MassDEP Guidance for Disposal Site Risk Characterization

Chapter 14
Environmental Risk Characterization: General Considerations

14.0 Method 3 Environmental risk Characterization: General Considerations

14.1 INTRODUCTION

The Massachusetts Contingency Plan ("MCP", 310 CMR 40.0000) requires characterization of the risk of harm to health, safety, public welfare and the environment at all disposal sites, except where the site has been remediated to background levels. Environmental Risk Characterization is used to establish whether a level of no significant risk of harm to the environment exists or has been achieved at a disposal site. The results of the Environmental Risk Characterization provide information necessary to evaluate the need for remediation and to determine whether a permanent solution can be achieved for the disposal site. The MCP uses the term "Environmental Risk Characterization" in the way that other agencies use the terms "environmental risk assessment" and "ecological risk assessment".

MassDEP first published guidance for environmental risk assessment in 1996 (MassDEP, 1996). Since that time, various "Technical Updates" have been published to modify, clarify and or add to the original document. Based on experience gained since the first document was published, this revised guidance expresses MassDEP's general preferences for assessment approaches and data interpretation practices. By following the recommended procedures, investigators can be more certain that the assessment is consistent with the requirements of the MCP. ***However, nothing in this document is intended to preclude the use of alternative approaches deemed more appropriate by the site investigators and risk assessors***. Alternative approaches, however, call for more extensive technical justification and documentation.

While this chapter highlights general considerations for planning an environmental risk characterization, Chapters 15, 16 and 17 provide more specific guidance for characterizing risk from contaminants in aquatic, terrestrial and wetland habitats respectively. This Chapter updates and replaces the general guidance found in Chapter 9, Sections 9.1 through 9.3, of MassDEP's 1996 Guidance for Disposal Site Risk Characterization (MassDEP1996). Like that document, this revision draws from the EPA's Framework for Ecological Risk Assessment (U.S. EPA, 1992) and from other EPA guidance (U.S. EPA, 1997 and U.S. EPA, 1998). Advances in risk assessment principles and practices published more recently have been incorporated to the extent that they are compatible with the MCP and Bureau of Waste Site Cleanup (BWSC) policies and program goals.

14.1.2 Guidance Objectives

The objectives of the guidance in Chapters 14 through 17 are:

- To make clear the regulatory and management objectives for MCP environmental risk

characterization;

- To provide a framework for designing, conducting and interpreting the results of environmental risk characterizations pursuant to MCP regulatory objectives; and

- To indicate the level of effort considered by the Bureau of Waste Site Cleanup (BWSC) to be appropriate for various types of sites.

This guidance provides a general framework for using technical knowledge and expertise to design and conduct investigations to meet MCP requirements. To ensure that risk assessment activities are coordinated with other sampling and analysis efforts, all project managers should collaborate with an ecological risk assessor and consult this guidance in the early stages of site assessment planning. The overall investigation plan should be developed in cooperation with the risk assessor(s). While this guidance outlines many of the factors to be considered in designing and conducting an environmental risk characterization, it does not provide the knowledge necessary to conduct such an assessment. Extensive professional judgment is required, and site-specific conditions will affect assessment options. Involving the risk assessor at an early stage will enable project planners to develop the most efficient field work schedule. If the risk assessor is not brought in until a later stage, re-mobilization may be necessary for additional site work, significantly increasing project costs.

In addition to providing guidelines for conducting environmental risk characterization, this document is intended to help risk managers and other stakeholders understand the process and interpret the results. To that end, an effort has been made to use plain language, define terms and minimize the use of jargon.

14.1.3 Guidance Applicability

The MCP provides three approaches for characterizing human health and environmental risk at disposal sites. These are described in the MCP at 310 CMR 40.0941:

- Method 1 is a chemical-specific approach that involves comparing site soil and groundwater concentrations to Method 1 Standards. Method 1 is allowed where soil and groundwater are the only contaminated media of concern and where specified bioaccumulative contaminants are not present. Guidance for applying Method 1 is provided in Chapter 9.

- Method 2 allows adjustment of some fate/transport factors incorporated in the Method 1 Standards and/or calculation of standards. It also allows the calculation of Method 1-type standards for chemicals not included in the Method 1 Standards list. Guidance for applying Method 2 is provided in Chapter 10.

- Method 3 Risk Characterization is a site-specific procedure that considers site-specific exposure patterns, contaminant distribution, and contaminant mixtures. Guidance for Method 3 Human Health Risk Characterization is provided in Chapter 11. Method 3 *may be used* in any case, but it *must be used* wherever Method 1 is not applicable. This Chapter focuses on general concepts for Method 3 environmental risk characterization.

Method 3 may be used for human health risk characterization, environmental risk characterization or both. The selection of the appropriate risk characterization method(s) is detailed in 310 CMR 40.0942 of the MCP

and Chapter 8 of this guidance document.

Method 3 Environmental Risk Characterization is conducted under the following circumstances:

- When the Method 3 site-specific approach is used to assess human health risks, and

- When the Method 1 chemical-specific approach is selected to assess human health risks, but cannot be used alone for assessing environmental risk because of the existence of one of the following conditions:

  (a) oil or hazardous material (OHM) is present in environmental media other than soil or groundwater (such as surface water and sediment), where nonhuman organisms are exposed, or where OHM may migrate to such media and potentially could reach concentrations resulting in significant exposures to organisms; or

  (b) substances known to bioaccumulate are present within the top two feet of soil, and organisms likely to be exposed to surface soil contaminants have been identified at the site. Substances known to bioaccumulate include, but are not necessarily limited to, mercury, cadmium, PCBs, dioxin and pesticides (See Master MCP Q&A, 1993-2018, Page 81).

  In these two cases, Method 1 may be used to assess the risk of harm to human health, but a Method 3 Environmental Risk Characterization must be used to address environmental risk.

14.1.4 Guidance Specificity

These guidelines are tailored to the requirements of the MCP and the goals of the Massachusetts Waste Site Cleanup Program. They consider the nature and extent of MCP sites and the limited resources available to assess them compared to typically larger Superfund sites. Consequently, in some ways this guidance differs from that developed by other regulatory agencies:

- In contrast to federal CERCLA Superfund sites, which are generally large and heavily contaminated, the spatial scale and severity of contamination can vary widely, from small, slightly contaminated sites to large, heavily contaminated sites. In general, though, the spatial scale of most MCP sites is small relative to federal Superfund sites. For this reason, measurable impacts from an MCP site on a regional or population scale are unusual. MCP environmental risk assessments should target the habitat components and the organisms actually exposed to the contamination at the site. Potential landscape-, ecosystem- and population-level receptors are not typically affected by site contamination, and large-scale effects from small-scale sites are generally not readily measurable. Under the MCP, organism-level effects (such as increased mortality and decreased growth and/or reproduction) are interpreted as indicators of biological harm and significant risk.

- Some of the ***screening criteria*** published by MassDEP and recommended in this document are more permissive than those employed in other states or jurisdictions. This is intended to preclude more extensive environmental risk assessment projects at sites where adverse effects are not likely to be detected by measurements routinely used for risk assessment.

- Because of the historically industrial character of Massachusetts, site surroundings are seldom pristine. Site-related contamination often lies adjacent to or within contamination from other sources that contributes to exposure and risk. Such conditions can limit the utility of field-based measures of effects.

- Consistent with the MCP's ***provisions on background conditions***, assessment and cleanup requirements apply only to the oil and hazardous materials that are present above background levels and are attributable to the site/release in question (see Section 14.2.1). For characterizing waste sites on waterways, the background exclusion is even broader. Specifically, any contaminant present at concentrations consistent with local (upstream) conditions is not subject to MCP risk characterization and cleanup requirements. However, the requirement to eliminate risks from site-related contamination is not eliminated by the presence of non-site-related contaminants that may pose a greater risk. Massachusetts Waste Site Cleanup requirements are intended to address the incremental contaminant impacts from a specific waste site.

- The Waste Site Cleanup Program in Massachusetts is semi-privatized, which means that assessment and cleanup are funded by private entities and managed without MassDEP involvement or oversight and without the benefit of government funding. Thus, the budgets and resources available for assessing MCP sites are generally much more limited than those available for assessment of Federal Superfund sites. This guidance emphasizes the use of assessment approaches that are relatively sensitive and straightforward to execute and interpret.

Box 14.1
Local Conditions

Local conditions are concentrations of OHM that are higher than background levels but are nevertheless ubiquitous throughout the section of a river or stream (upstream and downstream) within which the site or part of a site is located.

Local conditions are contaminant concentrations in sediment or surface water attributable to sources other than the site in question, for example permitted discharges or upstream sites.

For these reasons, not all the risk assessment and characterization guidelines and requirements set for other states or jurisdictions are proposed for adoption for Massachusetts. Nevertheless, guidance provided by EPA over the years and more recently by the Canadian government (CCME, 2020) provide important and relevant resources for risk assessors and site managers.

14.1.5 MCP Environmental Risk Assessment Objectives

This section provides a general description of goals for all MCP risk assessments. Objectives for individual assessments depend on site setting and habitat types and are discussed in Section 14.3 of this Chapter.

The overall objective of MCP environmental risk characterization is encapsulated in specific regulatory requirements. The MCP requires that **"a Stage II Environmental Risk Characterization shall be used to determine whether there is a significant risk of environmental harm or evidence of environmental harm"** (310 CMR 40.0995(4)). The MCP further states: "Characterization of harm to the environment shall include an assessment of chemical data, potential contaminant migration pathways, and an evaluation of **biota and habitats** in the vicinity of the disposal site" (310 CMR 40.0995). As described in Section 14.3, the need for a Stage II Environmental Risk Characterization is determined by a Stage I Environmental Risk Characterization.

The objective of an MCP environmental risk characterization is to determine whether the site-related contamination has impaired the function of a habitat or is causing (or could cause) biologically significant harm to exposed organisms.

The MCP criteria for demonstrating that a condition of no significant risk of harm to the environment exists or has been achieved (310 CMR 40.0995) are:

1. There is no physical evidence of a continuing release of OHM at or from the disposal site to surface waters and/or wetlands which significantly affects environmental receptors; and
2. There is no evidence of biologically significant harm known or believed to be associated with current or foreseeable future exposure of wildlife, fish, shellfish or other aquatic biota to OHM at or from the site;
3. Concentrations of OHM at or from the disposal site do not and are not likely to exceed Massachusetts Surface Water Quality Standards as promulgated at 314 CMR 4.00 (and as amended) at current and reasonably foreseeable exposure points; and
4. There is no indication of the potential for biologically significant harm to environmental receptors, considering their location and the fate and transport characteristics of the OHM at or from the site, currently or for any foreseeable period of time.

Box 14.1
Key Terms

- **Biologically significant harm** in this document means an adverse effect at any level of biological organization, including organism, population, community, or ecosystem level effects.
- **Evidence** of biologically significant harm means past or current exposures have degraded an area of habitat, are impairing a community or are exerting stress on a population.
- The **potential** for biologically significant harm may exist due to either (1) the possible effects of ongoing or past exposures or (2) the possibility that contaminant distribution may change in the future. Both current and future site conditions should be considered.

MCP requirements for environmental risk assessment consider the kinds of sites typically evaluated under MassDEP's Waste Site Cleanup program. To meet the requirements, an environmental risk assessment must evaluate the ***risk of harm*** **to** ***habitats and biota exposed to OHM*** **at or from the disposal site**. More specifically:

- ***Risk of harm or evidence of harm*** and not proof of harm, is the crucial question in an MCP environmental risk assessment. Proving or disproving with certainty that biota at a disposal site have been harmed by contaminants may be impractical. Variability in natural systems can obscure the effects of contaminants. The presence of other site conditions or stressors can interfere with measurements of contaminant effects. Where site contaminants act in combination with non-site related stressors to contribute to environmental impairment, distinguishing the harm attributable to the site may not always be practical. Contamination that is a likely contributor to impairment is considered a risk of harm.

- ***Habitats and biota actually exposed to contaminants*** at the site are the focus of MCP environmental risk assessments. The spatial scale of contamination at Chapter 21E sites is generally small, so adverse

effects on entire populations or ecosystems are seldom, if ever, measurable at waste sites. Risks should be evaluated for the subpopulations and communities that inhabit the contaminated area.

14.1.6 Environmental Risk Assessment and Natural Resource Damage Assessments

Method 3 environmental risk assessment conducted to meet the requirements of the MCP often have components in common with evaluations conducted to support Natural Resource Damage Assessments (NRDAs). Definitions related to damage assessments are included in Appendix 1A. Environmental risk assessment is a basic component of site investigation under the MCP and is required at Chapter 21E sites where contaminants have made their way into media other than soil and/or groundwater. Natural Resource Damage Assessments are a separate process directed by state and federal agencies designated as Trustees; they are conducted at a relatively small subset of Chapter 21E sites. When both types of assessments are conducted at one site, there can be substantial overlap in data requirements, and many data collection and analysis activities can be used for both types of assessments.

In cases where both types of assessments are being conducted, coordination of efforts can be beneficial to both the regulatory agencies and the responsible parties. Collaboration between NRD assessors and risk assessors can improve the overall economy of data collection and analysis. Coordinated prior planning can minimize duplication of efforts and maximize the usability of data for both purposes. A carefully planned sampling program that uses resources efficiently can benefit both the agencies and the responsible parties involved.

Beyond improving efficiency, collaboration with NRD risk assessors brings more extensive expertise to the process of planning, executing and evaluating an MCP risk assessment. Natural Resource Trustees include the Department of Interior (DOI), the Massachusetts Executive Office of Environmental Affairs (EOEA) and the National Oceanographic and Atmospheric Administration (NOAA). These agencies have staff with expertise in biology, ecology and ecotoxicology, whose knowledge and experience complements DEP staff expertise. Similarly, the DEP Project Manager's detailed knowledge and understanding of the site can be invaluable to the Trustees. Cooperation can strengthen both the MCP environmental risk assessment and the Natural Resource Damage Assessment.

Coordination of efforts with Natural Resource Trustees, however, should not alter the scope or focus of the MCP risk assessment. In spite of substantial overlap in data requirements, it is important to recognize that the objectives and application of risk assessments done to meet the requirements of the MCP differ from those of NRDAs. Environmental risk assessment is conducted to determine whether there is a ***risk*** of harm that warrants remedial action at a Chapter 21E site. In contrast, a NRDA is a process by which natural resource ***injuries*** are determined, and compensation is sought for lost resources. Consequently, there are differences in the assessment approaches and types of data that are best suited for these different goals.

Examples of these differences are:

- MCP risk assessments and NRD assessments in theory address fundamentally different questions. NRD assessments focus on *observable* harm and the past and/or present loss of resources. MCP Risk assessments, on the other hand, are concerned with the *potential* for harm, both at present and in the foreseeable future. Risk assessments often evaluate subtle impacts on population health or community balance, which often cannot be measured directly. The potential for such subtle effects may be determined

by extrapolation, about which there may be substantial uncertainty. Such an extrapolation may not provide a sufficient basis for an NRD case; thus, a risk assessment could conclude that there is a significant risk at a site where natural resource damages are not identified. The difference in the nature of the questions being addressed means that MCP risk assessments and NRD assessments are likely to use data in different ways. That said, however, in practice NRD assessments have often made use of some of the assessment approaches and tools that have conventionally been used for risk assessment.

- Environmental risk assessments and NRD Assessments often focus on different kinds of resources. Natural Resource Damage Assessments typically focus on resources which have intrinsic societal value. Examples are fisheries, shellfish beds, migratory birds, endangered species and usability of recreational areas. In contrast, environmental risk assessments often focus on entities that have value because of their function in a natural community rather than direct use by people. One example is benthic invertebrates that are important as a prey base for other aquatic organisms.

- Some components of the MCP environmental risk assessment procedures recommended in this document may not apply to NRDAs. In particular, the screening criteria and procedures outlined here are expected to eliminate substantial numbers of sites from further assessment requirements under the MCP. However, there may be situations where action is not required under the MCP, but where a NRDA is appropriate and necessary. Nothing in this guidance document limits the regulatory or procedural requirements of the NRDA process, or those of any other program.

The differences and the commonalities between risk assessments and damage assessments should be considered in the planning stage of both processes, so that data acquisition and analysis can be accomplished as efficiently as possible. The risk assessment and NRD assessment should be conducted separately, however, because the objectives are entirely different. Further, to avoid confusion about how the data is used in each type of assessment, Environmental risk assessments and NRDAs should be documented in separate reports.

14.1.7 Risk Assessment/Remediation Sequence

Under the MCP, risk assessment may be performed at any point during investigation and cleanup when sufficient data are available. Site investigators and managers are not required to follow a rigid, sequential assessment process. Like human health risk assessment, environmental risk assessment may be conducted either before or after remediation to determine whether a condition of no significant risk exists or has been achieved. When a risk assessment is conducted prior to remediation, it is considered a baseline risk assessment; it should not incorporate exposure reduction achieved by temporary measures or planned remedial actions.

