

## CHAPTER 5

### PROBABILISTIC RISK ASSESSMENT AND PRELIMINARY REMEDIATION GOALS

#### 5.0 INTRODUCTION

According to the National Contingency Plan (NCP) (U.S. EPA, 1990a, 40CFR §300.430(d)(4)), risk assessment and risk management decision making go hand-in-hand: data from the remedial investigation are used to characterize risk, and results of the baseline risk assessment help to establish acceptable exposure levels for use in developing remedial alternatives. In practice, risk managers may identify two major objectives of risk assessment: (1) to determine if remediation is necessary (i.e., *Is there unacceptable risk at the site?*); and (2) if remediation is necessary, to determine a preliminary remediation goal (PRG) (i.e., *What chemical concentrations would result in a risk estimate that will be adequately protective of human health and the environment?*). The answer to the first question (*is there unacceptable risk?*) depends upon a number of factors, including the measured or estimated concentration levels of contaminants in site media, and takes uncertainty in the measurements into account. In contrast, the answer to the second question (*what is the PRG needed to achieve a specified level of protection?*) does not necessarily depend on any knowledge of the actual level or pattern of site-specific concentration data, and does not necessarily depend on the uncertainty in site concentration data. Thus, while exposure point concentrations (EPCs) and PRGs are closely related to each other, they have important differences (see Section 5.1 for further elaboration on EPCs and PRGs).

Once a risk manager has selected a PRG at a site, determining whether a particular area meets or will meet the PRG requires careful comparison of site data with the PRG, including a consideration of the uncertainty in the site data. For a further discussion on variability and uncertainty in the concentration term, readers are urged to consult Appendix C in this guidance.

#### EXHIBIT 5-1

##### SUMMARIES OF SOME KEY TERMS

**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, or exposure scenarios evaluated prior to or as a result of the baseline risk assessment. (U.S. EPA, 1991a).

**Generic PRG** - a chemical concentration protective of human health developed prior to the baseline risk assessment that uses default exposure assumptions representing common exposure scenarios, e.g., Region 3 risk-based concentrations (RBCs) or Region 9 PRGs.

**Site-specific PRG** - site-specific chemical concentration, protective of human health and ecosystems, based on exposure scenarios in the baseline risk assessment. Generally calculated for the various exposure scenarios considered in the baseline risk assessment.

**Remediation Goals (RG)** - site-specific chemical concentration, protective of human health and ecosystems, chosen by the risk manager as appropriate for a likely land use scenario.

**Remediation Action Level (RAL)** - the "not-to-exceed" level; a concentration such that remediation of all concentrations above this level in an exposure unit lowers the EPC sufficiently to achieve a target risk level. The RAL will depend on the mean, variance, and sample size of the concentrations within an exposure unit as well as considerations of short-term effects of the chemicals of concern.

**Cleanup Level (Final Remediation Level)** - chemical concentration chosen by the risk manager after considering both RGs and the nine remedy selection criteria of the NCP (U.S. EPA, 1990a). Also referred to as Final Remediation Levels (U.S. EPA, 1991a), chemical-specific cleanup levels are documented in the Record of Decision (ROD). A cleanup level may differ from a PRG because risk managers may consider details of the site-specific exposure, various uncertainties in the risk estimate, and implementation issues (e.g., the technical feasibility of achieving the PRG).

## EXHIBIT 5-2

### DEFINITIONS FOR CHAPTER 5

95% UCL for mean - The one-sided 95% upper confidence limit for a population mean; if a sample of size ( $n$ ) was repeatedly drawn from the population, the 95% UCL will equal or exceed the true population mean 95% of the time. It is a measure of uncertainty in the mean, not to be confused with the 95<sup>th</sup> percentile (see below), which is a measure of variability. As sample size increases, the difference between the UCL for the mean and the true mean decreases, while the 95<sup>th</sup> percentile of the distribution remains relatively unchanged.

95<sup>th</sup> Percentile - The number in a distribution that is greater than 95% of the other values of the distribution, and less than 5% of the values. When estimated from a sample, this quantity may be equal to an observed value, or interpolated from among two values.

Applicable or Relevant and Appropriate Requirements (ARARs) - Federal or state environmental standards; the NCP states that ARARs should be considered in determining remediation goals. ARARs may be selected as site-specific cleanup levels.

Backcalculation - A method of calculating a PRG that involves algebraic rearrangement of the risk equation to solve for concentration as a function of risk, exposure, and toxicity.

