

## CHAPTER 2

### WORKPLAN AND THE TIERED APPROACH

#### 2.0 INTRODUCTION

While probabilistic risk assessment (PRA) can provide useful information for risk management, not all site decisions will benefit from probabilistic approaches. Similarly, not all PRAs need involve complex models and quantitative uncertainty analysis methods; often, very useful information can be obtained by taking the point estimate approach one step further to explore variability in selected input variables. The level of effort and complexity of the risk assessment should match site-specific needs. The use of a tiered approach for moving from a point estimate risk assessment to PRAs of varying levels of complexity is recommended (Figure 2-1 and 2-2). This chapter outlines the basic steps of a tiered approach for including PRA in a site risk assessment. The major feature of the tiered approach is an iterative evaluation of the risk estimates developed at each tier to determine if they are sufficient for risk management decisions. Built into the tiered approach are opportunities for communication with stakeholders with a view to saving time and costs, and facilitating a successful remedial process.

#### 2.1 WORKPLAN

In practice, the potential value of PRA may be considered at various planning stages of a risk assessment. For some sites, PRA and point estimate risk assessment approaches may be discussed in the initial scoping of the risk assessment. For other sites, PRA may become a viable option only after the point estimate risk assessment results are available. Ideally, PRA should be considered as early as possible in the planning of risk assessment activities at a site so that sampling plans and data collection efforts may be appropriately directed. Initial PRA discussions should be included as part of the risk assessment workplan. If a PRA is being considered following completion of a point estimate risk assessment, the original workplan for the point estimate assessment should be expanded to include needs that are unique to PRA.

The methods and procedures used to prepare a workplan to gather additional information for a baseline point estimate risk assessment are documented in RAGS Volume I: Part A (U.S. EPA, 1989). This chapter of RAGS Volume 3: Part A describes the procedures that would be used to prepare a workplan to gather additional information to conduct a PRA. Separate workplans may be warranted for human health and ecological risk assessments.

Like the quality assurance project plan (QAPP), the workplan for a PRA should document the combined decisions of the remedial project manager (RPM) and the risk assessor. Meaningful involvement of stakeholders early in the decision-making process also will save time and effort.

EXHIBIT 2-1

DEFINITIONS FOR CHAPTER 2

Central Tendency Exposure (CTE) - A risk descriptor representing the average or typical individual in a population, usually considered to be the mean or median of the distribution.

Countably Infinite - Used to describe some discrete random variables, this term refers to a set of numbers that can be counted with integers (e.g., one, two, three) and that has no upper limit. Examples include the number of tosses required for a coin to show a head—we can count each toss, but it is possible that at least one more toss is needed. The number of dust particles in a volume of air is another example. Countably finite implies there is an upper limit (e.g., days of work per year).

CTE Risk - The estimated risk corresponding to the central tendency exposure.

Monte Carlo Analysis (MCA) or Monte Carlo Simulation - A technique for characterizing the uncertainty and variability in risk estimates by repeatedly sampling the probability distributions of the risk equation inputs and using these inputs to calculate a range of risk values.

Parameter - A value that characterizes the distribution of a random variable. Parameters commonly characterize the location, scale, shape, or bounds of the distribution. For example, a truncated normal probability distribution may be defined by four parameters: arithmetic mean [location], standard deviation [scale], and min and max [bounds]. It is important to distinguish between a variable (e.g., ingestion rate) and a parameter (e.g., arithmetic mean ingestion rate).

Point Estimate - In statistical theory, a quantity calculated from values in a sample to estimate a fixed but unknown population parameter. Point estimates typically represent a central tendency or upper bound estimate of variability.

Point Estimate Risk Assessment - A risk assessment in which a point estimate of risk is calculated from a set of point estimates for exposure and toxicity. Such point estimates of risk can reflect the CTE, RME, or bounding risk estimate depending on the choice of inputs.

Potentially Responsible Party (PRP) - PRPs are individuals, companies, or any other party that are potentially liable for payment of Superfund cleanup costs.

Preliminary Remediation Goal (PRG) - Initially developed chemical concentration for an environmental medium that is expected to be protective of human health and ecosystems. PRGs may be developed based on applicable or relevant and appropriate requirements (ARARs), or exposure scenarios evaluated prior to or as a result of the baseline risk assessment. (U.S. EPA, 1991a, 1991b).

Probabilistic Risk Assessment (PRA) - A risk assessment that yields a probability distribution for risk, generally by assigning a probability distribution to represent variability or uncertainty in one or more inputs to the risk equation

Probability Density Function (PDF) - A graph that shows the probability of occurrence of an unknown or variable quantity. A PDF is used to characterize a continuous random variable, X. PDFs can be used to display the shape of the distribution for an input variable or output variable of a Monte Carlo simulation. The term *density* comes from the concept that a probability at a point, x, for a continuous distribution is equal to the area under the curve of the PDF associated with a narrow range of values around x.

Probability Distribution - A mathematical representation of the function that relates probabilities with specified intervals of values for a random variable. Also called a *probability model*.

Probability Mass Function (PMF) - A function representing the probability distribution for a discrete random variable. The mass at a point refers to the probability that the variable will have a value at that point.

Random Variable - A variable that may assume any value from a set of values according to chance. Discrete random variables can assume only a finite or countably infinite number of values (e.g., number of rainfall events per year). A random value is continuous if its set of possible values is an entire interval of numbers (e.g., quantity of rain in a year).

Reasonable Maximum Exposure (RME) - The highest exposure that is reasonably expected to occur at a site (U.S. EPA, 1989). The intent of the RME is to estimate a conservative exposure case (i.e., well above the average case) that is still within the range of possible exposures.

Remedial Investigation/Feasibility Study (RI/FS) - Studies undertaken by EPA to delineate the nature and extent of contamination, to evaluate potential risk, and to develop alternatives for cleanup.

EXHIBIT 2-1

DEFINITIONS FOR CHAPTER 2—Continued

RME Risk - The estimated risk corresponding to the reasonable maximum exposure.

Scientific/Management Decision Point (SMDP) - A point during the tiered process in PRA when the risk assessor communicates results of the assessment to the risk manager. At this point, the risk manager determines whether the information is sufficient to arrive at a decision or if additional data collection or analysis is needed. SMDPs provide a tool for transitioning to a subsequent tier or for exiting the tiered process.