In some cases, it may be appropriate to take remedial action prior to completing a full risk assessment. Under the MCP, Immediate Response Actions (IRAs; 310 CMR 40.0410) or Release Abatement Measures (RAMs; 310 CMR 40.0440) are taken to reduce obvious human health risk prior to performing a full risk assessment. With regard to environmental risk, site managers should carefully consider the practical implications of conducting remediation before assessment, including:

- The potential effect of the sequence on the overall number environmental samples that will be necessary for chemical analysis;

- The potential disruption of ecological processes by remediation, which may affect subsequent ecological assessment findings;

- The uncertainty about whether the risk assessment conducted after remediation will demonstrate that (a) a condition of no significant risk has been achieved, or (b) further assessment and/or remediation are necessary.

14.1.8 Two Stages of Environmental Risk Assessment

The MCP Environmental Risk Characterization requirements are structured so that very early in the process the ecological risk assessor will identify exposure pathways unlikely to pose significant and/or measurable risk of harm and rule out the need for further detailed quantitative assessment of those pathways.

To facilitate the elimination of insignificant exposure pathways from extensive assessment procedures, the MCP divides the Method 3 Environmental Risk Characterization process into two stages:

- Stage I Environmental Screening, in which numerical and/or qualitative criteria published by MassDEP are used in a streamlined decision process to determine the need for a risk assessment. Stage I Screening should also be conducted by ecological risk assessment experts, except in limited cases where screening involves only comparing site concentrations to screening benchmarks.

- Stage II Environmental Risk Characterization, in which the potential impacts of site-related contamination on biota and habitats are comprehensively evaluated. Stage II Environmental Risk Characterizations should always be conducted by individuals with expertise in ecological risk assessment.

Stage I Screening is described in Section 14.3, and Stage II is covered in all subsequent sections.

14.2 CONCEPTUAL SITE MODEL (CSM)

The environmental risk assessment must be firmly grounded in the conceptual site model (CSM) for the site. As detailed in Chapter 2, the CSM represents a working understanding of environmental conditions and processes at a site. It identifies the types and sources of site contaminants and tracks them through environmental transport pathways and through the food web to the organisms and/or habitat features that could be exposed. The CSM is the foundation for the risk assessment and forms the basis for the design by:

- Facilitating the identification of receptors that are most susceptible to contamination;
- Providing a framework for evaluating contaminant transport and exposure pathways;
- Presenting the information needed to conduct a Stage I (screening) environmental risk characterization;
- Providing a point of reference for selecting measurement methods and assessment endpoints for the Stage II environmental risk characterization;
- Serving as a framework for integrating and evaluating different measures of exposure and effects; and
- Serving as a communication tool to establish a common understanding among stakeholders of the bases for judgments exercised by risk assessors in planning and interpreting the risk assessment.

The CSM should be presented as a narrative description and a graphical representation of the links between contaminant sources, exposure pathways, and receptors, including a comprehensive narrative of site conditions and potentially affected resources. Risk Characterization reports without a clear and comprehensive CSM may not be acceptable to MassDEP.

Two styles of graphical CSM representations have been used extensively in risk assessment practice: box diagrams and pictorial models (Figures 14.1 and 14.2 respectively). In general, box diagrams are recommended. These use flow diagrams to show links between contaminant sources, environmental media and environmental receptors. This style of CSM is preferred because it facilitates a more detailed and comprehensive representation of exposure pathways. Pictorial models are figurative depictions of inter-media transport pathways and environmental receptors. Pictorial CSM models may be a useful addition for sites with diverse stakeholder involvement because conceptually it is simpler and more concrete.

The **conceptual site model** represents the operative understanding of connections between contaminants and environmental receptors. It provides the framework for planning the risk assessment and for assimilating new information.

Figure 14.1

CSM for Pesticide Application with Impacts on an Aquatic Habitat

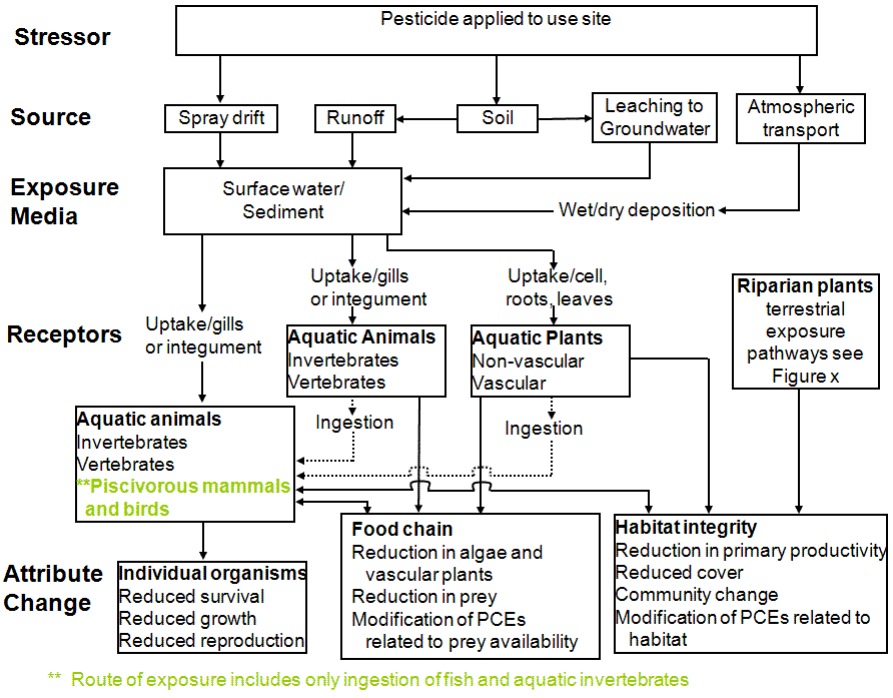


Figure 14.1 Source:
U.S. EPA *Guidance for the Development of Conceptual Models for a Problem Formulation Developed for Registration Review*
March 2011

Figure 14.2

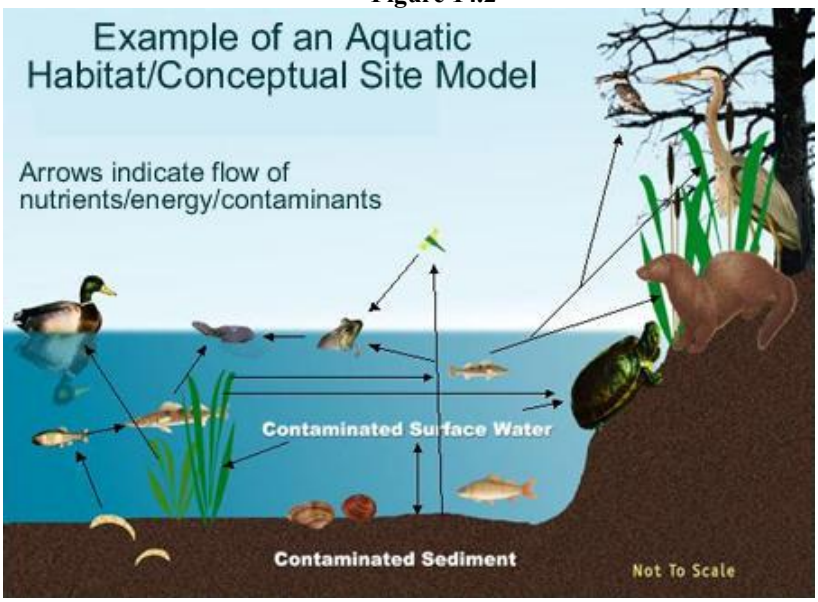


Figure 14.2 Source:
USEPA Region 5
Ecological Risk Assessment
Step 3: Baseline Problem Formulation (Online)

As stated previously, the CSM should be reviewed and revised throughout the assessment process to accurately portray an increasingly refined understanding of contaminant transport receptor exposure. In the final risk characterization stage, the CSM will provide a framework for integrating and evaluating the results of different measures of effects and exposure.

14.3 STAGE 1 ENVIRONMENTAL SCREENING

14.3.1 Stage I Environmental Screening Considerations

The purpose of Stage I Environmental Screening at an MCP site is to evaluate the need for a quantitative Stage II Environmental Risk Characterization. Screening evaluations are done separately using a different approach for each contaminated medium (soil, sediment or surface water) in which OHM concentrations are present above background levels. Based on Stage I screening, a Stage II Risk Characterization is not necessary where:

- All concentrations of OHM in a medium are below MassDEP's published screening levels. In these cases, exposures are considered unlikely to pose a significant risk of harm to biota or the habitat. Published screening benchmarks include the *Revised Sediment Screening Values* included as Appendix 15A.

- Environmental conditions at the site or resource area in question meet non-numerical criteria established by MassDEP for screening out a contaminated medium. Resources supporting screening based on qualitative criteria include:
    - The soil screening decision process, which considers the size of the contaminated area and is depicted in Chapter 16 of this document;
    - Area-Based Screening for Contaminated Sediment, which is discussed in Appendix 15G; and
    - Ecological Value of Surface Water Features, which is included as Appendix 15B.

- The OHM at the site is present at levels that pose Readily Apparent Harm, and remediation is clearly necessary to eliminate significant risk. In cases where an environmental risk assessment result will not affect the cleanup decision it is not required. An example of Readily Apparent Harm is sediment that is saturated with oil. This provision applies where one type of the hazardous material predominates at the location driving the Readily Apparent Harm condition, and where elimination of the Readily Apparent Harm condition would eliminate significant risk. Examples of such Readily Apparent Harm situations are oil spills or coal tar release sites. The MCP provides criteria for identifying Readily Apparent Harm (310 CMR 40.0995(3)(b).

Stage I Screening decisions apply to environmental media as a whole. In other words, if the concentration of each contaminant of potential concern in the sediment is below the applicable screening criterion, the need for further sediment assessment and cleanup can be ruled out. If some but not all sediment contaminants are present below the screening criteria, then all of the contaminants are carried into Stage II.

To rule out the need to further assess any contaminant present in a medium using screening benchmarks, DEP-published screening values must be available for all contaminants.

The specific screening decision criteria required will vary substantially for different types of sites and habitats. Detailed habitat-specific Stage I Screening procedures for aquatic, terrestrial and wetland habitats are presented separately in Chapters 15, 16 and 17.

A note on MCP-specific terminology is called for at this point. The MCP uses the term "Environmental Risk Characterization" in the way that other agencies use the terms "environmental risk assessment" and "ecological risk assessment". In U.S. EPA's Framework for Ecological Risk Assessment (U.S.EPA, 1992) "risk characterization" is used only in reference to the final, interpretive stage of a risk assessment. Given that this guidance like most others is based on the EPA Framework, terminology consistent with that Framework is used from this point on to minimize confusion. Thus, the term "environmental risk assessment" will be used to refer to the overall assessment process, except when referring to specific MCP provisions. In general, the term "environmental risk characterization" will be used only in reference to the final phase of the assessment.

14.3.2 Background Evaluation

The MCP states that contaminants present at concentrations consistent with background conditions need not be included in the risk assessment or cleanup requirements (310 CMR 40.0902(3)). Background means "those levels that would exist in the absence of the disposal site of concern." Guidelines for conducting background evaluations are detailed in Chapter 6 of this guidance document.

Background evaluations may be conducted at any point in the site assessment and cleanup process, including prior to Stage I. Although background evaluations are not technically part of Stage I Screening, they are mentioned at this point because they provide another way of limiting and refining the scope of a risk assessment. In contrast to screening benchmark comparisons, background evaluations may be used to eliminate individual chemicals from further consideration, even if the environmental medium in question contains other contaminants that must be carried through the risk assessment.

As described in Chapter 6, Background evaluations may be based on comparing site concentrations to published values or to levels detected in a reference area in the vicinity of the site. Published background levels of metals and PAHs in soil are listed in Appendix 6A of this document.

14.4 STAGE II ENVIRONMENTAL RISK CHARACTERIZATION

A Stage II Environmental Risk Characterization (subsequently referred to as an MCP environmental risk assessment) is a comprehensive site-specific assessment of the risk of harm to ecological receptors. Measures used to evaluate potential harm may be quantitative or semi-quantitative. The appropriate scope and level of detail for an MCP risk assessment varies widely from site to site. While the risk assessment at some sites may be very simple and inexpensive, other sites will require extensive field work and data analysis. For example, some assessments may be as simple as a comparison of site concentrations to effects-based benchmarks published in the technical literature and supported by a technical justification showing that the selected benchmarks are protective. On the other hand, risk assessments for some aquatic habitats with relatively high levels of contamination may require extensive fieldwork. The appropriate level of effort and complexity for a risk assessment is a matter of professional judgment and collaboration between the risk assessor and site manager. Those judgments should take into account the nature and extent of contamination and the environmental setting as well as site management objectives and options.

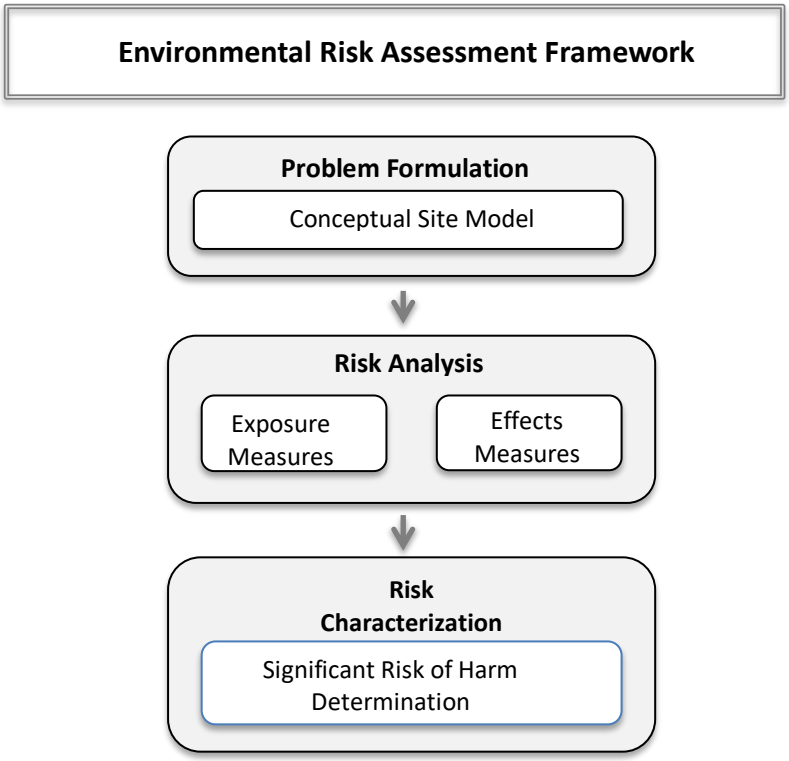
14.4.1 Framework for Stage II Environmental Risk Assessment

Regardless of the nature of the site or the complexity of the analysis, all Stage II MCP risk assessments should conform to the basic framework outlined in this guidance document. This guidance adheres to the structure introduced in EPA's 1992 *Framework for Ecological Risk Assessment* (U.S. EPA, 1992) and carried through later guidance (U.S.EPA, 1998). The Canadian Council of Ministers of the Environment (CCME, 2020) Ecological Risk Assessment Guidance Document also adopts this basic framework. The framework breaks the assessment process into three major components:

- **Problem Formulation** involves gathering available information on sources, stressors, effects and ecosystem and receptor characteristics. The initial conceptual site model is refined, and the scope and purpose of the assessment is articulated and a plan for analyzing and characterizing risk is determined.
- **Analysis** consists of two activities**:** (1) characterizing exposure by measuring or predicting the spatial and temporal distribution of a contaminant and its co-occurrence or contact with ecological components of concern; and (2) characterizing ecological effects by identifying and quantifying the adverse effects elicited by a contaminant (e.g., reduced survival). Analysis includes determining the strengths and limitations of data on exposure, effects and ecosystem and receptor characteristics.
- **Risk Characterization** combines the results of the exposure and ecological effects analyses to evaluate the likelihood of adverse effects associated with exposure to a contaminant. The final product is an estimation or description of risk that includes an interpretation of ecological adversity and descriptions of uncertainty and lines of evidence.

These basic phases of MCP risk assessments are described in greater detail in Sections 14.4.2, 14.4.3 and 14.4.4. Figure 14.3 is a simplified process diagram depicting the relationships between them. For simplicity and clarity, the process is depicted linearly, but in practice it is an iterative process. Throughout a site assessment project, as new information becomes available, the problem formulation and conceptual site model should be continually updated, and the possible need for additional data collection and analysis should be considered. If the CSM is not actively updated, the Risk Characterization could miss or omit important information that could affect the conclusion or remedial options.

