Risk Evaluation: Introduction

7.1 Introduction

Risk assessment is the collection and analysis of data to characterize the nature and magnitude of risk posed by one or more chemicals. Risk assessment is a complex topic and a full treatment is beyond the scope of the *Remediation Closure Guide* (RCG). What follows is a brief discussion of some of the steps that are important in assessing potential risks at release sites. The United States Environmental Protection Agency (U.S. EPA 1989a, 1991c, 1991d, 1991e, 1991f, 2004b, and 2009g) offers detailed guidance on various aspects of risk assessment. Sections 8 through 11 provide more detail on risk evaluation for the soil direct contact, ground water, vapor, and ecological exposure scenarios.

Risk assessment begins with the identification of potential contaminants, potential receptors, and exposure scenarios. An adequate conceptual site model (CSM) should provide all of this information. The next step – exposure assessment (Section 7.2) – involves calculation of a reasonable exposure estimate for each potentially exposed population. A standard risk assessment then combines exposure and toxicity assessments (Section 7.3) to characterize risk (Section 7.4). As noted earlier, this can be a complex and involved process.

However, there are acceptable alternatives to conducting a full risk assessment. For example, the Indiana Department of Environmental Management (IDEM) publishes risk-based **screening levels** that incorporate IDEM-approved toxicity parameters, exposure assumptions, and target risk levels suitable for several different exposure and land use scenarios. Succeeding sections also describe some of the many ways to develop **site-specific levels**. All permit direct comparison against observed concentrations (Section 7.2.3).

Risk management attempts to eliminate exposure via specific pathways, typically through engineering controls (ECs) or institutional controls (ICs). In doing so, this approach leaves the realm of risk assessment, simply removing effectively managed pathways from further risk assessment. However, risk management strategies always include ongoing commitments (Section 1.3.4).

7.2 Exposure Assessment

Exposure assessment estimates the magnitude, frequency, and duration of exposures via specific pathways to provide an estimate of dose. It incorporates information from the conceptual site model and assumptions about the behavior of receptors to derive estimates of exposure to contamination. U.S. EPA (1989a, 1992) offers a more complete description of exposure assessment.

7.2.1 Identifying Receptors and Exposure Scenarios

CSMs should identify potential receptors and associated exposure scenarios. A potential receptor is a person or organism that may undergo exposure to contamination as the result of a release. Examples of potential receptors include:

- People who live in an area
- Workers at a commercial or industrial facility
- Recreational users of a park or trail
- Persons who drink ground water
- Wild animals living in a wetland

Exposure scenarios are circumstances in which contamination does or could move from a source to a receptor. There are many possible exposure scenarios. IDEM publishes screening levels for some of the most common:

- Direct contact with soil by residents, commercial/industrial workers, and excavation workers (Section 8)
- Direct contact with ground water by residents (Section 9)
- Potential ground water contamination caused by downward migration of contamination through the unsaturated soil column (Section 9)
- Vapor inhalation by residents and commercial/industrial workers (Section 10)

Section 11.2 includes a brief discussion of additional exposure scenarios and references related to their evaluation.

7.2.2 Estimating Exposures

Following identification of receptors and exposure scenarios, the exposure assessment process uses assumptions about contact frequency and duration to estimate exposure patterns. For example, IDEM's ground water noncarcinogenic screening levels assume that a child consumes one liter of water during each of 350 days per year, for six years.

Site-specific evaluations may modify commercial/industrial, recreational, and excavation exposure assumptions based on site-specific factors, or current peer-reviewed research. IDEM considers potential long-term *residential* land use activities to be similar everywhere. Nevertheless, IDEM will consider changes to residential exposure assumptions for the purpose of providing central estimates of potential risks in conjunction with upper bound point estimates and a clear statement of the uncertainty associated with these estimates. IDEM will evaluate submittals that propose modified exposure assumptions using the following criteria:

- U.S. EPA acceptance
- Consistency with evaluation of central tendency and upper bound point estimates
- Reliance on ICs for limiting exposure
- Uncertainty
- Applicability and relevance

7.2.3 Estimating Media Concentrations

Exposure assessment also requires estimates of chemical concentrations in environmental media. IDEM refers to such estimates as **exposure point concentrations** (EPCs). EPCs are necessary for estimating risk through risk characterization, or for comparison against screening levels or site-specific levels. See Sections 8.4, 9.3, and 9.7 for guidance on calculating EPCs for soil direct contact, ground water direct contact, and migration to ground water scenarios, respectively.

7.3 Toxicity Assessment

Toxicity assessment addresses two related questions – whether exposure to a particular chemical causes harm, and the nature of the relationship between exposure dose and the likelihood of harm. These are usually challenging questions. Attempts to answer them may involve experiments on animals or studies of exposed workers, and the results are often tentative and difficult to interpret. In any case, those activities are outside the scope of IDEM's functions, and the agency relies on other organizations for toxicity information.