Sensitivity Analysis - Sensitivity generally refers to the variation in output of a model with respect to changes in the values of the model's input(s). Sensitivity analysis can provide a quantitative ranking of the model inputs based on their relative contributions to model output variability and uncertainty. Common metrics of sensitivity include:

- ▶ Pearson Correlation Coefficient - A statistic  $r$  that measures the strength and direction of linear association between the values of two quantitative variables. The square of the coefficient ( $r^2$ ) is the fraction of the variance of one variable that is explained by the variance of the second variable.
- ▶ Sensitivity Ratio - Ratio of the change in model output per unit change in an input variable; also called *elasticity*.
- ▶ Spearman Rank Order Correlation Coefficient - A "distribution free" or nonparametric statistic  $r$  that measures the strength and direction of association between the ranks of the values (not the values themselves) of two quantitative variables. See Pearson (above) for  $r^2$ .

Uncertainty - Lack of knowledge about specific variables, parameters, models, or other factors. Examples include limited data regarding the concentration of a contaminant in an environmental medium and lack of information on local fish consumption practices. Uncertainty may be reduced through further study.

A PRA workplan should be developed early in the risk assessment planning process for the site, regardless of who will actually develop the PRA (e.g., Environmental Protection Agency (EPA), EPA contractor, or potentially responsible party (PRP)). If a PRP performs the PRA, the workplan should be submitted to EPA for review and approval prior to commencing the PRA. It should describe the intended PRA in sufficient detail so that EPA can determine if the work products will adequately address risk assessment and management needs (see Exhibit 2-2 for contents of a typical workplan). It is important that the risk assessor and RPM discuss the scope of the probabilistic analysis and the potential impact it may have on the remedial investigation/feasibility study (RI/FS).

☞ *Given the time and effort that can be expected to be invested in conducting a PRA, it is important that a workplan undergo review and approval by EPA, prior to proceeding with the assessment.*

In general, regions should not accept probabilistic analysis when a workplan for the analysis has not been submitted to the Agency, and approved by the regional risk assessor and RPM.

The tiered process for PRA, described in Section 2.3, is an iterative process. As new information becomes available, it should be used to evaluate the need to move to a higher tier. The decision to move an assessment to a higher tier of complexity should result in a revised workplan reflecting the greater complexity and demands of the higher tier. The proposed probabilistic sensitivity analysis developed at the lower tier should be included in the revised workplan, along with a point estimate risk assessment based on any data collected as part of a lower tier. The probabilistic methods used in a PRA can often be restricted to the chemicals and pathways of concern that contribute the greatest risk. The less sensitive chemicals and exposure pathways should still remain in the PRA using point estimates, unless there is a compelling reason to exclude them from the assessment altogether. As stated in Appendix A (Section A.1, *Risk Communication*), the decision to represent an input variable with a point estimate, rather than a

probability distribution, will generally be made on a case-by-case basis. The decision will reflect an attempt to balance the benefits of simplifying the analysis (e.g., easier to communicate; focuses discussion on more critical areas) with the potential for arbitrarily reducing the variance in the output distribution (e.g., discounting variability in multiple variables with negligible contributions to risk may end up having a non-negligible effect on the RME percentile).

Throughout the process of developing the PRA, EPA risk assessor and other contributors to the assessment should have a continuing dialogue to discuss the elements of the workplan and their potential impacts on the assessment. This dialogue, along with interim deliverables, will help to ensure that the risk assessment report will meet the needs of the Agency and that any problems are identified and corrected early in the process.

## **2.2 SPECIAL ADMINISTRATIVE CONSIDERATIONS IN PRA**

Inclusion of a PRA in the RI/FS will generate certain administrative activities for the RPM. The scope of these activities will depend on whether the PRA is conducted by EPA and its contractors or by the PRP. The following sections provide practical advice for the RPM who is considering applications of PRA at a site.

### **2.2.1 SCOPING OF PRA**

The RPM will generally be involved in the discussions among EPA project team, as well as PRPs and other stakeholders, regarding the level of PRA that is appropriate for the site. As outlined in the tiered approach (see Section 2.3), the scope and complexity of the PRA should satisfy the risk assessment and management decision making needs of the site. Team members should meet to discuss the scope of the PRA, the anticipated community outreach, and the required level of review. These discussions can be useful for ascertaining the level of contractor involvement, specific requirements for deliverables from PRPs, and the anticipated number of responses to comments. These meetings should include consideration of funding, resources, and availability of personnel to work on the PRA.

#### **EXHIBIT 2-2**

##### **EXAMPLES OF IMPORTANT CONTENTS OF A PRA WORKPLAN**

1. Statement of the ecological assessment endpoints and/or human risk
2. Summary of the point estimate risk assessment
3. Potential value added by conducting a PRA and proceeding to the subsequent tiers
4. Discussion of adequacy of environmental sampling for PRA or moving to a successive tier (e.g., data quality issues)
5. Description of the methods and models to be used (e.g., model and parameter selection criteria)
6. Proposal for obtaining and basis for using exposure factor distributions or ecological toxicity distributions
7. Methods for deriving the concentration term
8. Proposal for probabilistic sensitivity analysis
9. Software (e.g., date and version of product, random number generator)
10. Bibliography of relevant literature
11. Proposed schedule, discussion points, and expertise needed

### **2.2.1.1 PRA SCOPE OF WORK FOR FUND-LEAD SITES**

A Statement of Work (SOW) should be developed before any work is started on a PRA, regardless of whether the PRA is to be submitted to the Agency or developed by the Agency. The SOW should outline the general approach that EPA and its contractor will use in developing the PRA. The SOW should include the general approaches for the following PRA items: selection of input probability distributions, documentation of methods and results, selection of computer programs, submission of computer codes and outputs, comparison of the results from the point estimate and probabilistic assessments, and the format for presenting the final PRA in the RI/FS document. The SOW should be sufficiently detailed to support a milestone schedule, which should be submitted as part of the SOW. Based on the complexity of the PRA, and consistent with the RAGS Volume I: Part D principles of involving the risk assessor early and often in the risk assessment process (U.S. EPA, 2001), it may be appropriate to obtain submission of interim deliverables to allow the risk assessor the opportunity to identify potential problems early in the process.

Within the RI/FS workplan, additional resources may be required to hold additional meetings, to respond to comments specific to the PRA, and to develop handouts describing PRA in terms accessible to a wider audience than risk assessors. Where appropriate, these additional resource requirements should be included in the SOW along with interim and final deliverable dates. Chapter 6 provides guidance on communicating concepts and results of PRA to various audiences.