Figure 14.3

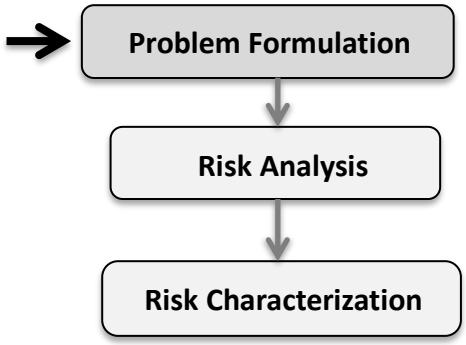


Although the risk assessment steps are presented sequentially in this framework for simplicity, they are interdependent. Each step must be taken in view of the results of the preceding work and the inputs that will be needed for the steps that follow. Thus, the selection of assessment endpoints is based on the existing site information reflected in the CSM. Just as important, the selection of receptors must anticipate the need to measure changes (or effects) in them in the risk analysis phase.

A Stage II MCP environmental risk assessment should always be conducted by an ecological risk assessment specialist. This guidance is intended to provide a comprehensive framework for ecological risk assessment, but it is not a "how to" manual. Efficient, effective execution of a site-specific risk assessment requires professional judgment based on extensive practical experience as well as an academic background in biology, chemistry and/or toxicology.

All Phases of the Stage II Environmental Risk Characterization should be done by or in collaboration with an ecological risk assessment professional.

14.5 PROBLEM FORMULATION



In accordance with the basic framework described in Section 14.4.1, the first phase in a quantitative MCP environmental risk assessment (Stage II Environmental Risk Characterization) is problem formulation. This phase involves gathering existing site information determining the appropriate scope and focus of the risk assessment, and deciding how environmental impacts will be measured. The steps include:

- Characterizing contaminant conditions by reviewing existing site information, including a summary of findings from previous investigations. As noted in Section 14.2, the CSM identifies the types and sources of site contaminants and tracks them through the exposure pathways leading to the organisms and/or habitat features that could be exposed;
- Describing exposure pathways;
- Identifying receptors of potential concern;
- Reviewing the CSM for completeness, and identifying any data gaps or information deficiencies;
- Identifying contaminants of concern (COCs) for the risk assessment;
- Identifying representative receptors for the risk assessment (An environmental receptor is an organism or group of organisms that could be exposed to contaminants of potential concern or an area of habitat that could be degraded with respect to normal support functions);
- Defining the assessment endpoints that will be evaluated;
- Articulating the specific risk questions to be answered;
- Selecting measurement endpoints that will answer the risk questions; and
- Specifying how the measurement results will be used to reach a conclusion about risk. This will involve describing the lines of evidence to be used to characterize the risk for each assessment endpoint.

14.5.1 Problem Formulation - Characterizing Contaminant Conditions

The MCP requires a comprehensive assessment of the nature and extent of contamination at all sites. General site assessment requirements are detailed in earlier Chapters of this guidance document, including:

- Chapter 2 – Conceptual Site Model
- Chapter 4 – Sampling
- Chapter 5 – Chemical Analysis
- Chapter 6 – Background
- Chapter 7 – Identifying Contaminants of Concern

Characterizing contaminant conditions involves reviewing existing site information, including a summary of findings from previous investigations.

As noted in section 14.2, the CSM identifies the types and sources of site contaminants and tracks COCs through the exposure pathways leading to the organisms and/or habitat features that could be exposed. Most often, contaminant conditions at MCP sites have been fairly well characterized prior to the initiation of an environmental risk assessment, and the available information is sufficient for problem formulation. However, additional data collection may be necessary to complete the risk assessment.

Both current and foreseeable future contaminant conditions must be considered to meet the requirements of the MCP. Current conditions must be characterized in all cases. Future conditions must be evaluated if exposures may change due to fate and transport processes, particularly if contaminant concentrations could increase at one or more exposure points. When the potential for future migration or bioaccumulation of contaminants exists, the risk assessor should estimate the maximum future contaminant level and assume that this level will occur under foreseeable future conditions.

14.5.2 Problem Formulation - Contaminants of Concern

Contaminants of concern (COCs) are the site-related contaminants evaluated in the environmental risk assessment. In some cases, COC's may include all the contaminants detected at the site (i.e., all contaminants of potential concern, or COPCs). In other cases, a shortened list may be justified. For example, contaminants present at levels consistent with background conditions may be excluded from the risk assessment in accordance with the guidance in Chapter 7 and the MCP (310 CMR 40.0902(3)). Furthermore, when the number of contaminants is so large that it is impractical to include all of them, establishing a shorter list of COCs may be justified based on information on exposure potential and relative toxicity.

To justify eliminating a substance from the risk assessment, the risk assessment report must show that it is unlikely to have an adverse effect on valued habitat or receptor of concern. Such a determination should consider the concentration, extent of the contamination, transport potential and toxicity. The risk assessment report must make a strong case for the elimination of any COPC from further consideration. If the elimination of a COPC cannot be adequately supported, it must be carried through the risk assessment.

<u>The characteristics of contaminants of concern are foundational for other elements of problem formulation:</u>

- A contaminant's physical and chemical properties determine its fate and transport characteristics, which in turn describe how it might move through the environment to potential receptors, forming complete exposure pathways. These characteristics are important determinants of which exposure pathways and receptors are most important to consider in the environmental risk assessment.

- Physical/chemical characteristics also govern the interaction of a contaminant with receptors. For example, bioconcentration factors, bioaccumulation factors and/or octanol-water partition coefficients can indicate the potential for bioaccumulation and biomagnification. (CCME, 2020).

- Toxic effects of contaminants of concern determine which receptors are likely to be adversely affected after exposure, and which effects are likely to be most severe.

- The chemical characteristics of contaminants of concern can also assist in selecting the most effective measures of exposure.

14.5.3 Problem Formulation - Describing Exposure Pathways

Exposure pathways connect contaminant sources with environmental receptors. Knowledge of contaminant transport mechanisms, site contaminant distribution and receptor groups of potential concern is required to describe relevant exposure pathways and to identify those most likely to "drive" risk at the site. The initial

conceptual site model should include *all potential exposure pathways* and should highlight the pathways that will be assessed. The risk assessment report must justify the omission of any potential pathways from the assessment. Only those exposure pathways judged to be trivial with regard to exposure and risk should be eliminated.

An **exposure pathway** describes the course a hazardous substance takes from a contamination source to an exposed person.

The process of describing exposure pathways provides an opportunity for the risk assessor to judge whether the nature and extent of contamination has been adequately characterized. Additional data may be necessary if the available data does not provide a conservative estimate of concentrations at the points of exposure, or if the data does not provide strong support for eliminating the exposure pathways that will not be carried through the risk assessment.

14.5.4 Problem Formulation - Identifying Receptors of Potential Concern

The conceptual site model should include all receptor groups likely to be exposed, considering site conditions and contaminant characteristics. In this context the term "receptor groups" means organisms grouped by habitat, ecological niche or feeding guild. Examples of receptor groups that may be of concern for environmental assessments include:

- Omnivorous fish
- Piscivorous birds or mammals (e.g., kingfisher or mink)
- Insectivorous birds or mammals
- Burrowing mammals (e.g., Star-nosed mole)
- Soil invertebrates
- Benthic invertebrates
- Amphibians
- Reptiles

The organisms likely to be exposed at a specific site, along with potentially degraded habitat features at that site, are referred to as the *receptors of potential concern*.

Receptors of potential concern are *all* the organisms and habitat features that could be adversely affected by the contamination at the site.

Representative receptors are those selected for evaluation in the risk assessment.

14.5.5 Problem Formulation - Defining Assessment Endpoints

Once the contaminants, exposure pathways and receptors of potential concern at the site have been identified in the Conceptual Site Model (CSM), the focus of the risk assessment will be narrowed by identifying assessment endpoints. These address the representative receptors and habitats on which the assessment will focus. Assessment endpoints have been defined (U.S. EPA 1998, U.S.EPA 2003) as "Explicit expressions of the environmental value to be protected, operationally **defined as an ecological entity and its attributes.**" In other words, the assessment endpoints are the attributes of the representative receptors selected for evaluation in the risk assessment. Table 14.1 shows examples of assessment endpoints for various representative receptors.

> **Assessment endpoints** are the attributes of representative receptors that are evaluated in the environmental risk assessment.

The MCP states that **"a Stage II environmental risk characterization shall be used to determine whether there is a significant risk of environmental harm or evidence of environmental harm"** (310 CMR 40.0995(4)). This broad requirement does not limit the number and type of receptors (organisms or habitat components) to be evaluated in a risk assessment and protected by risk the management decision. However, in most cases it is not practical to assess risk for all organisms and resources that could potentially be adversely affected by the COCs. Thus, it is left to the risk assessor to narrow down the larger groups of receptors of potential concern at the site to a smaller set of representative receptors. However, the CSM itself should not be pared down, but should retain the receptors of potential concern to serve as a record and reminder of the broader range of receptors and exposure pathways that are indirectly addressed by the assessment and protected by the ensuing risk management actions.

Table 14.1 offers examples of assessment endpoint receptors that might be used to represent larger groups of receptors of potential concern captured in the CSM.

Table 14.1
Examples of Assessment Endpoints

Receptors of Potential Concern (Based on the CSM)	**Representative Receptor Examples** (Assessment Endpoint Entities)	**Possible Assessment Endpoints** (Receptor Attributes)
Piscivorous Birds	Kingfisher	Survival or growth or reproduction of kingfishers exposed to contamination at or from the site
Piscivorous Mammals	Mink	Survival or growth or reproduction of mink exposed to contamination at or from the site
Amphibians	Frog species	Survival or reproduction of a frog species
Amphibians	Frogs	Abundance of frogs
Reptiles	Snapping turtle	Abundance of turtles
Soil Invertebrates	Earthworm	Earthworm abundance
Benthic invertebrates	Benthic invertebrate Community	▪ Diversity ▪ Abundance ▪ Survival of representative species
Benthic invertebrates	Freshwater mussel species	Abundance of a freshwater mussel species
Vernal pool	Vernal Pool	Contamination of vernal pool sediment or surface water
Burrowing mammals	Mole species	Survival of a mole species
Fish species	Gross Anomalies	An increase in the occurrence of gross anomalies in a species of fish
Fish species	Fish species	Survival or growth or reproduction of a fish species

Note: These examples were chosen to illustrate relationships and concepts, and they should not be interpreted as a list of recommended assessment endpoints for any particular risk assessment.

Three general Considerations in defining assessment endpoints have been identified in several ecological risk assessment risk assessment guidance documents (U.S. EPA, 1992; U.S. EPA, 1998 & CCME 2020)

1. Policy Goals and Societal Values
2. Susceptibility to the stressor
3. Ecological relevance

These are detailed in the following subsections.

1. Policy Goals and Societal Values

While the risk assessment guidance for other states and jurisdictions includes identifying policy goals and societal values as a step in problem formulation, the general goals applicable to MCP risk assessments are established and defined by a number of existing laws, regulations and policies. Therefore, a practitioner conducting an MCP risk assessment is not asked to identify policy goals and societal values but rather to be cognizant of those that have been expressed in relevant laws, regulations and policies. Several are summarized below:

- **Massachusetts General Law Chapter 21E (M.G.L. Ch. 21E)**: no substance of concern shall present a significant risk of damage to health, safety, public welfare, or the environment during any foreseeable period of time. In determining whether a permanent solution will achieve a level of no significant risk, the department shall consider existing public health or environmental standards where applicable or suitably analogous and any current or reasonably foreseeable uses of the site and the surrounding environment that may be affected by the OHM at the site or in the surrounding environment.

- **The Massachusetts Contingency Plan (the MCP)** states that an Environmental Risk Characterization "shall be used to determine whether there is significant risk of environmental harm or evidence of environmental harm." (40.0995(4)). A conclusion that a level of no significant risk of harm exists or has been achieved requires a demonstration that there is no evidence of current or potential biologically significant harm known or believed to be associated with current or foreseeable exposures to oil and/or hazardous material (OHM) at or from the disposal site (310 CMR 40.0995(4)(d)).

- **Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)**: The primary goal of the CERCLA program is to protect human health and the environment from current and potential threats posed by uncontrolled releases of hazardous substances, pollutants, and contaminants.

- **Federal Clean Water Act:** The purpose is "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters."

- **Massachusetts General Law Chapter 21 (**M.G.L. c. 21, §§ 26 through 53) charges the Department with the duty and responsibility to protect the public health and enhance the quality and value of the water resources of the Commonwealth. It directs the Department to take all action necessary or appropriate to secure to the Commonwealth the benefits of the federal Clean Water Act, 33 U.S.C. § 1251 et seq. The objective of 33 U.S.C. § 1251 et seq. is the restoration and maintenance of "the chemical, physical and biological integrity of the Nation's waters" 33 U.S.C. § 1251(a). To achieve the foregoing requirements **the Department has adopted the Massachusetts Surface Water Quality Standards** which designate the most sensitive uses for which the various waters of the Commonwealth shall be enhanced, maintained and protected. The surface water standards prescribe the minimum water quality criteria required to sustain the Designated Uses, as defined in 314 CMR 4.02: Designated Uses; and which contain regulations necessary to achieve the Designated Uses and maintain existing water quality including, where appropriate, the prohibition of discharges (Purpose statement, 314 CMR 4). Biological integrity is defined by the regulations as "The capability of

supporting and maintaining a balanced, integrated, adaptive community of organisms having species composition, diversity, and functional organization comparable to that of the natural habitat of the region" (314 CMR 4.02).

- **The Massachusetts Endangered Species Act (MGL c. 131A)** extends special protection to over 400 native plant and animal species in Massachusetts.

2. Relative Susceptibility to the Stressor

Assessment endpoints and representative receptors should be chosen so that exposure and risk are not underestimated for any receptors of potential concern at the site. When selecting representative receptors for assessment endpoints, **susceptibility should generally be a major consideration.** Susceptibility is determined by exposure and sensitivity combined (U.S.EPA 1992). Organisms are considered relatively more susceptible when the available information on exposure and effects indicates they are more likely to experience adverse effects (or likely to experience more significant adverse effects) than other organisms. The risk assessor should refer to the CSM, along with exposure and toxicity information reported in the literature, to identify the groups of organisms that are most susceptible. In considering exposure and sensitivity combined, the risk assessor's professional judgment plays an essential part selecting a combination of assessment endpoints likely to encompass the most susceptible receptors.

The two components of susceptibility, exposure and sensitivity, are described in more detail in the sections that follow.

Susceptibility: Exposure Frequency and Magnitude

Exposure frequency and magnitude are important determinants of susceptibility. Examples of conditions that affect susceptibility include:

- **Home range relative to contaminated area:**
  Wildlife that range over areas much larger than the site (or contaminated area) are generally less susceptible than wildlife with smaller home ranges, as the latter spend more time feeding in the contaminated area. For example, kingfishers feed within relatively small river segments, while eagles range over areas much greater than the size of a site and consume a smaller fraction of contaminated food from any one site.

- **Trophic level:**
  For contaminants that biomagnify (i.e., tissue levels increase at higher trophic levels), species that prey on predators are highly susceptible. For example, spiders that feed on emergent insects from rivers contaminated with mercury or PCBs can have high contaminant body burdens. Consequently, birds that prey on those spiders are even more susceptible than birds preying on emergent insects.

- **Dietary requirements:**
  Food intake per unit body weight can vary widely among different species. For example, consider two different piscivorous birds, a Belted Kingfisher and a Bald Eagle. The Belted Kingfisher consumes about 0.5 grams of food per gram body weight per day, while the Bald Eagle consumes about 0.1 gram of food per gram body weight per day. If both consume fish with similar tissue

contaminant concentrations, the kingfisher will receive a daily contaminant dose (in terms of milligrams of contaminant per kilogram body weight per day) that is five times higher than the dose received by the eagle (EPA 1993).

- **Life-history and physiological characteristics:**
  Physiological and behavioral characteristics can markedly affect vulnerability to environmental contamination. Amphibians are a prime example of a highly susceptible group. Contact with contaminated water, sediment or soil during fertilization, embryonic development, larval stages and metamorphosis can intensify exposures to contaminants. Another characteristic that makes them particularly vulnerable is their moist, highly vascularized and relatively thin skin, which may be in contact with contaminated sediment or surface water for prolonged periods (Murphy et al., 2000).

Susceptibility: Relative Sensitivity

Relative sensitivity refers to the likelihood or magnitude of adverse effect at a given level or exposure to the contaminant(s) of concern. In cases where information on sensitivity is available, it is an important consideration in evaluating susceptibility. If the assessment can demonstrate that the most sensitive species or taxa are shown to be unharmed by site contamination, it is reasonable to rule out harm for other species at the site. An overview of toxicity reference values (TRVs) presented in Appendix 14b provides an indication of relative sensitivity of various species to a number of contaminants.

In some cases, differential sensitivity in and of itself is used as an indicator of adverse effects on a community. For example, as part of a benthic invertebrate community assessment for a river or stream, the total number of distinct taxa within the orders, Trichoptera (caddisflies), Ephemeroptera (mayflies), and Plecoptera (stoneflies) are counted. In this case, the presence of fewer taxa (e.g. species) in site samples relative to reference samples would indicate an impaired community.

