documents. Additional COCs may need screening value development or those screening values currently proposed by various research organizations or agencies may need to be reevaluated for applicability.

Determination if Site Exceeds Screening Criteria
This step can be performed as a conservative screening step if the 95%UCL of the mean observed COC concentrations are used as the exposure concentration. Before use, however, screening values are evaluated for their practicality. Experience has shown that development of risk-based screening values below background concentrations is a distinct possibility. Similarly, some risk-based values developed using conservative inputs are below laboratory practical quantification limits (PQLs). If the screening values are below background levels, then performing a screening evaluation using these values is futile as no sites would be screened out.

Specific Human Health Decision Points at Tier 1

- For the screening evaluation, if the 95% UCL of the mean COC concentration in sediments is less than the appropriate screening value, then no further action is necessary to address human health risks.
- If the 95% UCL of the mean COC concentration in sediments is greater than the appropriate screening value, then further work, including a site-specific (Tier 2) human health risk assessment (SSHHRA), may be necessary.
- If there are small risks estimated by the conservative screening approach, then a risk management decision is made as to the value of an additional Tier 2 SSHHRA. If minor (realistic but conservative) adjustments of the assumptions used in development of screening values can bring risk estimates to acceptable levels, then concerted Tier 2 studies may not be needed. If these minor adjustments demonstrate acceptable risks, then no further action may be necessary to address human health risks.
- Risk managers may also decide to develop RAOs at this point. RAOs may be developed if the benefits of undertaking remedial action at this point in the process are greater than the likely benefits that might be realized by conducting additional studies to further refine risks or RAOs.

Box B-2
Specific Considerations in Screening Level Comparisons for Tier 1 Ecological Risks

Approaches and Considerations for Direct and Indirect Exposures
Develop an exposure estimate based on direct and indirect exposure pathways and an appropriate representation of COC concentrations (either the average or 95% UCL) for comparison to screening levels for toxic effects. Some sediment-specific screening values are recommended by the USEPA for a variety of COCs (USEPA 1996a and 1997d). Observations from field studies of marine and coastal areas were developed into screening values, particularly from direct exposure, based on the range of responses observed in the field for exposed communities. Other sources of sediment-specific screening values include the Ontario Ministry of the Environment (MOE 1994). Ingersoll et al. (1997) contains various discussions regarding the interpretation and application of these types of generalized screening values for sediments. Before using screening values, the rationale and basis for their development should be understood.

For screening ecological concerns, the most commonly employed values are taken from the effects range-low (ER-L) and effects range-median (ER-M) criteria proposed by Long et al. (1995). These values are singled out for discussion because of their widespread use and impact on how subsequent sediment screening criteria have been evaluated. Long et al. (1995) reviewed data from 89 reports that contained chemical data and simultaneous measures of biological effects. The sediment concentrations were categorized into those that are rarely, occasionally, and frequently associated with biological effects. The ER-L and the ER-M represent the 10th and 50th percentiles of concentrations associated with toxic effects. The ER-L is the concentration below which toxicity to sediment-dwelling organisms is unlikely, whereas the ER-M is the concentration above which toxicity to the benthic organisms is possible (Long and MacDonald 1998). Long, et al. (1998) recently performed a quantitative evaluation of the potential for false-positive and false-negative results in the ER-L and ER-M values. The authors concluded that the values are reasonable predictors of nontoxicity or toxicity in sediment bioassays, but should be used in conjunction with other tools (e.g., in situ biological analyses) for a detailed assessment.

The USEPA evaluated the ER-Ls and ER-Ms as part of the Environmental Monitoring and Assessment Program [EMAP] program and concluded that ER-Ms are better screening values than ER-Ls since many sediments fail ER-Ls without exhibiting toxicity [National Oceanic and Atmospheric Association (NOAA) 1999]. Both ER-Ls and ER-Ms, however, were based on data where effects were observed, and the information from data where no effects were observed were not included. Data where no effects were observed can provide additional information on the relationship between exposure and potential effects. Use of ER-Ls and ER-Ms as screening tools has been challenged when making decisions based on single chemical exposures since all of the field samples upon which they are based contained multiple contaminants. Using approaches that combine several measures of benthic community health, such as the sediment quality triad, or approaches that account for sediment samples in which adverse effects were not observed, such as the apparent effects threshold, can provide more realistic screening values for evaluating potential direct effects of COC concentrations in sediments for use in the site-specific ecological risk assessments (Chapman 1996 and Chapman et al. 1997).