### **2.2.1.2 PRP SCOPE OF WORK FOR PRP-LEAD SITES**

The SOW for PRP-lead sites should follow the same general outline as the SOW for fund-lead sites (Section 2.2.1.1). Legal documents such as Unilateral Orders, Administrative Orders of Consent, and Consent Decrees should contain language requiring the PRP to submit a workplan before any work on the PRA is started. It is also important that interim deliverables, including computer code or spreadsheet models, be submitted so that EPA can review and verify the results of the PRA. A comparison of the results of the PRA and the point estimate assessment should be included in the final RI/FS.

Depending on the complexity of the site and the anticipated PRA, the RPM may be involved in more extensive negotiations with the PRPs. These negotiations may involve both EPA staff and contractor support. These activities may need to be included in the appropriate SOWs.

If warranted by the complexity of the PRA, the RPM may consider the need to expand oversight contracts to include additional resources for the contractor to review and comment on the interim deliverables and finalize the PRA. This may require a specialized level of expertise that will need to be discussed with the contractor. Further, the contract section regarding community involvement may also need to be expanded to include additional resources for developing handouts describing PRA in terms accessible to a wider audience than risk assessors and for holding additional community meetings.

### **2.2.2 DEVELOPMENT OF PROBABILITY DISTRIBUTIONS**

A key component of any PRA is the selection of representative probability distributions. The information available to support the characterization of variability or uncertainty with probability distributions may be an important factor in the decision to conduct a PRA. In some cases, this may require resources to conduct exploratory data analysis or to collect site-specific information. As part of this process, a PRA using preliminary distributions based on the available information may be considered to identify the variables and exposure pathways that may have the strongest effect on the risk estimates. Appendix B (Section B.2.0) provides a more detailed description of preliminary distributions and their potential role in the tiered process. All of these activities may require extensive discussions with the PRPs and the community. In addition, for PRP-lead sites, they may require additional resources to critically review the proposed distributions. The RPM should consider these potential activities in developing the SOW and legal documents to assure adequate resources are available to address them.

### **2.2.3 EPA REVIEW OF PRA DOCUMENTS**

The review of PRA documents may require more time than is usually allocated for point estimate risk assessments. In part, the additional time is needed for reviewing and discussing input distributions, for developing and running computer simulations, and for discussing outcomes of the assessment with the PRP or EPA contractor. The early involvement of an EPA risk assessor may reduce the time needed for review of the final risk assessment documents, although additional review time may still be required, depending on the complexity of the PRA conducted.

In addition to EPA's review, it may also be important to include external reviewers with specialized expertise in PRA to aid in the review. This additional support may involve resources and time to review documents and verify simulation results, as well as additional contractual arrangements. As stated in Chapter 1, Section 1.4 (Conducting an Acceptable PRA), it is important that negotiations with the PRP address the assurance that adequate details will be included in the submission so that the methods can be evaluated, and the results independently reproduced.

### **2.2.4 PEER-REVIEW**

Depending on the level of complexity of the PRA, and whether new science is being used, it may be necessary to conduct a peer review of the document. The Agency's guidance on peer review (U.S. EPA, 2000b) should be consulted for information regarding the criteria for determining whether or not a peer review is appropriate and, if it is, the process that should be followed.

### **2.2.5 RESPONSE TO COMMENTS ON PRA**

The time and resources needed to respond to comments on a PRA may vary depending on the complexity of the PRA. In developing the SOW, workplan, and schedule for the RI/FS, it is important that the RPM include adequate resources and time for the thorough evaluation of the PRA. In developing the response to comments, it may be necessary to consider alternative PRAs submitted by reviewers. The RPM should plan for sufficient time and resources needed for such activities.

### **2.2.6 ADMINISTRATIVE RECORD**

Criteria should be established for documentation to be included in the administrative record. Examples may include documentation regarding the basis for selection of input distributions, a description of the design of the PRA conducted, the computer codes used in simulations, how tiering decisions are made, and the results of the PRA. The RPM should consider using technologies such as a CD-ROM to document the appropriate information for the record.

### **2.2.7 COMMUNICATION WITH STAKEHOLDERS**

Chapter 6 provides details regarding the goal of early involvement of the public in the PRA process. For example, Section 6.1 of Chapter 6 provides additional topics for consideration in development of community involvement plans (CIPs) where PRA is considered. In general, early involvement of the community in the RI/FS process is important, but such involvement should meet the site-specific needs. Important considerations include resources, funding, and the level of effort appropriate for the site.

### **2.2.8 COMMUNICATION WITH EPA MANAGEMENT**

Communication with EPA managers regarding PRA is discussed in Chapter 6. The RPM may need to consider allocating additional resources for prebriefings of appropriate management levels, development of handouts, and follow-up to the management meetings. Coordination with appropriate EPA staff and contractors may be necessary to assure the communication is effective.

## **2.3 OVERVIEW OF THE TIERED APPROACH**

The tiered approach presented in this guidance is a process for a systematic, informed progression to increasingly more complex risk assessment methods including PRA. A schematic presentation of the tiered approach is shown in Figure 2-1 and Figure 2-2. Higher tiers reflect increasing complexity and, in many cases, will require more time and resources. Higher tiers also reflect increasing characterization of variability and/or uncertainty in the risk estimate, which may be important for making risk management decisions. Central to the concept of a systematic, informed progression is an iterative process of evaluation, deliberation, data collection, work planning, and communication (see Figure 2-2). All of these steps should focus on deciding (1) whether or not the risk assessment, in its current state, is sufficient to support risk management decisions (a clear path to exiting the tiered process is available at each tier); and (2) if the assessment is determined to be insufficient, whether or not progression to a higher tier of complexity (or refinement of the current tier) would provide a sufficient benefit to warrant the additional effort.