Species known or observed to have adapted to a COC or a category of COCs are not reliable as a means of assessing adverse effects and should not be employed as representative receptors. Most species are unlikely to develop chemical tolerance. Characteristics that allow for adaptation to chemical exposures include (Whitehead et al., 2017):

- A large population size, which can protect against extinction after a population decline due to an environmental change;
- A high level of preexisting genetic diversity in the population; and
- A short generation time, which allows evolutionary change to follow environmental change closely in time.

Using a relatively tolerant species as representative receptor will result in underestimates of risk for non-tolerant species.

There is a great deal of data available in the scientific literature to assess the toxicity of common chemicals of concern to many different organisms. U.S. EPA has published a comprehensive database on chemical toxicity for aquatic and terrestrial organisms that contains data on over 14,000 species (U.S.EPA ECOTOX

Knowledgebase).

3. Ecological relevance

Ecological relevance of an assessment endpoint refers to the importance of the receptor's biological and physical function in the environment and its impacts on other organisms. A description of ecological relevance is offered in U.S.EPA's 1998 *Guidelines for Ecological Risk Assessment*:

> *"Ecologically relevant endpoints may be identified at any level of biological organization (e.g., individual, population, community ecosystem, landscape). The consequences of changes in these endpoints may be quantified alteration of community structure from the loss of a keystone species) or inferred (e.g., survival of individuals is needed to maintain populations)... Ecologically relevant endpoints often help sustain the natural structure, function, and biodiversity of an ecosystem or its components. They may contribute to the food base (e.g., primary production), provide habitat (e.g., for food or reproduction), promote regeneration of critical resources (e.g., decomposition or nutrient cycling) or reflect the structure of the community, ecosystem, or landscape (e.g., species diversity or habitat mosaic)" (EPA 1998).*

Two aspects of ecological relevance considered in endpoint selection are: (a) trophic level, and (b) level of ecological organization (also referred to as biological organization). These are explained in the two sub-sections that follow:

Ecological Relevance: Trophic Level

Trophic level refers to the place an organism occupies in its food chain, with plants (producers) occupying the lowest levels and predators the highest. While upper trophic level organisms receive higher contaminant doses through the food chain, organisms at lower trophic levels must also be considered in the risk assessment and protected by risk management decisions. In general, organisms lower on the food chain are less mobile than top predators and therefore may be more constantly exposed at small sites. Moreover, lower-level organisms often serve ecological functions beyond serving as prey bases.

Invertebrates are an important group of low trophic level organisms that warrant particular attention due to their vital ecological roles. They are critical components of most ecosystems, linking primary producers (plants) with higher trophic levels in the flow of energy and nutrients through natural systems. There are several compelling reasons to be concerned about even moderate impacts on invertebrates:

- Terrestrial invertebrates build and maintain soil structure (aggregation and porosity) and contribute to soil organics matter (Lavelle et al. 2006), and also provide important food sources for birds, small mammals and amphibians.

- Aquatic Invertebrates play a critical role in organic matter decomposition and nutrient cycling, making energy and nutrients available to organisms that otherwise would not be able to use the available resources. Different groups and species perform specialized functions in these processes. For example:

  "Benthic invertebrates are estimated to process 20 – 73% of riparian leaf litter inputs to headwater streams...Certain species of aquatic insects that live in small headwater streams use specialized mouthparts or feeding appendages to break up large pieces of organic detritus into smaller fragments... Other species are specialized to filter variously sized particles and are typically located downstream from the shredders. Such specializations suggest that the loss of some pivotal species would alter food availability for suspension feeders and thereby alter ecosystem processing of detrital carbon" (Covich et al. 1999).

Box 14.2
A Change in Guidance on Assessing Invertebrates

MassDEP's 1996 Guidance identified importance to higher trophic (feeding) levels as a key consideration in evaluating ecological relevance, suggesting that adverse effects on organisms low on a food chain are only significant if effects on organisms higher on the food chain can be measured. More specifically, the 1996 Guidance Document suggested that **invertebrates** were ecologically relevant mainly by virtue of providing food for fish and other higher trophic level animals. In conjunction with that premise, it was stated that a substantial reduction in invertebrate abundance would not impair the prey base function and may not be considered a significant risk of harm. MassDEP's position on this issue has changed. MassDEP has concluded that the prey base function of invertebrates is not a sufficiently sensitive indicator of environmental harm. After 1996, MassDEP began recommending that invertebrates should be included as endpoint species.

- Some aquatic invertebrates are important prey for other species of invertebrates and vertebrates, and loss of a preferred prey species is not necessarily mitigated by the survival of other species.

  "...the exact consequences of each species loss cannot be predicted... However, because environmental conditions change over time, populations of some of these remaining species would most likely become locally extinct, disrupting ecosystem processing. Consequently, ecosystems composed of a bare minimum of species in a fluctuating environment probably could not continue to function over time merely by compensating for the losses of some species with increased densities, biomass, or processing rates of the few remaining species" (Covich et al. 1999).

- Loss or diminishment of a sensitive group that plays a key role could significantly impair a critical function:

  "...the presence or absence of a single species can dramatically alter ecological processes such as rates of grazing and decomposition... Different species of sediment-dwelling macro-invertebrates are unlikely to be interchangeable in many complex ecosystem processes" (Covich et al. 1999).

- Many important invertebrates are already threatened or endangered:

  "In the US, the three most endangered groups of organisms – freshwater mussels, crayfish, and stoneflies – are all invertebrates. Almost 70% of all freshwater mussel species are in

*need of immediate conservation measures, compared to just 16% of mammals and 14% of birds" (*American Museum of Natural History: amnh.org*).*

MassDEP recommends including an assessment endpoint for invertebrates in all cases for sediment contamination, and in many cases for soil contamination.

Ecological Relevance: Level of Ecological Organization

A key decision in selecting assessment endpoint(s) is the level (or levels) of ecological organization on which the assessment will focus. The term "level of ecological organization" (or level of biological organization) refers to the hierarchy and interactions of biotic components of ecosystems. A conventional hierarchy is shown in Box 14.3.

Ecological risk assessments for waste sites in Massachusetts generally focus on the organism, population and/or community level. An assessment endpoint will represent one of these levels. Attributes of these levels of organization named in assessment endpoints include:

- Organism level: Survival, Growth and reproduction (as measured by toxicity tests);
- Population level: Abundance (as measured by field studies); and
- Community level: Species richness, composition (as measured by field studies).

Over the last two or three decades, risk assessment experts have called for a shift away from organism-level risk assessment and toward population-level assessments. However, different levels of biological organization are inter-dependent, and **MassDEP considers adverse effects observed at the community, population, *and organism* level to be ecologically relevant**. For MCP risk assessments, organism level attributes (such as survival, and reproduction) are appropriate assessment endpoints, and they provide more practical bases for assessing risk than direct measurement of sub-population and community characteristics (See Box 14.4).

Box 14.3
Levels of Ecological Organization
(From Odum and Barrett, 2004)

- Ecosphere
- Biomes
- Landscapes
- Ecosystems
- Communities
- Populations
- Organism
- Organ system
- Organs
- Tissues
- Cells
- Molecules
- Atoms

Box 14.4
Considering Organism-Level effects on Populations when Identifying Assessment Endpoints

In a paper published to clarify the concepts of assessment endpoints and levels of biological organization, Dr. Glenn Suter and his co-authors support using organism level attributes with a population as the entity for the assessment endpoint (Suter et al., 2005). Similarly, for most MCP assessments, MassDEP advocates simply using organism level assessment endpoints as measures of stress on populations of concern.

Assessment endpoints recommended for assessing terrestrial, aquatic and wetland habitats are described in detail in Chapters 15, 16 and 17 respectively.

MassDEP considers organism level effects to be reasonable assessment endpoints for assessing risk under the MCP.

14.5.6 Problem Formulation: Articulating Risk Questions

A "risk question" asks about the evidence for an adverse effect on an assessment endpoint. It will guide the risk assessor in selecting measurements that will produce relevant and useful information for reaching a conclusion in the final risk characterization step. Formulating at least one risk question for each assessment endpoint is a crucial step in planning a coherent assessment project.

A clearly stated risk question will form a tight link between an assessment endpoint and the measurements used to evaluate it. **A risk question is answered by the result of exposure and effects measurements used to evaluate the assessment endpoint.** The answer to each risk question is one line of evidence for evaluating an assessment endpoint. Figure 14.4 depicts the relationships between assessment endpoints, risk questions and measures of effects.

The following **examples of risk questions** are from a U.S. EPA discussion paper on problem formulation (MacDonald Environmental Sciences Ltd. and Cantox Environmental, Inc., 2004):

- Are the levels of contaminants in surface water from the site appreciably greater than the concentration benchmarks for the survival, growth, or reproduction of fish?
- Is the survival, growth or reproduction of fish exposed to surface water from the site significantly lower than that for reference (or control) media?
- Is the frequency of deformities, fin erosion, lesions and tumors (DELT) significantly higher in fish from the site than in fish from reference areas?
- Are the levels of contaminants in whole sediments from the site greater than the concentration benchmarks for survival, growth or reproduction of aquatic invertebrates?
- Is the survival, growth or reproduction of aquatic invertebrates exposed to whole sediments from the site significantly lower than those attributes for test organisms exposed to sediment from reference

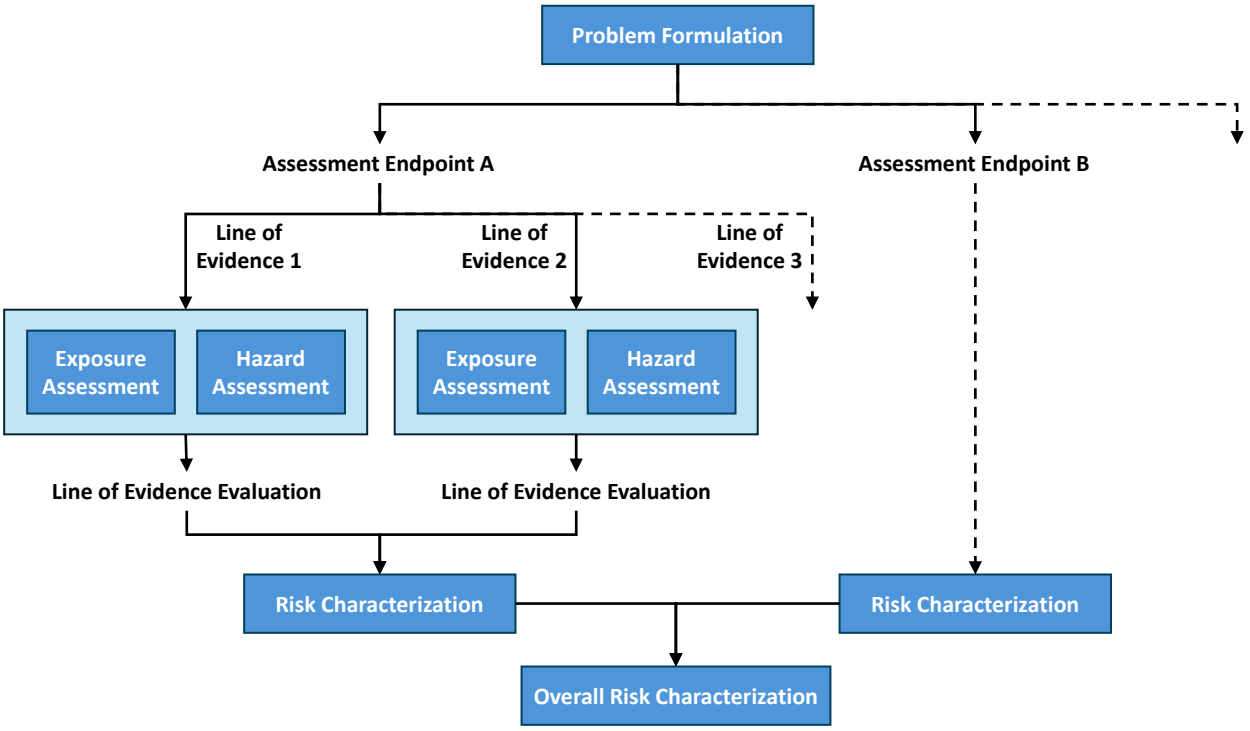
Box 14.5
Terminology note:
Risk hypothesis vs. Risk Question

While guidance developed for other jurisdictions may use the term "risk hypothesis" to express the effects that will be evaluated by measurements, MassDEP guidance uses the term "risk question" to avoid implying that formal hypothesis testing is required to reach a conclusion about risk.

locations?

- Is the survival, growth, or reproduction of amphibians exposed to surface water, whole sediments or wetlands soils from the site significantly lower than for reference media?
- Is the frequency of amphibian abnormalities significantly higher at the site than in the reference areas?
- Does the daily dose of contaminants received by birds from consumption of tissues of prey species and from other media at the site exceed toxicity reference values (TRVs) for survival, growth or reproduction of birds?
- Are the concentrations of contaminants in bird eggs from the site greater than the benchmarks for survival growth or reproduction of birds?
- Does the daily dose of contaminants received by mammals from consumption of tissues of prey species and from other media at the toxicity exceed the TRVs for survival, growth or reproduction of mammals?

Figure 14.4



Each risk question should be based on a known or potential effect of the COC(s). The number of risk questions

addressed for each assessment endpoint is determined by the risk assessor, taking into account site conditions, the nature of the contamination and the tools and resources available for measuring the relevant exposures and effects. In many cases, one risk question for each assessment endpoint will suffice. Several examples of assessment endpoints with related risk questions are presented in Table 14.2.

Table 14.2
Examples of Risk Questions for Specific Assessment Endpoints
(Adapted from U.S. EPA, 2004)

Assessment Endpoint	Possible Risk Questions
Survival, growth and/or reproduction of amphibians	♦ Are the levels of contaminants in surface water, whole sediments and/or soil from the site greater than benchmarks for the survival, growth, or reproduction of amphibians? ♦ Is the survival, growth, or reproduction of amphibians exposed to surface water, whole sediments or wetlands soils from the site significantly lower than for reference media. ♦ Are the frequency of abnormalities significantly higher in amphibians from the site than in amphibians from reference areas?
Survival, growth and/or reproduction of aquatic invertebrates	♦ Are the levels of contaminants in in surface water and/or whole sediments from the site greater than the concentration benchmarks for survival, growth or reproduction of aquatic invertebrates? ♦ Is the survival, growth or reproduction of aquatic invertebrates exposed to whole sediments from the site significantly lower than that in reference sediments? ♦ Is the structure of aquatic invertebrate communities at the site outside the normal range for aquatic communities in reference areas?
Survival, growth and/or reproduction of fish	♦ Are the levels of contaminants in surface water and/or whole sediments from the site greater than the concentration benchmarks for the survival, growth, or reproduction of fish? ♦ Is the survival, growth or reproduction of fish exposed to surface water from the site significantly lower than that for reference media? ♦ Is the frequency of deformities, fin erosion, lesions and tumors (DELT) significantly higher in fish from the site than in fish from reference areas? ♦ Are the levels of contaminants in fish tissues from the site greater than critical tissue values for the survival, growth or reproduction of fish.
Survival, growth and/or reproduction of mammals	♦ Does the daily dose of contaminants received by mammals from consumption of the tissues of prey species and from other media at the site exceed the toxicity reference values (TRVs) for survival, growth or reproduction of mammals? ♦ Are the concentrations of contaminants in mammal tissues from the site greater than benchmarks for the survival, growth, or reproduction of mammals?

Clearly stated **risk questions will link the assessment endpoints and effects measurements** and will provide solid bases for planning the assessment and evaluating the results.

To develop risk questions that will lead to definitive measures of harmful effects, it is necessary to consider the types of effects that would be "evidence of biologically significant harm" or "evidence of the potential for biologically significant harm" under the MCP. A risk question should invoke a condition or an effect on a receptor attribute that would be considered biologically significant harm for MCP purposes. Examples of biologically significant harm include:

- Sublethal effects with potential population level implications, including growth or reproductive effects
- Lethal effects on test organisms in laboratory or field toxicity tests
- Bioaccumulation of a substance to a level associated with toxic effects in the species in question
- Bioaccumulation in prey species to a level that could result in toxicity to organisms at higher trophic levels
- Increased rate of deformities
- Absence of a species normally expected to occur in the area
- Reduction of a population or a subpopulation (reduced abundance)
- Change in the structure of a community
- Habitat degradation or destruction
- Loss or diminishment of ecological function

The indicators of biological harm listed above are consistent with the Department's objectives with respect to the level of environmental protection appropriate for MCP investigation and remediation projects. They clearly indicate that assessment objectives should *not* be limited to measurable population- or ecosystem-level effects, and that effects at lower levels of biological organization should in many cases be considered significant, even if a quantitative link with population- or ecosystem-level effects cannot be established due to site size or resource limitations.