There are additional data sources on exposure and effects to ecological receptors available to assist in screening value development for COCs or as alternatives to existing values (Suter 1996, Beyer 1990, Van den Breg et al. 1993, although they require extrapolation from other media (soils, water, food). The development of toxicological benchmarks and screening values must incorporate a variety of inputs and perspectives since the screening values integrate the ecological resource values incorporated into the ecological assessment endpoints (Clark et al. 1999). In any case, screening values are likely to be based on conservative assumptions regarding the sensitivity of the receptor species and their exposures.

Determining if a Site Exceeds Screening Values

This step can be performed as a conservative screening step if the mean (or its 95% UCL) COC concentrations are used as the sediment exposure concentration and compared to screening values. Before use, however, screening values must be evaluated for their practicality and relevance to site conditions. Experience has shown that development of risk-based screening values below background levels is a distinct possibility. Similarly, some risk-based values developed using conservative inputs are below laboratory PQLs or were developed in very conservative, static exposure conditions. If the screening values are below background levels, then a screening evaluation using these values is futile since no sites would be screened out.

Specific Ecological Risk Decision Points at Tier 1

- For the screening evaluation, if the mean (or its 95% UCL) COC concentration in sediments is less than the appropriate screening value, then no further action is necessary to address ecological risks. (This scenario assumes that there is both a relevant ecological receptor and a potentially complete exposure pathway.)
- If the mean (or its 95% UCL) COC concentration in sediments is greater than the appropriate screening value, then further work, including a site-specific (Tier 2) ecological risk assessment (SSERA), may be necessary.
- If there are small risks estimated by the conservative screening approach, then a risk management decision is made as to the value of an additional Tier 2 SSHHRA. If minor (realistic but conservative) adjustments of the assumptions used in development of screening values can bring risk estimates to acceptable levels, then concerted Tier 2 studies may not be needed. If these minor adjustments demonstrate acceptable risks, then no further action may be necessary to address human health risks.
- Risk managers may also decide to develop RAOs at this point. RAOs may be developed if the benefits of undertaking remedial action are greater than the likely benefits that might be realized by conducting additional studies to further refine risks or RAOs.

— <u>Determine Relationship between Result of Screening and RAOs</u>

At some sites, potential risks may exist from both direct and indirect (i.e., food chain) exposures. Indirect (i.e., bioaccumulative) effects generally occur when a COC has a relatively broad distribution, while direct effects, at least to individuals, may occur on a more localized basis. Thus, removal of hot spots (identified by comparing sediment COC concentrations to a direct exposure screening value) may not be required to protect humans, fish, and wildlife from potential food chain effects. Alternatively, remediation of sediments with COC concentrations that meet direct toxicity screening values may be needed, if the COC concentration over a relatively large area exceeds indirect exposure (i.e., food chain bioaccumulation) screening values. Alternatively, this condition may require a refinement of the risk assessment before committing resources to remediate a large area that may not provide a risk reduction yield. The development of a final RAO for a site requires evaluating the separate RAOs that were developed for reduction of effects due to direct exposure and RAOs for effects resulting from exposures from bioaccumulative pathways. The final site-specific risk management approach can contain several components within the sitewide RAO.

Whenever human health or ecological evaluations indicate the need to evaluate RAOs, a comparison of the risks associated with existing site conditions and implementation of the RAOs (i.e., risk of remedy) is conducted. If risks associated with RAO implementation are similar to the risks of leaving the site as is, further evaluation of RAOs is needed, and natural attenuation is reevaluated as a remedial option.