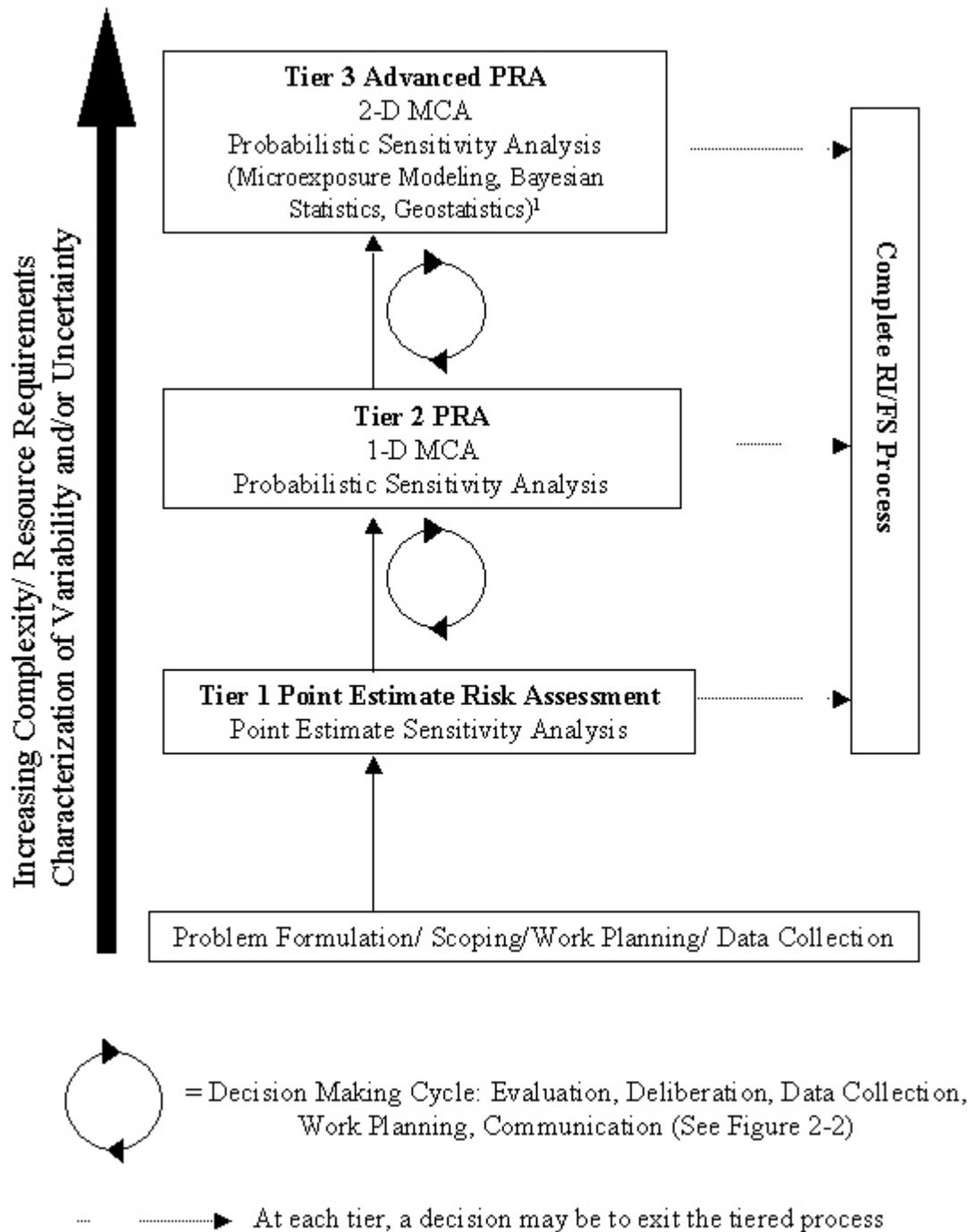
The deliberation cycle provides an opportunity to evaluate the direction and goals of the assessment as new information becomes available. It may include evaluations of both scientific and policy information. The risk manager, in the decision-making process, is encouraged to seek input on a regular basis from EPA staff and other stakeholders. Exhibit 2-3 lists some of the potential stakeholders that may contribute to the deliberation process.

Although PRA may involve technical dialogue between EPA and outside “experts”, input from members of the general public who may have an interest in the outcome of the remedial process should also be sought at appropriate stages of the process. Frequent and productive communication between EPA and stakeholders throughout the risk assessment process is important for enhancing the success of a PRA.

**EXHIBIT 2-3**

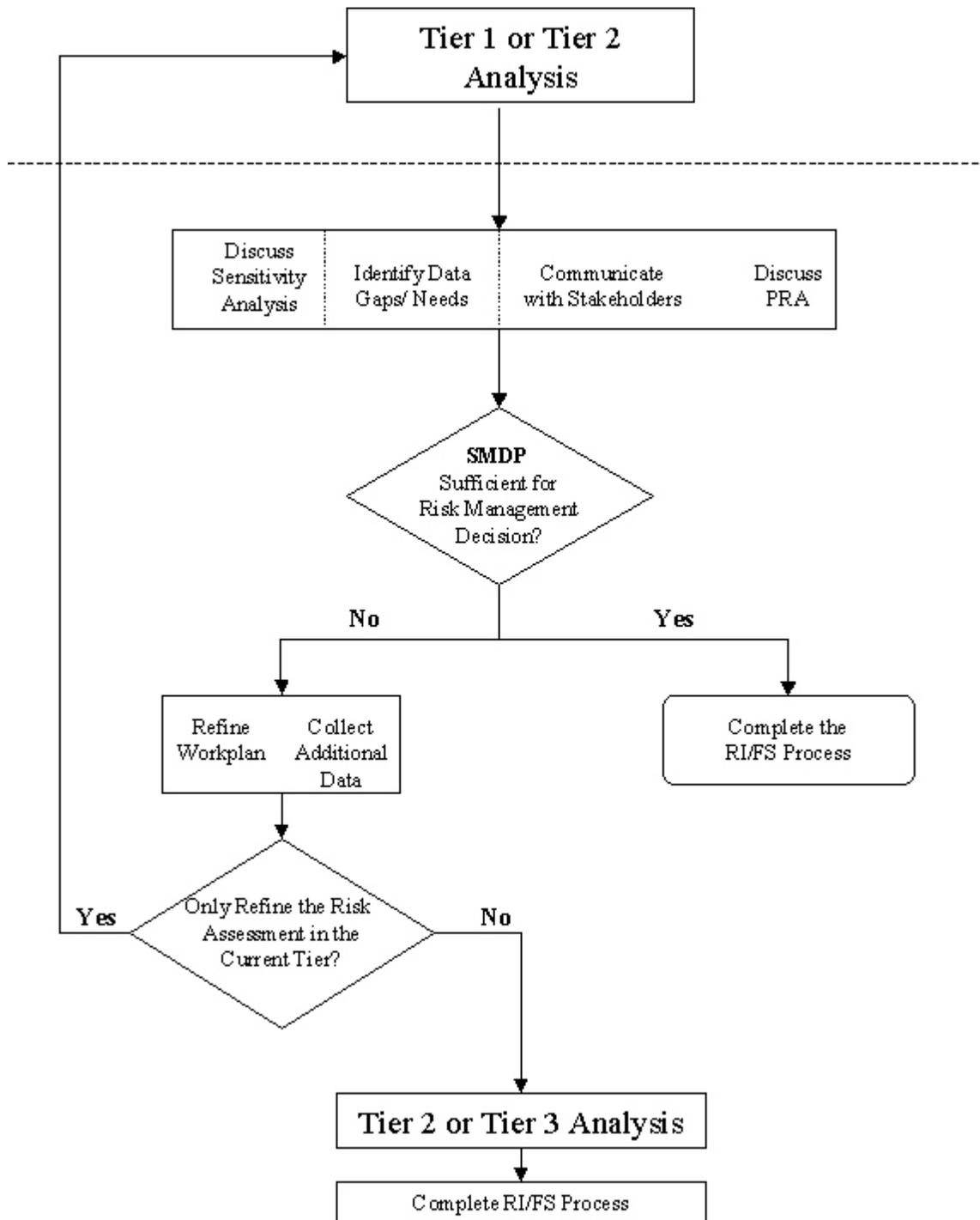
**STAKEHOLDERS POTENTIALLY INVOLVED IN EPA’S  
DECISION-MAKING PROCESS FOR PRA**