The following subsection describes selection of the measurement(s) that will be used to answer each risk question. As already noted, a risk question only pertains to one assessment endpoint, but multiple risk questions (multiple lines of evidence) may apply to a single assessment endpoint.

The result of the measurement(s) used to answer one risk question is one line of evidence for evaluating an adverse effect on the assessment endpoint.

Categorizing lines of evidence can help to organize measurement endpoints and evaluate and communicate the strengths and weakness of various measurement endpoints in the problem formulation phase and later in

the analysis and risk characterization phases. In their 2020 Ecological Risk Assessment Guidance, the Canadian Council of Ministers of the Environment identified these categories (CCME, 2020):

- *Site-specific toxicological evidence:* Considers measurement endpoints related to studies of test organism exposure to contaminated site media under controlled conditions. Results of sediment toxicity tests in which standard test organisms are exposed in laboratory settings to sediment with various contaminant levels are examples of this type of evidence.

- *Indirect toxicology evidence:* Considers toxicological information gleaned from other sites, under an assumption that the concentration-response relationship is either similar to, or can be estimated from, the data collected at other sites. This approach may be especially useful where practical limitations constrain the possibility of collecting site-specific toxicological data. Further, assessment of effects based on toxicological information published in the literature (e.g., sediment toxicity benchmarks and wildlife toxicity reference values) may be considered indirect toxicology evidence.

- *Site*-specific *biological evidence*: Considers direct assessment of the site's biological condition. Examples are biological assessment of soil or sediment invertebrate communities.

- *Indirect biological evidence:* Considers indirect assessment of biology, through extrapolation of knowledge obtained at other sites.

Typical risk assessments for MCP sites will not include all of these categories of lines of evidence. Moreover, different lines of evidence in the same category will have different strengths and weaknesses. Nevertheless, identifying the categories into which the lines of evidence for a site fall may help when evaluating and communicating the strengths and weakness of the evidence in the problem formulation phase and later in the analysis and risk characterization phases, and also when describing the overall uncertainty of the risk assessment.

The following subsections describes selection of the measurement(s) that will be used to answer each risk question. As already noted, each risk question only pertains to one assessment endpoint, but multiple risk questions (multiple lines of evidence) may apply to a single assessment endpoint.

14.5.7 Selecting Measurement Endpoints

As has been stated, measurement endpoints are the measures of exposure and effects employed to answer the risk question(s). For the purpose of MCP assessments, the two main types of measurement endpoints are:

- **Measures of effect:** Measurable change in an attribute of an assessment endpoint or its surrogate in response to a stressor to which it is exposed (U.S. EPA, 1998).

- **Measures of exposure**: Measures of contaminant levels and movement in the environment and their contact or co-occurrence with the assessment endpoint receptor group (U.S. EPA, 1998).

In many cases**, supplemental exposure measures** are also called for. These are site conditions that modify exposure or effects. Most are indicators or measures of reduced bioavailability. Examples include

organic carbon content in soil or sediment, acid volatile sulfides in sediment and dissolved organic carbon in surface water.

Measures of effects are used in combination with related measures of exposure to answer a risk question and form a line of evidence, as detailed in the Risk Analysis section (14.6). To illustrate these connections, examples of risk questions with corresponding measurement endpoints are given in Table 14.3

Table 14.3
Examples of Measurement Endpoints

Risk Question	Measure of Effects	Measure of Exposure
Are the levels of contaminants in surface water from the site greater than the concentration benchmarks for the survival, growth, or reproduction of fish?	The water concentration associated with a specified level of effect (ECx) for survival for a surrogate fish species.	The surface water concentration at the site.
Is the survival, growth or reproduction of aquatic invertebrates exposed to whole sediments from the site significantly lower than that in reference sediments?	Percent survival for a standard test organism (e.g., *Hyallela azteca*) exposed to site sediment samples, compared to the survival rate for sediment samples from a reference (uncontaminated, background or local conditions) area.	Site sediment concentrations to which indigenous organisms at the site are exposed.
Does the daily dose of contaminants received by birds from consumption of tissues of prey species and from other media at the site exceed toxicity reference values (TRVs) for survival, growth or reproduction of birds?	A toxicity reference value (TRV), in units of average daily dose, published for a surrogate species.	An estimate of the average daily contaminant dose, based on the contaminant concentrations in soil and prey items (e.g., invertebrates) and consumption rates published in the literature.

The answer to each risk question forms one line of evidence.

Careful planning of exposure and effects measurements will ultimately support the development of valid and compelling lines of evidence. Section 14.5.10 discusses evaluation of lines of evidence.

14.5.8 Problem Formulation - Selecting Measures of Effects

The measurements used to assess contaminant effects are selected in the problem formulation phase and carried out in the analysis phase. For MCP risk assessments, some of the most commonly used measures of

effects are:

- **Benchmark comparisons**: site contaminant concentrations are compared to effects-based concentrations published in the technical literature.

- **Site-specific laboratory toxicity tests**: test organisms are exposed to contaminated soil or sediment from the site.

- **Observational studies**: community-, population- or organism-level characteristics observed at a site are compared with the same characteristics observed at a reference location.

- **Food chain evaluations**: estimated contaminant dose for an organism consuming prey at a site is compared with a dose associated with toxic effects (or no effects).

The relative sensitivity to contamination of different measurements should be the primary consideration in selecting measurements for MCP risk assessments. If a measurement is not sufficiently sensitive to detect harmful effects, the ensuing site management decisions may not be adequately protective. When selecting the measurements to answer questions about assessment endpoints, the risk assessor should be mindful that the data and findings used for risk management decisions must be both technically defensible and environmentally protective.

In selecting measures of effects for MCP risk assessments, relative sensitivity to the effects of contamination should be the primary consideration.

Different effects measures have different strengths and weaknesses and different advantages and disadvantages. These are described below for the most common measures of effects listed at the beginning of this section. Additional considerations related to the execution of measurements are discussed in the section on risk analysis (Section 14.6).

Problem Formulation: Benchmark Comparisons

Benchmark comparisons are the simplest, least site-specific measures of effects. In this guidance, a "benchmark" is an effects-based concentration in soil, water, or sediment that is compared with site concentrations to evaluate the risk of harm.

There are numerous sources of benchmarks that may be used for MCP environmental risk assessments. These include:

- Screening benchmarks published by MassDEP for use in Stage I screening environmental risk characterizations;

- Regulatory limits, such as National Recommended Water Quality Criteria (NRWQC) for surface water;

- Toxicity test data reported in the scientific literature, including effects concentrations (ECx) and species sensitivity distributions;

- Risk-based concentrations identified at other waste sites, including federal Superfund Sites and sites managed by other state agencies;

- Concentrations associated with low risk based on rigorous field studies at other waste sites, including Federal Superfund Sites.; and

- Compilations of data from field studies and/or toxicity tests done at other number of locations.

Published benchmarks represent a range of risk levels. A benchmark may be a no adverse effect level (NOAEL), a lowest adverse effect level (LOAEL), a level derived from a distribution of effect levels (e.g., a species sensitivity distribution), or a specified effect level (e.g., a 10% effect level, or EC_{10}). Specified effect levels impart more information about the potential magnitude of adverse effects than NOAELs and LOAELs. The risk level associated with the benchmark is an important consideration in the problem formulation as well as the risk analysis and characterization phases of the assessment. The final risk assessment report must provide technical justification for benchmark concentrations selected for use in a Stage II MCP environmental risk assessment, and must address:

- Applicability to the contaminant(s), environmental medium and receptor(s) of concern at the site;
- Effects on which the benchmark is based (i.e. chronic or acute, lethal or sublethal);
- Risk level associated with the benchmark (for example, protective for 90% of organisms tested or protective for x % or species tested at a specified risk level); and
- Uncertainty associated with the benchmark, in qualitative and/or quantitative terms.

In many cases, benchmark comparisons offer an efficient and protective way to assess the possibility that site contaminant concentrations are causing biological harm.

Problem Formulation: Food Chain Evaluations

A **food chain** is a series of organisms that sequentially feed on one another. Food chains show the relationships between producers, consumers, and decomposers—what eats what. Food chain evaluations are mainly used to evaluate the risk of harm to birds and mammals from contaminants in soil, water, sediment and prey items in terrestrial and aquatic environments. At MCP sites, a food chain evaluation typically focuses on estimating exposures and effects for an organism (or organisms) that have been identified as representative receptors for an assessment endpoint.

A food chain model provides an estimate of the average daily contaminant dose from ingesting soil prey items, soil or sediment and water. The estimated average daily contaminant dose is then compared to a toxicity reference value (TRV); if the site dose is lower, it is reasonable to conclude a condition of no significant risk exists for terrestrial birds or mammals.

Food chain evaluations may be viewed as a specialized type of benchmark comparison, because the toxicity reference values (TRVs) and the ingestion rates used to characterize the potential for effects are values obtained from the technical literature and are not site-specific. TRVs are available in the technical literature, with a comprehensive list provided in U.S.EPA's Ecotox Database.

Typically, the representative receptor (assessment endpoint) evaluated in a food chain model serves as a surrogate for a number of other species of concern at the site. Therefore, it is important to select representative species that are relatively susceptible to effects from the contaminant in question. Species with small home ranges are preferred, as they are more likely to feed primarily within a contaminated area of concern.

Problem Formulation: Site-Specific Laboratory Toxicity Testing

Site-specific laboratory toxicity tests offer a relatively straightforward way to evaluate the toxic effects of contaminated water, soil or sediment. At MCP sites, these tests are most often used to evaluate the effects of sediment contamination on benthic invertebrates. They involve exposing standard test organisms to samples of sediment from a site and evaluating survival, growth and/or reproduction of the test organisms. Sediment (or water or soil) from "reference" locations (nearby areas not affected by the site) is tested concurrently in order to determine whether toxicity that may be observed in site samples is attributable to site contamination or, alternatively, to conditions prevalent throughout the surrounding area (U.S. EPA, 1991).

Compared to observational studies to assess the community structure, toxicity tests conducted under controlled laboratory conditions generally have lower data variability and greater sensitivity. By exposing standard test organisms to sediment or soil from the site under controlled conditions, **toxicity tests balance site specificity with sensitivity**.

Compared with laboratory tests of individual contaminants in laboratory media, testing contaminated media from the site has a number of advantages. Dr. Glenn Suter and his coauthors have listed several reasons that site-specific toxicity tests are more useful (Suter et al., 2000). They include:

- The bioavailability of the contaminants is realistically represented;
- The form of the contaminants is realistic;
- Combined toxic effects are elicited;
- The effects of contaminants for which few or no relevant test data are available are included;

Details on these points and a list of disadvantages are presented in the reference (Suter et al., 2000).

As stated previously in Section 14.5.1, the effects on survival, growth or reproduction measured by toxicity tests are considered to be organism-level effects (as opposed to population- or community-level effects), because the effects measured involve the disruption of biological processes within rather than among organisms. There are conflicting opinions about the applicability and interpretation of toxicity testing results in environmental risk assessments. Nevertheless, toxicity testing has long been used to assess

environmental risk. In a staff paper, EPA has clearly expressed continued support for this approach:

> *"Where possible, toxicity tests are performed using measurement endpoints that are related to population effects (e.g. measurements of growth rate or reproduction). . . the protection of organism-level attributes is generally interpreted as occurring in a population or community context (USEPA, 2003j). That is, increased mortality or decreased fecundity or growth of organisms in an assessment population or community is assumed to be significant, even with no demonstration that a population- or community-level property is affected . . . That assumption is necessitated by the extreme difficulty of predicting effects at higher ecological levels" (U.S. EPA, 2004b).*

Consistent with this view, MassDEP considers toxicity to be a valid and relevant measure of effects, particularly for assessing the effects of contaminants on benthic invertebrates.

Where benthic invertebrates are identified as a receptor of concern, MassDEP strongly recommends including toxicity testing as a component of the environmental risk assessment.

Problem Formulation: Observational Studies

Observational studies (biological surveys) are site-specific measures used to evaluate the effects of contamination on organism condition, population characteristics and/or community structure.

- Measures of organism condition include the proportion of diseased or deformed individuals.
- Population measures are often applied to fish, including biomass, abundance and proportion of diseased individuals.
- Community structure measurements include species abundance, taxa richness (an indicator of diversity), composition, and the proportion of tolerant/intolerant taxa. These measures of effects have been employed in field studies of aquatic invertebrates.

Observational field studies have the advantage of incorporating realistic site-specific exposure conditions. They account for both direct contact and food chain exposures, and they integrate exposures over time and space, thus accounting for temporal and spatial variations in exposure conditions. Field studies are necessary for direct observation of population- and community-level characteristics.

At the same time, there are significant drawbacks to the use of field studies/direct observations in environmental risk assessment. The attributes measured tend to be highly variable because community and population assessment metrics respond to a myriad of non-site related biological, chemical and physical environmental factors. Adverse effects on highly variable endpoints are difficult to measure and may not be sufficiently sensitive indicators of harm (See Box 14.6).

Another challenge when conducting observational studies is determining whether adverse effects on representative receptors might be masked by the acquisition of chemical tolerance. While chemical tolerance allows certain populations to thrive under highly polluted environmental conditions, others may be susceptible to adverse effects from the same exposure. It is critically important to avoid selecting chemically tolerant organisms as representative receptors. As noted in Section 14.5.5, the combination of a large population size, a short generation time and a high level of genetic diversity can lead to the acquisition of chemical tolerance through genetic adaptation.

Box 14.6
Observational Study Challenges

In the 1998 Guidelines for Ecological Risk Assessment, **EPA voiced this caution related to the difficulty of detecting adverse effects using observational studies** (EPA 1998):

Because conditions are not controlled in field studies, variability may be higher and it may be difficult to detect differences. For this reason, it is important to verify that studies have sufficient power to detect important differences.

Natural ecosystem variability can make it very difficult to observe (detect) stressor-related perturbations. . . . Predicting the effects of anthropogenic stressors against this background of variation can be very difficult.

Some species can develop a tolerance to contaminants; in these cases, a population or community survey would be ineffective for evaluating existing impacts.
(EPA 1989 Superfund Guidance)

In summary, the utility of population or community observational studies for MCP risk assessments is limited for several reasons:

- The time frame within which MCP assessments are conducted is not long enough to discern a central tendency from fluctuating values of population or community attributes such as density, abundance or production;
- The organisms exposed to contamination at a waste site are often a small subset of a larger population. Any effects on the exposed group may be masked by recruitment into the larger area-wide population (e.g., reproduction) and by migration within that population (e.g., invertebrates drifting from upstream to downstream locations);
- Chemical tolerance acquired by exposed organisms can allow them to survive in the presence of significant contamination, masking biological harm (such as increased energy requirements and

susceptibility to other stressors) that is not reflected in population metrics such as abundance or density of organisms.

Given these limitations, observational studies alone may not provide conclusive or compelling evidence of the presence or absence of contaminant effects on communities or populations in the vicinity of an MCP site. Such studies may nevertheless provide useful supplementary information and risk assessors may opt to employ them in certain cases. Although we recognize that there are divergent opinions on this point, MassDEP does not consider observational studies to be superior to other measures. The absence of observable effects in a field study should not necessarily overrule or be given more weight than toxic effects observed in a laboratory toxicity test.

Observational field studies are not sensitive indicators of harm from contaminants. In general, a field study should not be used as the primary measure of harm for an MCP risk assessment.

In some cases, extrapolation of knowledge gained from bioassessment studies previously conducted at other sites may be appropriate (CCME, 2020). This approach is not site-specific; it has more in common with benchmark comparisons. Nevertheless, readily available data on community or population effects from a rigorous long-term study (or studies) of exposure to the same contaminant mixture at a site in a geographically similar setting, may offer an efficient and economical way to evaluate the potential for biological harm.

Measures of Effects Less Commonly Used at MCP Sites:

Some measures of effects employed extensively in other jurisdictions (sites not governed by the MCP) are generally used less often at MCP sites. Two are described here:

Problem Formulation: Effects Thresholds Based on Body Burdens

To a limited extent, tissue concentration-based effects thresholds published in the literature may be used as measures of effects for environmental risk assessments. This involves comparing internal contaminant concentrations (tissue concentrations measured in the receptor of concern) to published thresholds. This approach can be used where certain conditions are met (CCME, 2020):

- The contaminant of concern is known to accumulate in tissue;
- Effects thresholds based on body burdens for the receptors and contaminants of concern have been published in the literature; and
- There are practical methods for collecting the tissue type in question.

References for tissue-based threshold values include Beyer and Meador (2011), Suter *et al.* (2000), and the Environmental Residue-Effects Database compiled jointly by the U.S. Army Corps of Engineers and U.S. EPA (CCME, 2020).

Assessing toxicity based on body burdens is not typically used due to the difficulty of obtaining and analyzing tissue samples and the resources required to use this approach, and the limited data available to assess effects based on tissue samples.