Toxicity values differ between carcinogens and noncarcinogens. Toxicity values for carcinogens are slope factors (SFs) for ingestion and inhalation unit risks (IURs) for inhalation. Toxicity values for noncarcinogens are reference doses (RfDs) for ingestion and reference concentrations (RfCs) for inhalation.

7.4 Risk Characterization

Risk characterization combines the exposure assessment and the toxicity assessment to provide an estimate of risk. Risk characterization typically provides conclusions about risks associated with a site as well as an evaluation of uncertainty and bias in the risk assessment.

Risk assessments that rely on screening levels or site-specific levels reveal only whether or not risk exceeds a given level, like a thermometer that reads either "above 70˚F" or "below 70˚F." Further, screening level calculations typically employ, by design, default values (and sometimes worst case assumptions) that tend to overstate risks.

In contrast, a risk characterization provides a quantitative risk estimate, like a thermometer that reads a full range of temperatures. To the extent practicable, such assessments should also provide central tendency risk estimates in conjunction with upper bound risk estimates and a clear statement of the uncertainty associated with those estimates. Especially when coupled with the use of realistic exposure assumptions, risk characterization provides a more meaningful evaluation of risks associated with a site (U.S. EPA, 2005). The result should better inform decision making.

However, risk characterization is typically more resource intensive than using screening levels or site-specific levels. Responsible parties will need to weigh the costs and potential benefits of each approach for themselves.

A full description of the risk characterization process is beyond the scope of this document. Section 1.3.3 provides additional discussion and U.S. EPA (1989a, 2004b, and 2009g) provides detailed guidance.

7.5 Target Risk Level

The 1990 National Contingency Plan[47] calls for the use of a target risk range of 10^{-4} to 10^{-6} when evaluating the need for remedial action due to the presence of carcinogenic chemicals at Superfund sites. EPA (1991f) clarified the use of the target risk range in risk assessments as follows:

> "Generally, where a risk assessment indicates that a cumulative site risk to an individual using reasonable maximum exposure assumptions for either current or future land use exceeds the 10^{-4} lifetime excess cancer risk end of the risk range, action… is generally warranted at the site. For sites where the cumulative site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10^{-4}, action generally is not warranted, but may be warranted if a chemical specific standard that defines acceptable risk[48] is violated, or unless there are non-carcinogenic effects or an adverse environmental impact that warrants action. A risk manager may also decide that a lower level of risk to human health is unacceptable and that remedial action is warranted where, for example, there are uncertainties in the risk assessment results. [EPA decisions about] remedial actions taken at sites posing risks within the 10^{-4} to 10^{-6} risk range must explain why remedial action is warranted… Furthermore, the upper boundary of the risk range is not a discrete line at 10^{-4}, although EPA generally uses 10^{-4} in making risk management decisions. A specific risk estimate around 10^{-4} may be considered acceptable if justified based on site-specific conditions…"

IDEM will evaluate target risk proposals within the 10^{-4} to 10^{-6} risk range consistent with the intent summarized above. This means that target risk proposals should characterize site risks using standard U.S. EPA risk assessment methodologies rather than calculating site-specific levels. Risk characterization best incorporates the decision-making process associated with Superfund and IDEM's broad application of risk based decision making across all cleanup programs.

[47] 40 Code of Federal Regulations (CFR) Section 300.430(d)(1)

[48] Examples include maximum contaminant levels (MCLs), maximum contaminant level goals (MCLGs), or applicable or relevant and appropriate requirements (ARARs).

7.6 Additivity: Multiple Contaminants

Risk-based screening and site-specific levels are usually based on chemical-specific toxic effects on a particular end point (target organ) or mode of action. However, people may experience simultaneous exposure to two or more chemicals that affect the same target organ, or exhibit the same mode of action. When this happens, it is theoretically possible for those chemicals to produce an additive effect where exposed persons may incur a risk that exceeds a noncarcinogenic hazard quotient of 1, or a carcinogenic risk of 10^{-4}.

It is not necessary to evaluate additivity when soil chemical concentrations do not exceed screening levels. The inherently protective procedures used to derive screening levels make it very unlikely that exposures to multiple chemicals present at or below screening levels will result in excessive risk or hazard to the exposed population. This is particularly true of carcinogens, where an order of magnitude difference exists between the screening level target risk (10^{-5}) and the upper end of the risk range (10^{-4}). It *is* appropriate to consider the potentially additive effects of multiple chemicals in a single medium when site-specific exposure factors are integrated into the derivation of site-specific levels, or a risk characterization suggests potential site risks exceeding 10^{-4} or a hazard index of 1.

The cumulative hazard index of chemicals that affect the same target organ should not exceed 1, and the cumulative target risk of chemicals that exhibit the same mode of action should not exceed 10^{-4}. U.S. EPA risk assessment guidance views these criteria as “points of departure”, and IDEM will generally require some further action at sites where these risks are exceeded. Further action may include remediation, risk management, or a demonstration utilizing appropriate lines of evidence that the risk characterization overstates the actual risk.