- EPA risk assessors and managers
- Members of the public
- Representatives from state or county environmental or health agencies
- Other federal agencies (e.g., health agencies, Natural Resource Damage Assessment trustees, etc.)
- Tribal government representatives
- Potentially responsible parties and their representatives
- Representatives from federal facilities (e.g., Department of Defense, Department of Energy, etc.)



**Figure 2-1.** Schematic Diagram of Tiered Approach.

<sup>1</sup> Examples of advanced methods for quantifying temporal variability, spatial variability, and uncertainty (see Appendix D)



**Figure 2-2.** Schematic diagram of deliberation/decision cycle in the tiered process for PRA. SMDP refers to a scientific/management decision point, which implies that the decision involves consideration of not only the risk assessment, but also Agency policy, stakeholder concerns, cost, schedule, feasibility and other factors.

### 2.3.1 GETTING STARTED

All risk assessments should begin with problem formulation, scoping, preparation of a workplan (Section 2.1), and data collection. Problem formulation generally is an iterative process where reevaluation may occur as new information and data become available. The RPM should convene a scoping meeting prior to any risk assessment activities. Depending on the site-specific factors, discussion of performing a PRA may be appropriate at this initial scoping meeting. Alternatively, this discussion may be more productive at a later stage of the tiered process.

The risk manager should initiate discussions with EPA staff and other stakeholders early in the process, well before planning a risk assessment. Early communication with risk assessors or other EPA staff can help the risk manager evaluate the adequacy of the current information and plan additional data-gathering activities. Early communication with communities and other stakeholders should establish trust and facilitate a successful remedial process (see Chapter 6 on risk communication).

Generally, once the appropriate steps have been taken to adequately formulate and identify the problem and complete a workplan (Section 2.1), data collection efforts towards the point estimate risk assessment may begin. The process for conducting a point estimate risk assessment (Tier 1) is documented elsewhere in various RAGS volumes and related Superfund risk assessment guidance documents (e.g., U.S. EPA, 1989, 2001).

### 2.3.2 TIER 1

Tier 1 consists of the well-established process for planning and conducting human health and ecological point estimate risk assessments. Typical elements of a Tier 1 risk assessment, as they relate to higher tiers, are presented in Exhibit 2-4. A more detailed discussion of these elements can be found in Chapters 3 and 4 and Appendix A (Sensitivity Analysis).

A more detailed schematic presentation of the tiered process, showing the various elements of the deliberation/decision cycle and their linkage to higher tiers is shown in Figure 2-2. The two main factors to consider when determining whether the results of a risk assessment are sufficient for decision making are: (1) the results of a comparison of the risk estimate with the risk level of concern; and (2) the level of confidence in the risk estimate.

In Tier 1, comparison of risk estimates with risk levels of concern is relatively straightforward, since the outcome of a point estimate risk assessment is a single estimate of risk that either will exceed or not exceed the risk level of concern. Evaluating confidence in the Tier 1 risk estimates is more difficult because quantitative measures of

#### EXHIBIT 2-4

##### TYPICAL ELEMENTS OF TIER 1 RISK ASSESSMENT

**Analysis Tool** - point estimate risk assessment

**Variability Modeling** - semi-quantitative, using central tendency exposure (CTE) and reasonable maximum exposure (RME) estimates as input variables

**Uncertainty Modeling** - semi-quantitative using confidence limits on certain point estimates (e.g., concentration term)

**Sensitivity Analysis** - point estimate calculation of percentage contribution of exposure pathways, for both CTE and RME risk. Systematically vary one input variable at a time across a plausible range and rank inputs based on sensitivity ratios or sensitivity scores.

**Risk-Based Decision-Making Output** - point estimate of risk—*Does the point estimate exceed the risk level of concern?*

uncertainty often are not easily obtained from a point estimate analysis. Uncertainty arises from two main sources: (1) uncertainty in the inputs to the risk equations that stems from lack of knowledge (data gaps), and (2) uncertainty in the accuracy of the point estimate that stems from the mathematical simplifications that are inherent in point estimate computations.

There are usually many sources of uncertainty in the values used to calculate risk. One of the most familiar (but not always the most significant) is uncertainty in environmental concentration values of contaminants. This source of uncertainty is usually accounted for by calculating a 95% upper confidence limit (95% UCL) for the mean concentration in the exposure equation (U.S. EPA, 1992b). Chapter 5, Appendix C, and Appendix D provide more complete discussions of policies and methods for quantifying uncertainty in the exposure point concentration. Uncertainties in other variables in the risk equations (intake rates, exposure frequency and duration, toxicity factors, etc.) may also be significant, and are often addressed by choosing inputs that are more likely to yield an overestimate than an underestimate of risk. These sources of uncertainty are usually addressed qualitatively, by providing a discussion of the likely direction and magnitude of the error that may be associated with the use of the specific inputs (U.S. EPA, 1989). Stakeholders can provide useful information about uncertain variables and sources for site-specific data. This is an important reason to ensure that stakeholders are given the opportunity to review the risk assessment and be involved in the process.