Problem Formulation: Population Models

Population models are mathematical representations of relationships over time between biological processes (e.g., birth and death rates) and population characteristics (e.g., population size or growth rate). Models can be used to explore potential effects of changes in habitat or environmental conditions on population size, age structure or persistence. Wildlife managers have long made use of population models to explore the effects of fishing and hunting on the structure and long-term persistence of various fish and wildlife populations. Models have also been used to evaluate the impacts of specific stressors, such as pesticides, on non-target species of fish, birds and mammals. However, population models have not been routinely used in Massachusetts for waste site risk assessment.

In recent years, many leading environmental risk assessors have advocated focusing more on population and community attributes in waste site risk assessments, and less on organism-level effects. Advocates of population modeling hold that accounting for compensatory mechanisms and life history information can improve predictions of the effects of toxic chemicals on populations. The underlying premise is that incorporating more information in an assessment will lead to more accurate and realistic estimates of contaminant effects on populations and communities. Potential benefits of population models cited by various authors include:

- Incorporating more information on organisms' life history, behavior and environment, and thus improving the realism of the assessment;
- Providing information to managers on the expected population status and trends under a variety of stressor conditions or management actions; and
- Reducing the uncertainty in extrapolation of standard toxicity test results to effects on populations.

Potential advantages notwithstanding, significant technical challenges associated with using population models to assess the effects of contaminants persist. Considering these challenges, EPA has called into question the utility of population models for risk assessments at Superfund sites.

> *It is impractical to estimate density dependent responses in real populations, particularly when modeling the effects of toxicants . . . The bottom line is that, although models exist for predicting the effects of chemicals at levels of organization higher than the organism, they are still in the development*

phase and have not been shown to be reliable. On the other hand, assessment of ecological risks using measures of organism-level effects is justified by experience, policy and judicial decisions. (U.S. EPA, 2004b).

Additional drawbacks to using population models in MCP risk assessments are:

- To comply with regulatory deadlines, MCP risk assessments are often completed within a time frame of one or two years. Many natural populations fluctuate over much longer time scales. As a consequence, it is impossible to evaluate how well the model represents actual population characteristics. This programmatic time constraint stands in contrast with the application of models to evaluate the impact of stressors such as pesticides, hunting or fishing on wildlife populations. In these applications, model results can be compared with actual population conditions over time and adjusted as necessary. Therefore, population models may not be practical for many MCP sites.

- Actual population processes operate over a larger spatial scale than the limited areas typically assessed at MCP sites.

- Assessment endpoint species are usually surrogates for other species belonging to the same feeding group or occupying the same habitat. Site management decisions based on the risk of harm to a surrogate species should be broadly protective. A population model that incorporates life history information for one particular species may not be suitable for others.

Given these concerns, MassDEP does not recommend the general use of population modeling for assessing risks from exposure to OHM at MCP sites in Massachusetts. There may, however, be limited MCP sites where population modeling is useful. Where one particular species is of interest, a keystone species for example, and where the spatial scale is large enough and site management timeframe is long enough so that model evaluation is possible, a model may provide useful information for the decision process.
Practical information on using population models in risk assessments is offered by Barnthouse and coauthors (Barnthouse, et al., 2008).

14.5.9 Problem Formulation - Planning the Exposure Assessment

In the problem formulation phase, the risk assessor must identify exposure pathways and routes and formulate a plan for quantifying exposures for each assessment endpoint and representative receptor. The exposure assessment plan must specify exposure points for each representative receptor, and it must describe in general terms how sampling will be conducted to quantify exposures to contaminants at the site over both space and time. Depending on the receptor and the effect being evaluated, contaminant concentrations may be measured in one or more environmental medium, in prey items, and/or in the tissue of the receptor itself. Examples of measures of effects and related measures of exposure are offered in Table 14.4.

Table 14.4
Examples of Exposure Measures Corresponding to Selected Effects Measures

Measure of Effect	Measures of Exposure
Percent survival in a study population of test organisms associated with various sediment concentrations.	Concentrations in sediment samples with which indigenous benthic invertebrates are likely to come into contact.
Wildlife toxicity reference value (obtained from the literature) for a bird that preys on soil invertebrates.	The average daily dose estimate for the bird, based on average concentrations measured in prey items from the site combined with an estimated daily food consumption rate.
Water concentrations reported in the literature to be associated with toxic effects on fish.	Site surface water concentrations measured over the relevant time period, areas and depths where the receptor might contact the water contaminant.

Supplemental Measures of Site Conditions

Supplemental measures are often needed to assess physical, chemical or biological conditions that can modify the intensity of exposure or the severity of toxic effects. For the most part, these are indicators of bioavailability that can moderate exposure estimates or explain relationships between measures of effects and exposure. Examples of supplemental measures of site conditions include:

- The ratio of acid volatile sulfide (AVS) to simultaneously extracted metals (SEM) in sediment contaminated by divalent metals (App. 15I);
- Soil or sediment particle size distributions;
- Sediment organic carbon content;
- Dissolved organic carbon in surface water;
- Sediment grain size; and
- Surface water characteristics such as salinity, hardness and pH.

These measurements can be incorporated in lines of evidence to provide explanatory or supporting information related to the measure of effects.

Supplemental measurements should be planned in the problem formulation phase to ensure that they are conducted concurrently in space and time with exposure measurements in the analysis phase.

14.5.10 Overall Evaluation of the Utility of Each Line of Evidence

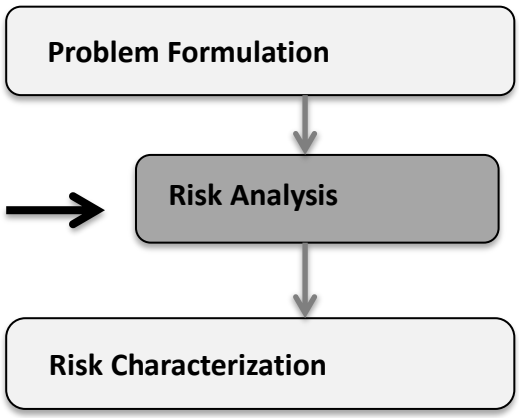
When choosing assessment endpoints and planning measurements in the problem formulation phase, the risk assessor must assess and document the expected utility of the resulting lines of evidence. Relevant criteria for judging the utility and sufficiency of each line of evidence include (CCME, 2020):

- *Ecological relevance*: To what degree is the assessment endpoint represented by the line of evidence?
- *Sensitivity*: To what degree can the line of evidence detect changes or differences from reference conditions? Are results reported quantitatively or using broad categories such as low, moderate and high? Does the line of evidence typically suffer from a high degree of random error?
- *Specificity*: Will the line of evidence be specific enough to identify effects from the COCs over and above other factors present at the site?
- *Spatial representativeness and site specificity*: Does the line of evidence provide information at the appropriate spatial scale, and does the line of evidence consider site-specific factors that may influence the results compared with other sites?
- *Temporal representativeness*: Does the line of evidence capture temporal variation relevant to potential ecological risks?
- *Expected data quality*: Based on the practitioner's experience, what is the likelihood that the quality of data generated by this line of evidence will be poor and result in reduced utility of the line of evidence?
- *Expected acceptability*: Does the line of evidence have standard test methods or a long history of use that provides confidence that regulators will accept the results?

These same considerations will be relevant in the risk characterization phase. While some of these questions can be answered in the planning stage, others can only be evaluated after the data has been collected. If the answer to any of these is no after the data are reviewed, consideration should be given to resampling or using alternate endpoints.

14.6 RISK ANALYSIS

14.6.1 Risk Analysis: Introduction



The objective of the risk analysis is to produce the data and information necessary to answer each risk question. The risk analysis phase involves measuring exposures and effects and evaluating the relationships between them to answer the risk questions (i.e., develop lines of evidence). It entails estimating the exposures of representative receptors to contaminants of concern (COCs) and assessing the effects of COCs on those receptors. Figure 14.4 depicts the connections between assessment endpoints, measures of exposure and effects and lines of evidence.

The risk analysis guidance in this section covers the same effects measurements as the problem formulation guidance, but from a different perspective. Problem formulation involves deciding **which** receptors and effects the assessment will focus on. Risk analysis entails deciding **how** those effects will be measured and how the results of those measurements will be analyzed.

While the problem formulation, risk analysis and risk characterization phases are depicted sequentially in simplified process diagrams like the one above, environmental risk assessment is an iterative process. For example, information discovered while collecting data in the risk analysis phase may lead to a revision of the problem formulation. Similarly, data gaps recognized in risk characterization phase may indicate the need to revisit the risk analysis phase and collect additional samples to increase confidence in the risk estimates and conclusions.

Most ecological risk assessment guidance documents, including previous MassDEP guidance, portray effects assessment and exposure assessment as separate lines of inquiry that only intersect in the risk characterization phase. This portrayal reflects the process outlined in EPA's *Framework for Ecological Risk Assessment* published in 1992 and carried through guidance published since then. However, in practice, the exposure and effects assessments are planned together and are best conducted concurrently to ensure that exposure data is consistent with the intended measures of effects. For this reason, exposure and effects measurements are described together in this document for the most commonly employed measures of effects.

14.6.2 Risk Analysis - Common Measures of Effects

Risk Analysis: Benchmark Comparison

Benchmark comparisons involve comparing contaminant concentrations at a site with published effect levels (or no effect levels). Samples from the site should be collected, processed and analyzed in a way that ensures compatibility with the benchmark. More specifically:

- Sample volume or mass, sample processing procedures, averaging procedures, and analytical methods can all affect comparability.

- Even when the same analytical methods are used, sample preparation methods can significantly affect comparability. For example:

    - Water sample preparation and analysis that target dissolved constituents are not appropriate for comparison to benchmarks that are based on total (dissolved and non-dissolved) contaminant concentrations.
    - The choice of drying method for sediment samples can affect the recovery of semi-volatile organics and mercury.
    - Different acid digestion methods for soil samples result in different recovery rates for some metals.

- Average concentrations of a contaminant may not be suitable for comparison to a benchmark, because averaging may mask areas with high concentrations that significantly exceed the benchmark. It follows that composite samples are not compatible with benchmarks that are based on individual grab samples.

When benchmark comparisons are used to evaluate the potential toxicity of soil or sediment, characterization of background conditions is crucial. In Massachusetts, it is not uncommon for background concentrations to exceed benchmark concentrations. Under the MCP, concentrations consistent with background conditions may be excluded from further assessment and remediation (See Chapter 6).

In contrast to benchmark exceedances observed in environmental screening, in Stage II risk characterization, an exceedance, or a few exceedances of the benchmark do not necessarily mean that there is significant risk. When used in Stage II risk assessments, the interpretation of results calls for professional judgement. Both the number and magnitude of exceedances should be considered, as well as the uncertainty associated with the benchmark.

Risk Analysis: Food Chain Analysis

Food chain analyses have typically been used to assess the potential for adverse effects on terrestrial or semi-aquatic mammals or birds from consuming contaminated prey. Consumption of contaminated water or incidental ingestion of contaminated soil or sediment may also be included in the food chain exposure analysis.

As stated previously in Section 14.5.8, the representative (assessment endpoint) species evaluated in a food chain model serve as a surrogate for other species of concern at the site. To avoid underestimating exposures and risks for these other species, exposure estimates and feeding habits should not be too narrowly tailored to the assessment of the representative species. In other words, exposure factors such as food and water intake rates should be selected with the aim of protecting both the endpoint species and other species of concern in the same feeding guild.

For birds and small mammals, dietary exposure concentrations should be based on measured prey concentrations if possible. The exposure concentration should be a conservative estimate of the average prey concentration within the exposure area(s). (Invertebrate prey samples for an area of concern may be composited.) The alternative is to estimate the prey concentration from soil levels by applying a bioconcentration factor. However, this approach is more uncertain and should be avoided.

The area evaluated in the food chain analysis should be limited to the contaminated area. The goal of the assessment is to determine whether the contaminated area is a sustaining component of the larger habitat. The surrogate receptor evaluated in the food chain analysis may have a home range that is larger than the site, but prey concentrations from the site should not be diluted by averaging with uncontaminated prey outside of the contaminated area.

Exposure factors for estimating food and water intake are published in the general technical literature and in EPA guidance (U.S. EPA, 1993). Additional references and data sources are provided by U.S. EPA's EcoBox Tools (U.S. EPA, 2024). Some factors vary considerably, and the choice of values can affect the outcome of the risk assessment significantly. Exposure factors should be selected to provide conservative intake estimates. The risk assessment report should document that the analysis is unlikely to underestimate the risk from the dietary exposure pathway.

Published toxicity reference values (TRVs) used as measures of effects often range widely as well. As noted in Section 14.5.8, TRVs are available in the technical literature. A comprehensive list is provided in U.S.EPA's Ecotox Database. TRVs may be published as concentrations or daily doses. The risk assessment report should justify the values selected and show that the values are protective.

Finally, the risk assessor must ensure that food intake rates and concentrations are consistent with regard to wet weight vs dry weight. For example, prey concentrations may be reported in terms of dry weight, while food intake rates may be reported as wet weight. Failure to make the necessary adjustment will lead to a significant error in the contaminant dose estimate.

Risk Analysis: Site Specific Toxicity Testing

Site specific toxicity tests involve exposing standard test organisms in the laboratory to aliquots of contaminated soil, sediment or surface water from the site and then evaluating the survival, growth and/or reproduction for a range of contaminant concentrations. The same tests are run on the samples of the medium from a reference area that is not affected by the site for comparison.

A comprehensive sampling plan should be completed before collecting samples for chemical analysis or toxicity testing. General sampling guidance is covered in Chapter 4. The references in that chapter include several detailed guidance documents published by U.S. EPA on planning and executing sampling projects.

A detailed, comprehensive sampling plan for field work is necessary to ensure the collection of data that is representative and usable.

Prior to collecting samples for toxicity tests, the nature and extent of contamination for the areas of concern should be comprehensively sampled to identify candidate locations to sample for toxicity testing. This will ensure that a relevant range of concentrations will be tested.

It is important for project managers and risk assessors to be mindful of the distinction between chemical analysis sampling projects done for different reasons. These include:

- **Sampling projects to evaluate the nature and extent of contamination.** This is a basic requirement of the MCP that is separate from the risk assessment (310 CM$ 40.0835(4)(f)). A sampling project to assess the extent of contamination may cover a wider area and greater depths than sampling conducted for the risk assessment.

- **Sampling projects to assess exposure of receptors of concern.** This should encompass the entire area in which receptors of concern are likely to come into contact with the contaminants.

- **Sampling projects to determine the level at which toxic effects are observed.** These samples should be collected at the same time and place and in the same way as the sediment samples for toxicity testing to ensure they are representative of the concentrations of contaminants that are in the samples that are tested for toxicity.

It is unusual for one single sampling project to provide results that meet all of these objectives. (Note that these distinctions among different sampling purposes also hold true for observational studies of population and community attributes that are described later.)

Examples of tests that have been widely used to evaluate freshwater sediment toxicity for benthic invertebrates are:

- 10-day (acute) test for survival and growth of *Hyalella azteca*
- 10-day (acute) test for survival and growth of *Chironomus tentans (Chironomus dilutus)*
- 28 to 42-day (chronic) test for survival, growth and reproduction of *Hyalella azteca*
- Life-cycle test for effects on *Chironomus tentans (Chironomus dilutus)*

Guidance on selection of test(s) to be used is provided in Chapter 15 of this guidance document. Additional guidance is provided by California Environmental Protection Agency (Cal/EPA, 2004).

Two basic study designs have been used to evaluate the toxicity of site-related contamination to test organisms:

(1) **Gradient designs**, also called stressor-response designs, in which the relationship or correlation between contaminant concentrations and the severity of an effect is quantified.

(2) **Control-impact** designs, in which the effects measurements for a contaminated site or area are compared with the same measures obtained for a reference area or areas.

Both types have strengths and weaknesses that warrant careful consideration when planning studies and interpreting the results.

Gradient Designs (Stressor-Response):

A stressor-response design involves testing sediment samples representing the range of concentrations present in site sediments to determine whether the effect levels (e.g., percent survival) correspond to a concentration gradient. Ideally, site concentrations will correspond to the severity of toxic effects observed. A gradient study design may also allow the identification

of concentration ranges associated with the presence or absence of toxic effects, which may enable the risk assessor to estimate a threshold concentration for the effect(s) of concern.

Detecting an association between adverse effects and contaminant concentrations at a site is the ideal outcome of effects measurement. Often, though, no clear concentration-response relationship emerges from the data. Even where contaminants are present at toxic levels, a discernible exposure-response relationship may be absent. Examples of factors that may obscure a relationship are:

- Physical, chemical and biological conditions in sediment and soil can be highly heterogeneous over a small spatial scale, making contaminant concentrations (and corresponding toxicity) highly variable.
- Physical or chemical conditions may affect test organisms' susceptibility to contamination.
- Contaminant concentrations in samples collected for chemical analysis may not be representative of the concentrations in samples used for toxicity testing. Differences in sampling location or sample volume can lead to significant differences in analytical results.