— *Tier 1 Decision Point*

Once the conceptual model is refined and the relevant human and ecological receptors are defined, a screening level decision is made based on conservative exposure assumptions and toxicological and/or bioaccumulative benchmarks. If additional data are developed to reevaluate the comparison to background levels, the initial comparison is updated as well. The decision process at Tier 1 involves the following five questions:

1. Are potentially exposed, relevant receptors present at the site, and do conditions exceed background exposures?
2. If risks do not exceed screening criteria, is a no further action option appropriate?
3. Are there sufficient uncertainties to warrant a Tier 2 risk assessment?
4. Are the risks sufficiently defined to support development of RAOs to guide remedial option development?
5. Will remedial option risks be less than those of current conditions? (If not, the situation warrants further consideration of no further action.)

The answers to these questions require discussion between risk managers and risk assessors, considering all of the technical, scientific, political, social, economic, and policy aspects of a risk management decision.

It is important to note that the assumptions and benchmarks used to develop screening levels in the Tier 1 decision process and those discussed below are not designed to become the basis to set cleanup goals. The sole purpose of these screening approaches is to evaluate quickly and conservatively the potential for a specified effect to occur and its potential magnitude based on the exposure assumptions and benchmarks used.

- *Tier 2 or 3 Risk Assessments*

  If the decision is made to proceed with additional effort and refine the risk estimates in terms of site-specific conditions and receptor attributes, the efforts can be organized in several ways. One approach is to collect specific information to address areas where assumptions in the previous efforts have been most unrealistic. Another is to address the greatest uncertainties, focusing specifically on exposure or hazard estimates for the receptors of concern or focusing on the parameters that affect the uncertainty of the largest risk driver. The exact sequence of analyses necessary to reach a decision as to whether the risks need mitigation and, if so, to what extent, depends on factors such as the magnitude of preceding efforts, the nature of the receptor groups at risk, and resources devoted to the assessment program. At less complex sites, a more streamlined approach using a qualitative risk assessment may be employed, avoiding the need to calculate site risk numbers. At other sites, a more detailed quantitative risk assessment may be necessary. In this situation, efforts proceed in an incremental fashion until the risk manager is comfortable with the risk estimations; the remedial options are presented; and technical, policy, and social relevancy issues are addressed. The discussion below focuses on several common efforts and themes that may be relegated to Tier 2 or 3 efforts.

During a Tier 2 or 3 risk assessment, a refinement in the portrayal of the dominant physical, chemical, and biological characteristics of the site may be necessary. This refinement usually is achieved by collecting additional site data to obtain specific information to use in a model, check or validate an assumption, or resolve uncertainty in an estimate. The goal is to develop a conceptual model that accurately depicts the relationships and rates of interactions between the physical, chemical, and biological components of the system. Additional consideration is given to characterizing exposure pathways. The underlying theme of these higher tier efforts is to allow more accurate and quantitative characterization of exposure pathways and understanding of the dynamic nature of the system. From this understanding, better estimates of exposure are developed as the toxicological issues are evaluated in more detail.

— Refine Target Receptor Groups

For SSHHRAs, additional data are developed to define highly exposed subpopulations or receptors with specific toxicological vulnerabilities. For SSERAs, additional data are developed to define the presence, distribution, and food web importance of various receptors considered in previous tiers. Broad, sweeping, and pointedly conservative assumptions are replaced with more accurate and realistic data. Again, the focus is on the ecological community and not specifically at the individual organism level, with the exception of endangered and threatened species.

During a Tier 2 or 3 SSHHRA, the discussions regarding receptors focus on potential risks among the receptor populations previously defined to have relevant human interaction with the contaminated site. For example, if an earlier risk management decision was made to evaluate risks to sport fishermen, it is not acceptable to switch to an evaluation of subsistence fishermen at the higher tiers of the risk assessment unless newly developed information supports the assertion that there is an important subsistence population that was unintentionally missed during earlier deliberations. Furthermore, field evaluation of actual fish consumption among local fishermen can be very revealing in these situations. For example, the presence of any institutional controls that limit consumption can be considered. Thus, estimates of potential risk among local anglers may differ appreciably from those based on more global surveys of angler behavior.