### ***Decision Alternatives***

The evaluation of the point estimate risk assessment will yield one of two outcomes: (1) sufficient for risk management decisions; or (2) insufficient for risk management decisions. If the risk manager views the results of the point estimate risk assessment as sufficient for risk management decision making, the risk manager can exit the tiered approach and complete the RI/FS process (Figure 2-2). Depending on site-specific information, the results may support a decision for “no further action” or for a “remedial action.” A “no further action” decision may result when the risk estimate is clearly below the level of concern (e.g., the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) risk range of  $1E-04$  to  $1E-06$ ) and confidence in the risk estimate is high. A decision for remedial action may result when a national standard (e.g., maximum contaminant levels (MCLs) applied to groundwater) may be exceeded, or when the risk is clearly above the level of concern (e.g., the NCP risk range of  $1E-04$  to  $1E-06$ ) and confidence in the risk estimate is high. The decision for a specific remedial action involves consideration of the NCP’s nine criteria for remedial decisions (U.S. EPA, 1990) and other site-specific factors.

An alternative conclusion would be that the results of the point estimate risk assessment are not sufficient for risk management decision making. For example, results may not be sufficient when the risk estimate is within the NCP risk range of  $1E-04$  to  $1E-06$  and confidence in the risk estimate is low. In this case, the risk manager should not exit the tiered approach. Instead, appropriate steps should be taken to increase the confidence that a management decision is protective. These steps may include discussing the point estimate sensitivity analysis, identifying data gaps, communicating with stakeholders (e.g., to obtain site-specific information), discussing the potential value of conducting a PRA (or a more advanced probabilistic analysis), work planning, and additional data collection (see Figure 2-2).

A sensitivity analysis can be a valuable component of the evaluation of a risk assessment. Sensitivity analysis can identify important variables and pathways that may be targets for further analysis and data collection. The type of information provided by a sensitivity analysis will vary with each tier of a PRA. Several methods are available at each tier, and the results of the analysis can vary greatly

depending on the methods used. A comprehensive discussion of these methods is presented in Appendix A and briefly summarized here. Sensitivity analysis in Tier 1 will usually involve relatively simple methods and will not involve Monte Carlo simulation. A typical approach would be to calculate the relative contributions of individual exposure pathways to the point estimate of risk. A more complex approach involves selecting values from a plausible range for a specific input variable to the exposure or risk equation and to use these values (i.e., low-end estimate and high-end estimate) to calculate corresponding point estimates of risk. The sensitivity of the risk estimate to each variable is then evaluated by calculating a sensitivity ratio, which is simply the percentage change in the risk estimate divided by the percentage change in the input variable value (see Appendix A, Section A.2.1.3, Sensitivity Ratios).

The sensitivity ratio (SR) approach is typically applied to one variable at a time because jointly varying point estimates for multiple variables can be cumbersome (see Chapter 3, Table 3-2 for an example of two jointly varied inputs). Information provided by the SR approach is generally limited to bounding estimates of risk based on small deviations and/or plausible ranges of point estimates for inputs. Because the point estimate approach does not generate a distribution of risk, SRs cannot provide quantitative information about the relative contributions of input variables to the variance in risk or the uncertainty in selected percentile of the risk distribution. This limitation of the SR approach may be particularly important if the ranking of input variables may change depending on the percentile range that is evaluated. For example, in a probabilistic analysis, the soil ingestion rate variable may contribute most to the variability in risk across the entire risk distribution, but the exposure duration may be the driver in the high-end (> 90<sup>th</sup> percentile) of the risk distribution, where the RME risk is defined. In addition, for standard product-quotient risk equations, the SR approach also has difficulty distinguishing the relative importance of exposure variables in the risk equation. Appendix A presents a hypothetical example to illustrate why this happens for the common risk equations. An improvement over the SR approach, called Sensitivity Score, involves weighting each ratio by the variance or coefficient of variation of the input variable when this information is available. In general, the most informative sensitivity analysis will involve Monte Carlo techniques (see Appendix A, Table A-1). Potential strengths and weaknesses of sensitivity analysis methods may be an important factor in deciding whether or not to conduct a probabilistic analysis in Tier 2.

Once data gaps have been identified, steps may be taken to gather additional data and revise the point estimates of risk based on these data. As with any data collection effort, the data quality objectives (DQO) process should be followed to obtain samples appropriate for the risk assessment and sufficient to support the remedial decision (U.S. EPA, 1992a, 1993, 1994, 2000a). The deliberation and decision cycle (Figure 2-2) should then be reiterated to determine if the refined risk assessment is sufficient to support risk management decisions. The collection of additional data may also provide a compelling reason to consider moving to Tier 2 and conducting a PRA. If, during the PRA discussions, it is determined that information from a PRA may influence the risk management decisions, PRA may be warranted. This iterative process of collecting data, recalculating point estimates, and reconsidering the potential value of PRA may continue until sufficient data are available to support risk management decisions, or data collection efforts are not possible due to resource constraints. For example, soil ingestion rate data may be limited to a few studies with small sample sizes, but a new soil ingestion study may be prohibitively expensive, time consuming, or difficult to conduct in a manner that will reduce the uncertainty in the risk estimate. Uncertainty due to data quantity is not necessarily a reason to exit the tiered process at Tier 1.

In cases where there is uncertainty in selecting a probability distribution because of small sample sizes, it may be informative to develop a preliminary probability distribution such as a triangular or uniform (see Appendix B, Section B.2.0). These preliminary distributions will contribute to the variability in the risk estimate, and can therefore be included in the probabilistic sensitivity analysis. Results of Monte Carlo simulations that include one or more preliminary distributions may lead to several alternative decisions. If the sensitivity analysis suggests that the risk estimate is relatively insensitive to the variable described with the distribution, then the uncertainty associated with the choice of a distribution should not affect the risk management decision process using the tiered approach (e.g., choice of RME percentile, derivation of a PRG). In other words, the choice would be to continue with the tiered process. If, however, the variables described by preliminary distribution are important sources of variability or uncertainty in the risk estimate, then this information should be presented in the scientific management decision point (see Figure 2-2). The uncertainty may be sufficiently important in the risk management decision to warrant additional data collection efforts. Conversely, it may be necessary to exit the tiered process if the uncertainty cannot be reduced. Although the tiered process may be stopped at this point, it can still be informative to present the results from the PRA. For example, information about uncertainty may affect the choice of the percentile used to characterize the RME risk. In addition, it may be appropriate to weight the results of the point estimate analysis more heavily in the risk management decision when uncertainty in the PRA is high. Further guidance on appropriate choices for distributions based on the information available to characterize variability is given in Appendix B.