In order to guard against false negative results where a gradient design is used to evaluate a stressor-response relationship among individual samples, the sampling project should be planned so that the results may also be used to compare contaminated areas with reference areas, consistent with control-impact designs described below.

Control-Impact Designs

Control-impact studies are used to compare toxicity measurements in an area of concern with the same measurements in a reference (uncontaminated) area. These studies can show whether contaminant conditions in general are causing or contributing to harm. In contrast to gradient studies, however, they are not intended to determine a level above which harm is likely, nor are they designed to show the severity of environmental impacts associated with different levels of contamination. Nevertheless, control-impact studies can provide a more definite indication of the presence or absence of toxic effects. In particular, control-impact study designs are called for in cases where it is not feasible to obtain a data set large enough to detect a quantitative concentration-response relationship due to (1) the size of the site; (2) the pattern of contaminant distribution; or (3) budget limitations.

All things considered, control-impact study designs are typically better suited than gradient designs for detecting contaminant impacts at MCP sites.

A valid control-impact study requires representative data for both a contaminated area(s) and a reference area, with both data sets being similar in size. When one data set is larger than the other,

the larger one is likely to comprise a larger range of results, even if there is no real difference between the two populations from which the samples are collected.

Data sets from multiple reference areas should be collected in order to characterize variability among references areas. Multiple discrete samples from one reference area only represent variability within that particular area, but not variability among reference sites in general. As a consequence, observing a difference between the toxic effects in site samples and toxic effects samples from a single reference area may not provide conclusive evidence of the presence or absence of toxic effects (CCME, 2020).

Other important elements to take into account when designing a site-specific toxicity testing study:

- ***Site Sampling Locations:*** Within the site or an area of concern, the number of locations sampled for toxicity testing depends on the size of the area and prior knowledge of contaminant variability, sediment heterogeneity and contaminant distribution. The goal should be to obtain samples from locations having a wide range of contaminant levels.

- ***Sampling Location Replicates:*** A minimum of three replicate samples should be collected from each sampling location. It is important to be mindful of the distinction between sampling location replicates and the treatment replicates of each sediment sample that are prepared in the laboratory.

    - *Sampling location replicates* should be collected separately in the field from each location of concern. This will provide an indication of soil or sediment heterogeneity and variability in toxicity present over a small spatial scale.
    - *Treatment replicates* are prepared from each sample submitted to the toxicity testing laboratory. EPA has suggested a *minimum* number of treatment replicates of between four and eight, depending on the type of test (U.S.EPA 2000). Treatment replicates indicate the consistency of laboratory procedures and provide a measure of test result precision. They provide no information, however, on variability of environmental conditions or toxicity at the site.

- ***Sensitivity:*** The sensitivity of the toxicity tests must be sufficient to detect effects of concern. For example, if toxicity tests are done to evaluate survival, the length of the test must be sufficient to detect responses to chronic exposure.

- ***Purpose of Chemical Analysis:*** Finally, when developing the sampling plan, the risk assessor should be mindful of the distinction between the concentration measures of exposure that are to be used for exposure-response assessment and the concentrations measures needed to characterize the extent and severity of exposures at the site overall. The concentrations of sediment samples used for toxicity testing are crucial for linking exposure levels with toxic effects, but they may not necessarily represent the range and areal extent exposure concentrations throughout the site. Both are necessary, but the sampling strategies may be quite different.

Risk Analysis: Observational Studies (Biological Surveys)

As described in Section 14.5.8, observational field studies typically involve assessment of community or

population attributes at a site (e.g., diversity, richness, abundance) to determine whether they are affected by contaminants at the site. At MCP sites, these studies are mainly used for bioassessment of benthic (bottom-dwelling) macroinvertebrate communities in streams, rivers and ponds, but they may also be used to assess soil invertebrate communities.

The following factors should be considered when deciding whether to use biological surveys as measures of effects and how surveys should be conducted and interpreted (Suter, et al., 2000):

- Scale - Biological surveys are only suitable for organisms that are not highly mobile and will not migrate into or out of the contaminated area of concern.

- Interpretation - Relative to the magnitude of effects that would be considered significant, the biological characteristics measured must be consistent across similar habitats in the absence of contamination.

- Difficulty - The community or population characteristics for the representative receptors must be readily quantifiable. A survey that is too expensive or time consuming is not appropriate.

- Appropriateness - Techniques used to measure biological characteristics must be appropriate for the species, community or habitat of interest and must be capable of producing data that meet the assessment objectives.

- Technical expertise - The risk assessor must have the background and experience necessary to interpret the biological characteristics and relevant adverse effects.

- Survey consequences - No survey should be undertaken if sample collection might itself cause harm to the site.

- Data availability - Data that have been generated for purpose other than the assessment should only be used if it is representative of the contaminated area(s) and if the quality meets the requirements of the risk assessment.

Sampling done to evaluate the relationship between contaminant levels and biological conditions (e.g., community metrics) must be planned and executed with careful attention. Spatial and temporal variability in contaminant concentrations and biological conditions can be quite high, as can physical and chemical conditions such as sediment grain size and organic carbon content. If this variability is not adequately accounted for in project planning and data analysis, it can easily obscure contaminant-response relationships.

As is the case with site specific toxicity tests described in the previous subsection, study designs may be impact-control designs or gradient designs. The discussion of these designs in the toxicity testing section also applies to field observation studies, and it provides important information that risk assessors should review when planning field observation studies. Gradient designs may be even more challenging to implement for observational studies because of the complex interactions of organisms with their environment and the high natural variation in the biological attributes measured.

Environmental scientists have demonstrated that population and community attributes can vary widely among reference sites. Using only one reference site (or area) for population or community measurements in a control-impact study is highly subject to error. Landis et al. (2011) have argued that "there is no such thing as a reference site when it comes to populations and landscapes", and that measurement endpoints of population and community effects should be evaluated along a concentration gradient rather than by comparing a contaminated site to a reference location. However, collecting and processing enough samples to detect a concentration-response relationship between community structure metrics and contaminant concentrations is resource intensive, and generally not practical for many MCP sites. For this reason, when an observational field study is being undertaken, control-impact studies are recommended.

To assess and control for natural and anthropogenic variability at different spatial scales:

- **Different areas of concern at a site should be characterized and compared to reference area conditions separately.** Areas of concern may be identified based on having different land use histories, habitat features, physical characteristics or contaminant levels. Multiple locations within each area of concern should be sampled to assess biological conditions to account for variability within the site. The number of locations depends on the expected variability within areas of concern and reference areas.

- **Samples for biological assessment must be collected from multiple reference areas.** The use of single reference site, discussed in the toxicity testing section, is viewed as particularly problematic for field observational studies where effects on a population or community characteristics are measured directly.

    - For a river or stream, multiple locations in an upstream reach or segment should be used as reference sites.
    - For a lake or pond, nearby similar water bodies should be identified as reference locations.
    - In urban areas where the watershed has likely been impacted by anthropogenic stressors (e.g., areas of reduced permeability, storm drain outfalls, culverts) multiple reference locations are particularly important to characterize the variability among areas not impacted by site-related contaminants.

    The range of results for different reference sites has been termed "reference conditions" (CCME, 2020). Drawing a conclusion from comparing biological conditions at a site or area of concern to conditions at several different reference areas generally will require the risk assessor to exercise professional judgment. If no appropriate reference areas can be identified, a biological survey may not be an appropriate way to assess effects.

- **Sediment or soil samples to determine chemical concentrations and those for biological assessment should be collected as close as possible from the same place at the same time and in the same way.** Ideally, subsamples for chemical analysis should be taken from the sample for effects analysis. Any differences in sample origin are likely to obscure the relationship between concentrations and effects.

The discussion in this subsection has so far focused on considerations for planning and carrying out invertebrate community assessment. However, observational field studies may also be used to assess the condition of organisms in a local population. Examples include abundance of individuals of a sensitive species such as freshwater mussels and rates of deformities in fish or amphibians.

14.6.3 Transition from Risk Analysis to Risk Characterization

For simplicity, the environmental risk assessment process is conventionally depicted as linear, progressing continuously from problem formulation to analysis to risk characterization. In practice, the process is iterative. For example:

- The data and information acquired in the analysis phase may warrant reconsideration of the problem formulation and/or analysis phases. It may be apparent that certain exposures or effects are insignificant and may be eliminated from further consideration. Alternatively, the data may call attention to the need to consider additional exposures and effects.

- The quality and/or quantity of data acquired before or during the analysis phase may not be as high as expected and may not be sufficient to evaluate the line(s) of evidence as intended. If not, collection of additional data must be considered.

To evaluate whether the data that has been collected is sufficient for risk characterization purposes, MassDEP's guidance on representativeness evaluations and data useability (REDUA Guidance, MassDEP, 2007) provides a useful starting point. The REDUA guidance addresses two aspects of the data.

- *An analytical data useability assessment is used to evaluate whether analytical results are scientifically valid and defensible, and of sufficient level of precision, accuracy and sensitivity to support the Response Action Outcome (RAO)*, including the environmental risk characterization.

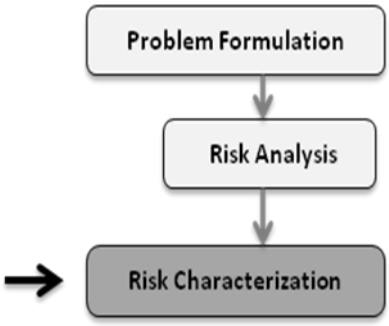
- *The representativeness evaluation is an evaluation and demonstration of the adequacy of spatial and temporal data sets used to support the RAO*, including the environmental risk characterization.

Other important aspects of data quality pertain to the relationship between measures of effects and measures of exposure and the correspondence between the samples used for these measures. Key questions include:

- Are exposure concentrations determined over a range that includes both effects and no-effects levels?
- For a gradient design, is a concentration gradient captured? Is an effect gradient captured?
- Are effects measures higher or lower in background areas?
- Are samples for exposure and effects measures collocated?
- Are samples for exposure and effects measures equal in volume?
- Is there variation in substrate or habitat characteristics that could confound the analysis of effects in community studies?

Any data deficiencies found in the course of the risk analysis phase, or the risk characterization phase must be remedied by resampling/reanalysis if possible.

14.7 RISK CHARACTERIZATION



Risk characterization is the final phase of the environmental risk assessment. In general terms, it is the process of estimating the likelihood, magnitude and extent of adverse ecological impacts from the data and information collected, evaluated and summarized in the analysis phase. Risk characterization involves these steps:

- **Evaluation of each line of evidence:** Data and information collected in the analysis phase on exposure and effects are combined to answer each risk question. (See table 14.2 for examples of risk questions that address various assessment endpoints.) The answer to each risk question is a line of evidence that indicates whether harmful effects are occurring or not. In some cases, the answer may be indeterminate. For each individual line of evidence, the risk assessment report must state whether the evidence indicates a risk of harm.

- **Evaluation of multiple lines of evidence:** When multiple lines of evidence are developed for a single assessment endpoint, the risk assessor must determine whether, taken altogether, they indicate a risk of harm for that assessment endpoint.

- **Preparation of the risk assessment report:** The report must justify the conclusion about risk, document the evidence and describe any sources of uncertainty.

Figure 14.3 shows the connection between the risk analysis and risk characterization phases in accordance with the widely used risk assessment framework described in Section 14.4.1. Figure 14.4 depicts the relationship between the assessment endpoint, risk questions and risk characterization as those elements are linked in this guidance document.

14.7.1 Evaluating Individual lines of evidence

For each line of evidence, the information on exposure and effects must be combined to assess the relationship between exposure to contaminants and existing or potential adverse effects. When the answer to the risk question is positive, indicating a risk of harm to the assessment endpoint, further evaluation may be necessary to determine whether the risk is significant.

Two aspects of each line of evidence must be considered by the risk assessor: the reliability of the result (answer to the risk question) and the significance of any effects detected.

- The **reliability of the line of evidence** depends on the quality and quantity of the data and the level and type of uncertainty about the measurement results.
- The **significance of the effects** represented in a line of evidence will depend on the nature, magnitude spatial and temporal scale and potential for recovery from the effect.

14.7.1.1 Lines of evidence based on Benchmark Comparisons

Box 14.7
Terminology Note

Benchmark comparisons are often expressed as a quotient, with the site concentrations in the numerator and effect-based concentrations in the denominator. In most guidance documents, this measure is referred to as the "**quotient method**." MassDEP prefers the term benchmark comparison to emphasize the qualitative nature of this evaluation method, and to discourage quantitative interpretations of the results.

Toxicity benchmark comparisons involve comparing contaminant concentrations in site sediment, soil or surface water to a published effects-based concentration, referred to in this guidance as a benchmark. Such comparisons are referred to in guidance published by U.S. EPA and other agencies as the quotient method (See Box 14.7).

Benchmark comparisons are typically portrayed as highly uncertain measures of effects, but the reality is more complicated. The reliability and significance of a comparison result depends upon both the magnitude and the direction of the difference. Most risk assessment experts would conclude with a high level of confidence that a site concentration that is lower than a benchmark, even by a small amount, is evidence of very low risk. In contrast, where concentrations exceed a benchmark by a small to moderate amount, the conclusion about risk is uncertain, as incremental increases cannot be interpreted quantitatively. The risk assessor must determine and justify whether a small or moderate exceedance of a benchmark may pose some risk. However, in general, MassDEP considers it reasonable to interpret large exceedances as indicators of potential harm.

Benchmark comparisons have the advantages of being inexpensive and seemingly simple to use. However, this simplicity can be overstated. The risk assessor must consider that the benchmark derivation method determines what it represents and how it should be interpreted.

The type of effect represented by the toxicity benchmark is a key factor when interpreting a benchmark exceedance. For example, does the benchmark represent a No Adverse Effect Level (NOAEL), a lethal dose (e.g., LD_{50}), or a specific effect concentration (EC_{10}) or a probable effects concentration (PEC). A NOAEL may either be near an effect level or well below it, and more information is needed to interpret an exceedance, even qualitatively. At the other extreme, an LD_{50} indicates the potential for significant effects.

Temporal consistency is also important. Benchmarks based on short term exposures will not protect against long term effects. Even some benchmarks for long-term exposures actually aim at a time period that is quite short in the context of waste site investigations. For example, consider the description of the Criterion Continuous Concentration definition for U.S. EPA's National Recommended Water Quality Criteria:

> *"Numeric criteria to protect aquatic life from toxic chemicals are expressed as short-term and long-term concentrations in order to reflect toxicological and real world conditions as accurately as possible. The combination of a Criterion Maximum Concentration (CMC). over a one-hour acute duration (a short-term average acute limit), and a Criterion Continuous Concentration (CCC), over a four-day chronic duration (a long-term average chronic limit) provide protection of aquatic life against both short and long-term effects. Recommended averaging periods are relatively short because events higher than the average can kill or cause substantial damage in short periods of time. . . The recommended chronic criteria or Criterion Continuous Concentration (CCC) is based on a once in a three year period chemical concentration"(U.S. EPA, 2004).*

Another consideration is whether the benchmark is based on the same organism(s) as the assessment endpoint or is being extrapolated to different organisms. Sensitivities among different species of closely related organisms can vary widely, so inter-species extrapolation can introduce a significant level of uncertainty.

Uncertainty about benchmark comparison results varies widely depending on the quality of data on which the benchmark is based. This is even true within a single set of benchmarks all developed using the same procedure. For example, when the predictive ability of the Threshold Effects Concentrations (TECs) were evaluated, the percentage of samples correctly predicted to be not toxic ranged from 72% to 82% for most metals, although for mercury the value was only 34%, indicating a higher level of uncertainty for the mercury TEC (MacDonald, et al., 2000).

14.7.1.2 Lines of evidence based on Food Chain Evaluations

For certain representative receptors, food chain evaluations are the only practical measures of exposure and effects. This is particularly true for terrestrial and semi-aquatic birds and mammals. The reliability of a food chain evaluation depends upon the availability of appropriate exposure factors and toxicity reference values (TRVs) in the technical and scientific literature. Where the availability of toxicity reference values is limited, a food chain evaluation may not be adequate to assess potential effects. Specifically, uncertainty in the risk characterization depends in part upon the extent to which inter-species extrapolation may be necessary to estimate exposure and/or toxicity, but it can introduce appreciable uncertainty.

The reliability of food chain evaluations also depends on accurate estimates of contaminant concentrations in water and prey items. Ideally, investigators should make every effort to obtain representative samples of prey items for chemical analysis to estimate exposure(s). If the concentrations in prey organisms are estimated from environmental concentrations and bioaccumulation factors, the estimates are likely to be much more uncertain.

The risk assessor must make every effort to identify the best available data and information. In the end, however, some level of uncertainty is inevitable. The risk assessment report should include a clear and comprehensive description of the sources and estimated magnitude of uncertainty.