During a Tier 2 or 3 SSERA, these discussions do not include reevaluation of the relevancy of selected receptors (i.e., mammals, birds, amphibians, fish, plants, invertebrates) and the level of organization selected for evaluation (e.g., local populations, communities, habitat services). These assumptions should remain the same in all Tiers of the evaluation process. The one exception is provided by threatened and endangered species. These species may need to be reevaluated with a new site inventory effort[1]

[1] Even for threatened and endangered species, the basic objective is that of protecting populations; however, their reduced numbers make it necessary to protect individual animals in order to sustain the population and the species. In both the theory and practice of ecological risk assessment, a reproducing population is the smallest ecological unit that can be meaningfully assessed and protected (Suter 1993). Thus, once such species are identified, different assessment techniques may be necessary to fully evaluate potential risks in the higher tiers of the assessment.

As mentioned in the discussion of Table B-1, there is an explicit value judgment placed on decisions regarding which ecological receptors are considered in the risk assessment, especially concerning the importance of protecting individuals among endangered species. The effect of protecting the individual versus the population can have a profound effect on the scope of RAOs and costs. Sediments with several small areas of elevated COC concentration can require no action when viewed from the perspective of a population, but remediation may be suggested for isolated areas to protect some of the individuals comprising the local population. The final decisions must recognize that a few individuals, but not the population, may be at risk. Therefore, no remedial action is warranted. It should also be recognized that removal of those areas will disturb the sediments at those locations and may also cause significant secondary injury when attempting to gain access to the locations with elevated concentrations. Ideally, the SSERA provides information about the probability of observing a predicted outcome. In that way, the probability of different outcomes can be compared. This is especially important when evaluating RAOs.

— Develop Enhanced Exposure Estimates

Advanced exposure assessments are assisted greatly by developing a model that describes the potential for COCs in sediment to result in direct and indirect exposures to humans and ecological receptors. Ideally, the model is made as quantitative as necessary to address the risk issues commensurate with level of effort appropriate for the site. The model can incorporate information on COC bioavailability, partitioning within components of the environment, and fate processes that reduce COC concentrations over time. Some model components can demonstrate the significance of human or wildlife capabilities to metabolize the COCs, lessening human and food chain exposures.

For direct exposures, the model integrates two sets of spatially organized information: the distribution of the COCs in sediments; and the activity or contact patterns of potentially exposed individuals among human receptors and ecological receptor populations.

The exposure models account for the accessibility of sediments and frequency and magnitude of contact. For example, exposure to intertidal sediments is much more likely than exposure to sediments continuously covered by more than a few feet of water. Additionally, exposure of wildlife or pelagic populations to surficial sediments is much more likely than exposure to deeper sediments continuously covered by a layer of relatively clean sediments. Ultimately, the link between exposure and COC concentrations allows one to relate a reduction in the sediment concentration (an overall reduction or a reduction in a specific area) to a reduction in exposure.

For indirect exposures, COC movement through the human and ecological food chain is incorporated. The model can incorporate information about what species are dominant in the food web of the receptors of concern, which species people eat or are seasonally important, where they are caught, and the concentration of COCs in the biota. Conceptually, indirect exposures for SSHHRAs integrate three sets of spatially organized information: distribution of the COCs in sediments; the COC concentrations in the food web and in biota eaten by humans; and locations where different people (populations) are harvesting fish. For SSERAs, the distribution of the COCs in sediments, distribution of prey items and their encounter rates by predators, concentration of COCs in prey of the receptor of concern, and habitat use by receptors of concern directly link COCs in sediment to COCs in the food chain. The more sophisticated models use information about what a species eats, the home range of the prey species, where the receptor forages, and the home range of the receptor. The level of effort and complexity of the evaluations performed reflect the assumptions and conditions developed in the conceptual model and the level of effort needed to resolve the ecological risk issues.