PRA also may be warranted if it would be beneficial to know where on the risk distribution the point estimate lies. An example of this would be a risk estimate that is within the NCP risk range of  $1E-04$  to  $1E-06$ . The assessment may be sufficient to support risk management decisions if it could be shown that the point estimate of risk lies sufficiently high in the risk distribution. For example, a “no further action” decision may be strengthened if the point estimate is at the 99<sup>th</sup> percentile of the risk distribution, if risks in lower percentiles of the RME risk range are below the NCP risk range, and if there is high confidence in the risk result. This type of evaluation can be conducted using PRA techniques.

Even if the RME point estimate of risk exceeds the risk level of concern, and PRA is not needed to confirm this result, information from a PRA can be helpful in determining a strategy for achieving a protective preliminary remediation goal (PRG). A detailed discussion of the use of PRA in setting remediation action levels is given in Chapter 5. The advantages and disadvantages of the point estimate approach and PRA are presented in Chapter 1 (Exhibits 1-5 and 1-6).

### **2.3.3 TIER 2**

Tier 2 of the tiered approach to risk assessment will generally consist of a simple probabilistic approach such as one-dimensional Monte Carlo analysis (1-D MCA). A 1-D MCA is a statistical technique that may combine point estimates and probability distributions to yield a probability distribution that characterizes variability or uncertainty in risks within a population (see Chapter 1). Guidance for selecting and fitting distributions is presented in Appendix B. Typical elements of a Tier 2 risk assessment, as they relate to higher and lower tiers are presented in Exhibit 2-5. A more detailed discussion of these elements can be found in Chapters 3 and 4, and Appendix A (Sensitivity Analysis).

While most of the Tier 2 assessments are expected to use 1-D MCA to characterize variability in risk, sometimes a 1-D MCA of uncertainty may be of interest. For example, as suggested in Exhibit 2-5, a probability distribution for uncertainty in the arithmetic mean or median (i.e., 50<sup>th</sup> percentile) for selected input variables may be specified in a 1-D MCA to yield a probability distribution for uncertainty for the central tendency risk estimate. However, as most Tier 2 assessments are expected to combine input distributions for variability, this guidance focuses on 1-D MCA for characterizing variability in the risk estimate.

### ***Decision Alternatives***

Generally, the three main questions to consider when determining whether the results of a 1-D MCA are sufficient for risk management decisions are: (1) What is the RME risk range and how does it compare to the level of concern?; (2) Where does the point estimate risk lie on the risk distribution?; and (3) What is the level of confidence in the risk estimate? In Tier 2, similar to the point estimate approach, the level of confidence in a single 1-D MCA risk distribution is generally addressed in a qualitative or semi-quantitative way. As discussed in Chapter 1 (Section 1.2.4) and Chapter 3 (Section 3.4.1), one should avoid developing input distributions to a PRA model that yield a single risk distribution that intermingles, or represents both variability and uncertainty. In Tier 2, the preferred approach for characterizing uncertainty in the risk estimate is to perform multiple 1-D MCA simulations (of variability), which uses a different point estimate for uncertainty for one or more parameters, combined with probability distributions for variability for one or more variables. Chapter 3 (see Table 3-2 and Figures 3-3 and 3-4) presents an example of iterative 1-D MCA simulations using combinations of point estimates characterizing uncertainty for two variables. More advanced PRA techniques such as two-dimensional Monte Carlo analysis (2-D MCA), in which distributions for variability and uncertainty are propagated separately through an exposure model, can be undertaken in Tier 3 (Appendix D).

In order to use a PRA to determine if risks are unacceptable and to develop preliminary remediation goals (PRGs) that are protective of the RME individual (see Chapter 5), a single point from the RME risk range should be selected (e.g., 95<sup>th</sup> percentile). In general, this can be accomplished by selecting an estimate within the RME risk range based on the level of confidence in the output of the 1-D MCA. Uncertainty in risk estimates may be quantified or reduced by considering site-specific factors, biological data, and toxicity data. Stakeholders can provide useful information about uncertain variables and sources for site-specific data. More detailed guidance for choosing a percentile value within the RME range is provided in Chapter 7.

#### **EXHIBIT 2-5**

##### **TYPICAL ELEMENTS OF TIER 2 RISK ASSESSMENT**

###### **Analysis Tool - 1-D MCA**

**Variability Modeling** - full characterization of variability in risk using PDFs or PMFs for input variables

**Uncertainty Modeling** - semi-quantitative estimate of uncertainty using iterative 1-D MCA simulations of variability, or a single 1-D MCA of uncertainty in the CTE risk

**Sensitivity Analysis** - varying multiple variables with probability distributions gives a quantitative ranking (e.g., correlation coefficient) of the relative contributions of exposure pathways and variables to CTE or RME risk

**Risk-Based Decision-Making Output** - risk distribution for variability: *Does the risk level of concern fall within an acceptable range on the risk distribution (i.e., RME range)?* Also, risk distribution for uncertainty: *What is the 90% confidence interval for the CTE risk?*

The evaluation of the risk assessment in a 1-D MCA in Tier 2 will yield one of two outcomes: (1) sufficient for risk management decisions; or (2) insufficient for risk management decisions. If determined to be sufficient, the risk manager can exit the tiered approach and complete the RI/FS process. The results of a 1-D MCA may support a decision for “no further action” or for a “remedial action.” A “no further action” decision may result when the RME risk range (or a specified point in the RME risk range) is clearly below the level of concern (e.g., Hazard Index=1) and confidence in the risk distribution is high. A decision for remedial action may result when a national standard (e.g., MCLs applied to groundwater) may be exceeded, or when the RME risk range (or a specified point in the RME risk range) is clearly above the level of concern and confidence in the risk distribution is high. The decision for a specific remedial action involves consideration of the NCP’s nine evaluation criteria for remedial decisions (U.S. EPA, 1990; see Chapter 1) and other site-specific factors.