14.7.1.3 Lines of Evidence Based on Site-specific Toxicity Testing

As previously described, site-specific toxicity tests involve exposing standard test organisms to sediment (or soil) from the site in a controlled laboratory setting. For sediment toxicity tests, the most common test organisms are *Hyalella azteca* (an amphipod) and *Chironomus dilutus* (a midge). Tests may be either acute (10 day) or chronic in duration. The relationship between adverse effects and sediment contaminant levels is evaluated to reach a conclusion about whether a risk of harm exists at the site.

The reliability of these tests depends in part on collecting and testing a representative number of sediment samples with a wide range of concentrations. A robust data set will improve the chances of detecting toxic effects if they are occurring. Testing a range of concentrations will improve the chances of:

- observing an exposure-response relationship; and/or
- identifying a level above which adverse effects are likely.

To optimize locations for collecting sediment samples for toxicity testing, sediment at the site should be comprehensively sampled for chemical analysis prior to collecting samples for toxicity testing.

Reliability also depends heavily on concurrently obtaining sub-samples for chemical analysis that are representative of the sediment subjected to toxicity testing. Contaminant concentrations in environmental media can be highly variable, even over small areas. Relationships between concentrations and toxicity can only be discerned if both are measured in aliquots from the same sediment, or immediately adjacent.

For a test to be valid, the survival rate of organisms in the laboratory control samples must meet the minimum criteria for the test. Laboratory control samples indicate whether the test conditions and procedures are acceptable. They do not replace tests on samples from reference areas. Samples from several reference areas should be subjected to toxicity tests to determine whether any apparent toxicity is attributable to site conditions or not. Comparison of toxicity testing results for samples from site and reference areas is key to assessing risk, so it is important to test reference samples that are from similar habitats in separate areas not affected by site contamination. Failure to characterize a range of reference conditions could lead to an indeterminate level of toxicity and erroneous conclusions about risk.

Assessing the significance of toxicity testing results with respect to the magnitude of effects is a challenge. Due to a background level of mortality observed in toxicity tests of around 20%, results generally are not considered significant unless survival is less than 70%. However, that level considers statistical significance, not biological significance. In principle, a 20% mortality rate attributed to contaminant exposure is a serious effect. For this reason, any detected level of toxicity may indicate a problem and should not be readily dismissed.

14.7.1.4 Lines of Evidence Based on Field Observational Studies of Benthic Communities

Field observational studies measure changes in communities or populations in natural settings by collecting chemical exposure and effects data and analyzing the relationships between them. They provide empirical evidence of the relationship between contaminant concentrations and biological conditions, both of which are sampled in natural settings. Examples of measured effects are community diversity and richness and population abundance.

Field studies are favored by many practitioners because they are based on direct measurement of natural conditions. However, there are significant drawbacks:

- Biological conditions are affected by numerous physical and chemical factors other than contamination and can obscure the relationship between the contaminants and measured effects. As a consequence, even where contamination might be contributing appreciably to adverse effects, a relationship between contaminant concentrations and biological conditions may not be detectable.

- Collecting enough samples for adequate replication may be impractical in some cases, for example from the sediment bed of small streams.

- Sampling and analyzing community structure and population attributes requires expertise that all practitioners may not possess.

***". . . a lack of observed effects in a field survey may occur because the measurements lack the sensitivity to detect ecological effects"* (U.S. EPA, 1998).**

14.7.2 Considering Multiple Lines of Evidence

The number of risk questions addressed for each assessment endpoint (and accordingly the number of lines of evidence indicating the presence or absence of risk for each assessment endpoint) is determined by the risk assessor. These decisions should consider conditions, the nature of the contamination and the tools and resources available for measuring the relevant exposures and effects.

In cases where only one risk question and line of evidence is used to evaluate an assessment endpoint, there is no need to consider multiple lines of evidence; the single result indicates either risk or no risk for the assessment endpoint in question. Similarly, where multiple risk questions/lines of evidence are used to evaluate an assessment endpoint and the results are consistent, the clear conclusion is either risk or no risk for the assessment endpoint. However, in cases where multiple lines of evidence for an assessment endpoint point in different directions, the task of considering multiple lines of evidence is more challenging.

Two different approaches have been proposed and employed for evaluating risk when the results of multiple lines of evidence appear to be contradictory:

- A *lines-of-evidence* approach. This approach is described by U.S. EPA's 1998 *Guidelines for Ecological Risk Assessment*:

  > *"The phrase lines of evidence is used to de-emphasize the balancing of opposing factors based on assignment of quantitative values to reach a conclusion about a "weight" in favor of a more inclusive approach, which evaluates all available information, even evidence that may be qualitative in nature. It is important that risk assessors provide a thorough representation of all lines of evidence developed in the risk assessment rather than simply reduce their interpretation and description of the ecological effects that may result from exposure to stressors to a system of numeric calculations and results" (U.S. EPA, 1998).*

  The same document goes on to say: "Sometimes lines of evidence do not point toward the same conclusion. It is important to investigate possible reasons for any disagreement rather than ignore inconvenient evidence". (U.S. EPA, 1998). For example, an evaluation of seemingly contradictory evidence should distinguish between true inconsistencies and those related to differences in sensitivity.

- A *weight-of-evidence* approach. This is a formal process for organizing, evaluating and scoring (numerically or qualitatively) different pieces of evidence based on properties such as relevance, strength and reliability. Several organizations have described formal ranking procedures. U.S. EPA's Risk Assessment Forum has published a comprehensive description of such a process (Suter, 2016), and Canada's Council of Ministries of the Environment outlined a similar process (CCME, 2020). A very early version was recommended in Mass DEP's first guidance for ecological risk assessment at waste sites (MassDEP, 1996).

Mass DEP prefers the lines-of-evidence approach. Without relative ranks or scores to justify conclusions about risk, a lines-of-evidence approach demands greater scrutiny by the risk assessor of the nature of uncertainty about each line of evidence and the relationships among different measurements. Canada's risk assessment guidance emphasizes the importance of the concept of *coherence* for integrating findings across multiple lines of evidence (CCME, 2020). They define coherence as "the degree to which components are logical and internally consistent". They emphasize that this does not mean that all lines of evidence give the same risk result, but that "lines of evidence should ideally tell a story that is logical and orderly" (CCME, 2020). MassDEP considers coherence assessment to be an essential component of the evaluation of divergent results for multiple lines of evidence.

The fact that a lines-of-evidence approach is less prescribed and less structured should not be misunderstood to mean that it is less rigorous. In general, it may require more professional judgement and a more detailed explanation of the evaluation and conclusions than the more structured weight of evidence approach.

14.7.3 Risk Characterization Conclusions

The assessment endpoint/risk question pairs offered in Table 14.2 are each deemed ecologically significant and relevant to MCP policy goals. A finding of significant risk of harm for any assessment endpoint/risk question means significant risk of harm for the site. In other words, a positive answer to one risk question cannot be over-ruled by a negative answer to another. For example, a finding that sediment from the site is significantly more toxic to test organisms than sediment from a reference location should be considered conclusive; it cannot be "over-ruled" by a negative finding from an observational field study in which a quantitative relationship between contaminant levels and effect levels is not detected. Therefore, in MCP risk assessments, the main task in risk characterization is to determine whether each positive finding is significant.

The risk assessment report should clearly describe the nature and potential magnitude of uncertainty for each line of evidence. Any professional judgments related to uncertainty must be fully described in the report. Based on a consideration of each line of evidence (and the logical connections between them), the risk assessor must draw a conclusion about risk for each assessment endpoint and the site overall.

14.8 RISK MANAGEMENT

The purpose of risk characterization under the MCP is to provide an objective basis for risk management decisions. If the environmental risk characterization concludes that a condition of no significant risk of harm to the environment does *not* exist, or has not yet been achieved, then that risk must be eliminated to achieve a Permanent Solution.

Risk management decisions are separate from the risk characterization process. This section on risk management is included in the guidance for completeness, to place the risk characterization requirements in context.

14.8.1 Possible Outcomes of an MCP Environmental Risk Characterization

The MCP describes categories of site closure that can result from the investigation and cleanup process. These categories are (a) Permanent Solution without Conditions, (b) Permanent Solution with Conditions, and (c)

Temporary Solutions. These categories are described in 310 CMR 40.1030 through 40.1050 of the MCP. The applicable closure category for a specific site depends on the conclusions of the risk characterization and the extent of remediation conducted at the site.

There are two possible conclusions from a Stage II Environmental Risk Characterization. The first is a conclusion that no significant risk of harm to the environment exists or has been achieved at the site. In this case, no further remediation to protect environmental receptors would be required. This outcome would support a Permanent Solution.

The alternative outcome is that a conclusion of no significant risk cannot be reached, and, therefore, remedial action must be implemented if feasible. The MCP requires remediation to achieve a permanent solution if a significant risk of harm to human health, safety, public welfare *or* the environment is determined. If remediation reduces levels of OHM to background concentrations, or if contamination is remediated to a level of no significant risk, a Permanent Solution applies. If remediation to a condition of no significant risk is not feasible, a Temporary Solution applies. If a remedy calls for ongoing monitoring and/or upkeep, a permanent solution with an AUL may apply.

14.8.2 Identification of Cleanup Goals

If significant risk of harm to the environment exists, and remediation is required to protect nonhuman receptors, then ecologically based cleanup goals may be needed. If so, it may be more efficient to obtain the data needed for cleanup goals in the course of risk characterization, rather than afterward. For example, one way of identifying levels that pose no significant risk of harm to environmental receptors is to assess adverse effects over a gradient of contaminant concentrations. Identifying remediation goals in this manner may require data above and beyond that which is necessary to determine whether existing conditions pose a significant risk. Thus, in the planning stage, it is important to consider whether the risk characterization process should include measures necessary to identify environmental media concentrations that pose no significant risk of harm to the environment and can serve as remediation goals.

14.8.3 Feasibility Study Considerations

In the MCP process, the purpose of the Environmental Risk Characterization is to determine whether remediation is necessary. If the assessment results show that a condition of no significant risk does not exist, then a Phase III Feasibility Study must be conducted to determine whether cleanup is feasible and to identify the most effective and efficient remediation approach (310 CMR 40.0852). In the feasibility study, technical and project budget limitations are considered along with human health and environmental risk characterization results to determine how best to manage the site.

When choosing among remedial alternatives, the risk manager should also consider the environmental risks posed by potential remediation activities. Risks from contaminants in the environment must be balanced with potential harm resulting from habitat destruction during remediation. This is particularly important where threatened or endangered species are present (App. 14A). In addition, wetland habitats are particularly susceptible to damage during remediation. The Massachusetts wetland regulations (310 CMR 10) detail rules related to the disturbance of wetlands. Guidance on balancing chemical risks against cleanup risks is beyond the scope of this document. Nevertheless, risks associated with each remedial alternative must be considered when selecting and implementing remedial action.

For comparing alternatives, eight evaluation criteria are set forth (310 CMR 40.0858):

The comparative effectiveness of the alternatives;
The comparative short-term and long-term reliability of the alternatives;
The comparative difficulty in implementing each alternative;
The comparative costs of the alternatives;
The comparative risks of the alternatives;
The comparative benefits of the alternatives;
The comparative timeliness of the alternatives; and
The relative effect of the alternatives upon non-pecuniary interests.

When comparing alternatives and evaluating the feasibility of a permanent solution, both the nature and magnitude of the risk(s) may be considered. At the risk management stage, however, consideration of the nature and magnitude of the risk is relevant only to the question of whether a permanent solution is currently feasible. It does not apply to the question of whether significant risk exists and remediation is necessary to achieve a permanent solution. If the risk characterization concludes that a condition of no significant risk has not yet been achieved, then remediation is necessary to achieve a permanent solution, and that conclusion cannot be modified through the risk management process.

14.9 CLOSING COMMENTS

The goal of this guidance is to support and encourage the design of risk assessments that meet the basic requirements of the MCP. The intent is to allow professional judgment in planning and conducting risk assessments, and not to set forth rigid assessment requirements. While each environmental risk assessment must include the basic components of problem formulation, analysis and risk characterization, the level of effort and detail appropriate for assessments at different sites will vary. The risk assessor must identify the best available data and an appropriate approach for appraising the potential environmental risks at a site. However, some level of uncertainty is inevitable, and the risk assessment should include a clear and comprehensive description of that uncertainty.

The habitat types and organisms that exist at a specific site are a major factor in designing the risk characterization, and the available investigation approaches and published criteria differ between aquatic, terrestrial and wetland habitats. In Chapters 15, 16 and 17 of this guidance, Stage I Screening and Stage II Environmental Risk Characterization are discussed separately for aquatic, terrestrial and wetland habitats.

References

Barnthouse, L.W., Munns, W.R, & Sorensen, M.T. (Eds.). (2008). *Population-level Ecological Risk Assessment*. Taylor & Francis.

Cal EPA (2004). *Overview of freshwater and marine toxicity tests: A technical tool for ecological risk assessment.* Office of Health Hazard Assessment, California Environmental Protection Agency.

CCME (2020). *Ecological risk assessment guidance document*. Canadian Council of Ministries on the Environment.

Covich, A.P., Palmer, M.A., & Crowl, R.A. (1999). The role of benthic invertebrate species in freshwater ecosystems. *BioScience*, 49(2).

Lavelle, P., Decaens, T., Aubert, M., Barot, S., Blouin, M., Bureau, F., Margerie, P., Mora, P., & Rossi, J.-P. (2006). Soil invertebrates and ecosystem services. European Journal of Soil Biology. 42(Supplement 1) S3 – S15.

MacDonald, D.D., Ingersoll, C.G., & Berger, T.A. (2000). Development and evaluation of consensus-based sediment quality guidelines for freshwater ecosystems. Arch. Environ. Toxicol. 39, 20-31.

Odum, E.P. & Barrett, G.W. (2004). *Fundamentals of ecology*, Fifth Edition. Thompson Brooks Cole.

Suter, G.W. (2016). *Weight of evidence in ecological risk assessment.* Risk Assessment Forum, United States Environmentntal Protection Agency. Office of the Science Advisor. EPA/100/R-16/001

Suter, G.W., Effroymson, R.A., BE Sample, B.E., & DS Jones. D.S. (2000). *Ecological Risk Assessment for Contaminated Sites.* Lewis Publishers.

U.S. EPA (1989). *Risk Assessment Guidance for Superfund, Volume II, Environmental Evaluation Manual*. Interim Final. U.S.EPA Environmental Response Team, Edison NJ.

U.S. EPA (1990). *Criteria for Choosing Indicator Species for Ecological Risk Assessments at Superfund Sites.* (90-6402) PB91-204321. Prepared by North Carolina University at Chapel Hill.

U.S. EPA (1991). *Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference*. EPA/540/R-92/003.

U.S. EPA (1992). *Framework for Ecological Risk Assessment*. EPA/630/R-92/001. February 1992.

U.S. EPA (1993). *Wildlife Exposure Factors Handbook.* EPA/600/R93/18Tb. United States Environmental Protection Agency (1993).

U.S. EPA (1997). *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Constructing Ecological Risk Assessments* – Interim Final. EPA-540-R-97-006. U.S. Environmental

Protection Agency Office of Solid Waste and Emergency Response. June 1997.

U.S. EPA (1998) *Guidelines for Ecological Risk Assessment*. EPA/630/R-95/002F. U.S. Environmental Protection Agency Risk Assessment Forum. Washington, D.C. April 1998.

U.S. EPA (2000). *Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates*. Second Edition. EPA 600/R-99/064. March 2000. Office of Research and Development, Mid-Continent Ecology Division, U.S. Environmental Protection Agency, Duluth, Minnesota; Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency, Washington, D.C.

U.S. EPA (2003). *Generic Assessment Endpoints for Ecological Risk Assessment.* EPA/630/P-02/004F. U.S. Environmental Protection Agency Risk Assessment Forum. October 2003.

U.S. EPA (2004a). *Problem formulations for Ecological Risk Assessments Conducted at Contaminated Sites under CERCLA: A Discussion Paper*. Prepared by MacDonald Environmental Sciences Ltd. and Cantox Environmental, Inc. for Dr. Marc Greenberg, Environmental response Team, U.S. Environmental Protection Agency, Edison, N.J.

U.S. EPA (2004b). *Risk Assessment Principles and Practices.* Office of the Science Advisor Staff Paper, EPA/100/B-04/001 March 2004.

U.S.EPA (2004c). *National Recommended Water Quality Criteria.* National Service Center for Environmental Publications.

U.S. EPA (2024). *EPA EcoBox Tools by Exposure Pathways – Food Chains*. Webpage last updated May 28, 2024.

U.S. EPA, (2025). *ECOTOX Knowledgebase*. Webpage last updated March 13, 2025.

U.S. EPA and U.S. Army Corps of Engineers. *Environmental Residue-Effects Database.*