The links between indirect exposure pathways are integrated and incorporated with the exposures from direct pathways to develop estimated total exposures for each receptor. For either SSHHRAs or SSERAs, the link between exposures and COC concentration in sediments must be close enough to relate a reduction in the sediment COC concentration (i.e., a change in the spatial distribution of COCs in sediments) to a reduction in exposure The reduction in COC concentration can be due to an overall reduction throughout a water body or reductions in specific areas. This relationship ultimately allows for exploring the effectiveness of different remedial options in reducing risk, both short- and long-term (assuming a model exists that quantifies expected changes in concentration in the future).

— Evaluate Hazard Data
Although much of the effort during higher tiered risk assessments often is focused on refining exposure estimates, selecting the direct and indirect toxicity endpoints is an important aspect of a Tier 2 or 3 risk assessment

SSHHRAs provide an opportunity to develop more refined estimates of dose-response relationships for human receptor groups. The bases of screening level toxicity benchmarks are reevaluated as well as their relevance to the receptor populations. Assumptions made in early tiers regarding extrapolations of animal test data to human health endpoints also are reevaluated. More extensive literature searches can be conducted to provide a better basis to more thoroughly characterize the hazard posed by the COC. A Tier 2 or 3 risk assessment allows an opportunity to test assumptions regarding additivity, metabolism, and other conservative aspects of the hazard assessment using published data or, if warranted, additional laboratory experimentation.

For SSERAs, the higher tiers provide an opportunity to establish a less conservative, more direct exposure-response relationship for the relevant receptors. Many of the available laboratory toxicity data used to set no observed effect levels (NOELs) for mammalian and avian species can be put into a population perspective at a higher tier, allowing for a true population-level assessment. Uncertainties surrounding field studies or monitoring data from reference sites or comparison sites can be evaluated to establish realistic environmental exposure levels that sustain populations of fish, wildlife, and birds. Similarly, the significance of a potential change in structure and diversity of benthic invertebrates can be assessed for its significance to the continued survival of populations that use the benthos as a prey base (i.e., the assessment endpoint is based upon the function of the benthos). These types of hazard assessments can be evaluated in an ecological context, rather than relying on the less relevant recording of changes in the diversity and structure of the benthic community. Although population sustainability and functional attributes are used as assessment endpoints, the data necessary to conduct a realistic evaluation of these endpoints is generally not available until Tiers 2 and 3.

— Tier 2 or 3 Decision Point
Once the conceptual model is refined and the relevant human and ecological receptors are defined, a site-specific risk decision is made based on updated assumptions, models, or field data on exposures and potential effects. If additional data are developed to reevaluate the comparison to background levels, the background level comparison is updated as well. The decision process at Tiers 2 and 3 involves the following five questions:

1. Are potentially exposed, relevant receptors present at the site, and do conditions exceed background/reference exposures?

2. If risks do not exceed site-specific criteria, is a no further action option appropriate?
3. Are there sufficient uncertainties to warrant an additional tier of risk assessment?
4. Are the risks sufficiently defined to support development of RAOs and to guide remedial option development?
5. Will remedial option risks be less than those of current conditions? (If not, the situation warrants further consideration of no further action.)

The answers to these questions, like those which precede them, require discussions between risk managers and risk assessors, considering all of the technical, scientific, political, social, economic, and policy aspects of a risk management decision.

CONCLUSIONS AND RECOMMENDED APPLICATIONS

The risk-based decision framework presented in this paper includes parallel evaluations for both human and ecological receptors, highlighting the importance of both direct contact and food web pathways when evaluating the effects of COCs in sediments. This format closely follows the emerging ASTM guidance for risk-based corrective action (ASTM 1999). More importantly, this framework contains a strong focus on identifying up-front the relevant human and ecological receptors and the appropriate assessment endpoints that are used as the basis for all subsequent evaluations. Typically, risk assessments evaluate many human receptors and ecological assessment endpoints with limited discussion and concurrence between risk managers risk assessors regarding critical remedial issues. This framework encourages and recommends such discussion and concurrence at the beginning of the risk assessment process. An integral part of that discussion is the explicit recognition and consideration of values in the evaluation of sediments and selection of RAOs.

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