7.7 Summary

The screening level approach integrates toxicity assessment with exposure assessment and tolerable risk to provide a protective estimate of a safe dose or screening level. Under the screening level approach, risk evaluation involves a direct comparison of screening levels against EPCs. If EPCs are below appropriate remediation objectives for a particular exposure scenario, then the exposure scenario is unlikely to pose an unacceptable risk.

Figure 7-A is a *simplified* decision tree that illustrates the application of EPCs and remediation objectives in making various site-related decisions. When EPCs are less than residential screening or site-specific levels, no further action is necessary. Options in the case of an exceedance include risk characterization, remediation, and/or implementation of risk management strategies. In general, site closure requires meeting remediation objectives in relevant media or controlling risks through appropriate and effective risk management strategies.
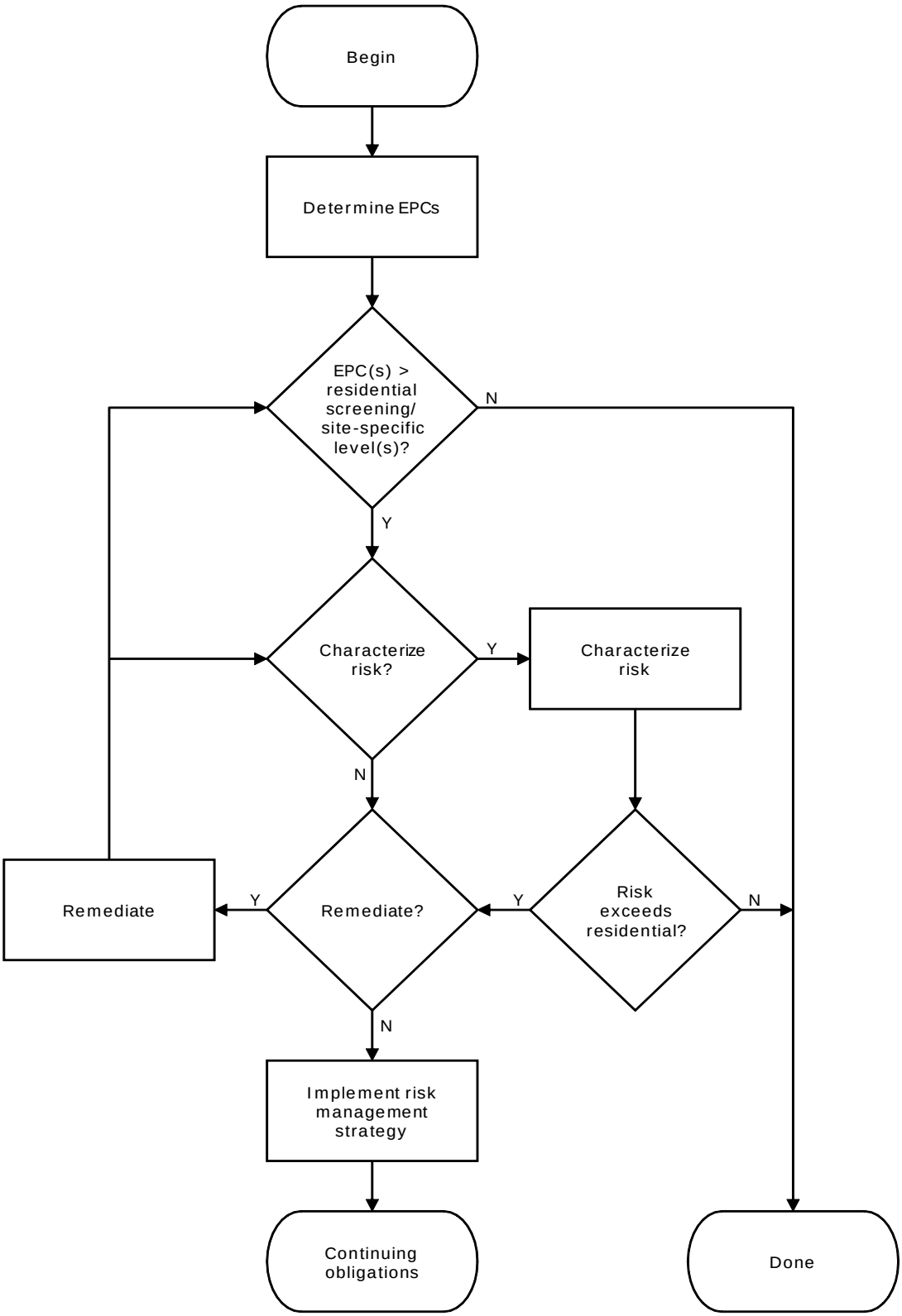
Figure 7-A: Application of Remediation Objectives and EPCs in Risk Evaluation