An alternative conclusion at the end of a Tier 2 analysis would be that the results of the 1-D MCA are not sufficient for risk management decisions. There are several factors that might support this conclusion:

- (1) The RME risk range is close to the NCP risk range and confidence in the risk distribution is low. In this case, the risk manager might decide to not exit the tiered approach, and instead continue taking appropriate steps to increase the confidence in the risk estimate.
- (2) Uncertainty is high and it is believed that more than one variable is a major contributor to the uncertainty in the risk estimate. It can be difficult to explore uncertainty in more than one variable using 1-D MCA simulations of variability, even using iterative approaches discussed in Chapter 3 (Section 3.4.1).
- (3) Results of the point estimate risk assessment differ significantly from the results of the 1-D MCA. While the RME risk estimates are not expected to be identical, typically the RME point estimate will correspond with a percentile value within the RME range (i.e., 90<sup>th</sup> to 99.9<sup>th</sup> percentile) of the risk distribution. If the RME point estimates fall outside this range, further steps may be warranted to evaluate the choices for input variables—both the RME point estimates, and the probability distributions and parameters (including truncation limits) for the 1-D MCA.

The deliberation/decision cycle (Figure 2-2) between Tier 2 and Tier 3 is similar to the cycle between Tier 1 and 2 and includes discussing the Tier 2 probabilistic sensitivity analysis, identifying data gaps, communicating with stakeholders (e.g., to obtain site-specific information), discussing the potential value of further analysis with probabilistic methods, work planning, and additional data collection. As with the Tier 1 assessment, additional data collection should follow the DQO process (U.S. EPA, 1992a, 1993, 1994, 2000a) and point estimates of risk should be revisited with the new data. The deliberation/decision cycle is an iterative process in which the level and complexity of the analysis increases until the scope of the analysis satisfies decision-making needs. This iterative process should continue until sufficient data are available to support risk management decisions. As in all tiers, stakeholder involvement should be encouraged. Once a 1-D MCA for variability or uncertainty is completed and is available for review and interpretation, a stakeholder meeting should be convened. Interested stakeholders should be given the opportunity to review the 1-D MCA and provide comments. Communication issues specific to PRA are discussed in Chapter 6 (Risk Communication).

In addition to identifying data gaps, consideration for a refined 1-D MCA or more advanced PRA techniques may begin as a means of determining what benefits they may confer to the decision-making process. If, during further discussions of PRA, it is determined that information from a more advanced PRA may influence the risk management decision, the use of an advanced PRA may be warranted. If additional data have been collected, the point estimate and 1-D MCA should be refined. Specifically, an advanced PRA may be warranted if it would be beneficial to characterize uncertainty in more than one variable at a time. A 2-D MCA can simultaneously characterize variability and uncertainty in multiple variables and parameter estimates. The decision to employ such advanced methods should be balanced with considerations of resource constraints and the feasibility of reducing uncertainty in a given variable. A detailed discussion of advanced PRA methods, including 2-D MCA, is provided in Appendix D.

### 2.3.4 TIER 3

Tier 3 of the tiered approach to risk assessment consists of advanced PRA methods, such as 2-D MCA, Microexposure Event Analysis (MEE), geostatistical analysis of concentration data, and Bayesian statistics. Typical elements of a Tier 3 risk assessment are presented in Exhibit 2-6. A more detailed discussion of these elements is given in Appendix D. As in other tiers, Tier 3 includes an iterative process of deliberation and decision making in which the level and complexity of the analysis increases until the scope of the analysis satisfies decision-making needs. As in all tiers, stakeholder involvement is encouraged.

Generally, the various elements of the deliberation/decision cycle for Tier 3 are the same as those for Tier 1 and 2 (Figure 2-2). An advanced PRA would be conducted and made available for review to the risk manager and stakeholders. The risk manager must determine if the results of the advanced PRA are sufficient for risk management decision making. Issues to consider when making this determination are similar to those identified for evaluating point estimate risk results and 1-D MCA results, and focus on evaluating the sources and magnitude of uncertainty in relation to the established risk level of concern. If the results are sufficient for risk management decisions, the risk manager may exit the tiered approach and complete the RI/FS process. If the results are not found to be sufficient for risk management decisions, data gaps should be identified and if additional data are collected, all stages of the risk assessment, including the advanced PRA, the 1-D MCA, and the point estimate risk assessment, should be refined. Alternatively, additional advanced PRA methods may be explored. Refer to Appendix D for a discussion of more advanced PRA techniques. Overall, analysis should continue within Tier 3 until sufficiently informed risk management decisions can be made.

#### EXHIBIT 2-6

##### TYPICAL ELEMENTS OF TIER 3 RISK ASSESSMENT

**Analysis Tool** - 2-D MCA, MEE, geostatistics, and Bayesian statistics

**Variability Modeling** - full characterization using PDFs or PMFs for input variables

**Uncertainty Modeling** - quantitative, segregating uncertainty from variability, and associated with multiple variables simultaneously

**Sensitivity Analysis** - varying parameters of probability distributions to identify and rank order parameter uncertainty with the same sensitivity analysis methods used for Tier 2 (see Appendix A). Also, explore alternative choices of probability distributions and sources of model uncertainty.

**Risk-based Decision-Making Criteria** - risk distribution for variability with confidence limits—*Does the risk level of concern fall within an acceptable range on the risk distribution (i.e., RME range), and with an acceptable level of uncertainty?*

### 2.3.5 FLEXIBILITY IN DEFINING TIERS

The assignment of specific analytical tools to Tiers 1, 2, and 3 (Figure 2-1 and Exhibits 2-4 through 2-6) results in generalizations that may not be applicable to all site assessments. Upon completion of the deliberation phase between Tier 1 and Tier 2, the conclusion may be that analytical tools in Tier 3 would be applicable and beneficial for addressing decision making issues. For example, geospatial modeling may be beneficial for improving estimates of uncertainty in the exposure point concentration or in designing field sampling plans to further reduce uncertainty. An improved estimate of the 95% UCL from geospatial analysis (shown in Exhibit 2-6 as a Tier 3 analytical tool) would then be integrated into a Tier 2 assessment, or the complete distribution for uncertainty in the mean concentration could be incorporated into a 2-D MCA in Tier 3. Flexibility in defining the level of complexity of the analysis used in a given tier is essential to accommodating the wide range of risk assessment issues likely to be encountered. An important benefit gained from use of the tiered approach is to ensure a deliberative process in the advancement of the assessment to higher levels of complexity. It is far more important that a deliberative process take place and be documented, than it is to constrain a set of analytical tools to a specific tier.

REFERENCES FOR CHAPTER 2

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