Bootstrap Methods - Parametric and non-parametric methods for estimating confidence intervals for a statistic by resampling directly from the data set with replacement.

Coverage - Confidence intervals are expected to enclose a true but unknown parameter according to a specified probability, such as 90% or 95%. This is the expected coverage of the confidence interval, given a specified significance level ( $\alpha$ ). The difference between the expected coverage and the actual coverage is one metric for evaluating statistical methods that yield different confidence intervals.

Exposure Point Concentration (EPC) - The average chemical concentration to which receptors are exposed within an exposure unit. Estimates of the EPC represent the concentration term used in exposure assessment.

Exposure Unit (EU) - For Superfund risk assessment, the geographical area about which a receptor moves and contacts a contaminated medium during the period of the exposure duration.

Forward Calculation - A method of calculating a risk estimate that involves the standard arrangement of the risk equation to solve for risk as a function of concentration, exposure, and toxicity.

Iterative Reduction (IR) - A method of calculating a PRG that involves successively lowering the concentration term until the calculated risk is acceptable. This method can be applied to any medium.

Iterative Truncation (IT) - A method of calculating a PRG that involves developing an expression for the concentration term in which higher values of concentration are removed or "truncated" to reduce the maximum concentration, and re-calculating risks associated with the reduced concentration. The method may be repeated with consecutively lower truncation limits until risk is acceptable.

Land Method - The conventional method for calculating uncertainty in the mean concentration (e.g., 95% UCL) when the sample data are obtained from a lognormal distribution (U.S. EPA, 1992).

Maximum Detected Concentration (MDC) - The maximum concentration detected in a sample.

True Mean Concentration - The actual average concentration in an exposure unit. Even with extensive sampling, the true mean cannot be known. Only an estimate of the true mean is possible. A greater number of representative samples increases confidence that the estimate of the mean more closely represents the true mean.

Two Office of Solid Waste and Emergency Response (OSWER) guidance documents in preparation: (1) *Draft Guidance on Calculation of Upper Confidence Limits for Exposure Point Concentrations at Superfund Sites* (U.S. EPA, 2001a), and (2) *Draft Guidance on Surface Soil Cleanup at Superfund Sites: Applying Cleanup Levels* (U.S. EPA, 2001b), also address topics related to the calculation of EPCs and comparison of those EPCs to a PRG.

In practice, calculations of risks, given concentration data, are commonly referred to as “forward calculations”, while calculations of PRGs, based on chosen target risk levels, are referred to as “back-calculations”. This terminology reflects the algebraic rearrangement of the standard risk equation needed to solve for the concentration term when point estimates are used to characterize exposure and toxicity input variables. For probabilistic risk assessment (PRA), the process for developing a PRG can be more complex. This chapter presents methods and recommendations for developing site-specific PRGs within the framework of PRA.

### ***Are there different types of PRGs?***

Generic PRGs have been developed for some chemicals and exposure media using point estimates based on standard default exposure assumptions (e.g., U.S. EPA, 1991b) and toxicity criteria available in the Integrated Risk Information System (IRIS) or Health Effects Assessment Summary Table(s) (HEAST) or from Environmental Protection Agency’s (EPA’s) National Center for Environmental Assessment. Soil Screening Guidance levels, Region 9’s PRG table and Region 3’s Risk Based Concentrations (RBCs) table are examples of generic point estimate PRGs. Generic PRGs are often used for screening chemicals of potential concern in Data Evaluation and Hazard Identification steps of the risk assessment process.

☞ *There is a clear distinction between generic PRGs, site-specific PRGs, remediation goals (RGs), and cleanup levels. The focus of this chapter is on site-specific PRGs.*

At this time, EPA does not recommend the use of PRA to develop generic PRGs. Until the science and policy decisions associated with the use of default assumptions in PRA have evolved, generic PRGs should only be developed from point estimate methods, as was done in the examples listed above.

As indicated in Exhibit 5-1, site-specific PRGs generally are developed after the baseline risk assessment. However, during the feasibility study or even later in the Superfund process, the methods described in this chapter may be used to modify cleanup levels at the discretion of the risk manager. However, it is generally not appropriate to use PRA for modifying cleanup levels during the feasibility study if PRA was not used in the baseline risk assessment.

☞ *Risk-based PRGs are initial guidelines and do not represent final cleanup levels.*

Only after appropriate analysis in the remedial investigation/feasibility study (RI/FS), consideration of public comments, and issuance of the record of decision (ROD) does a RG become a final cleanup level. A cleanup level may differ from a RG because risk managers may consider various uncertainties in the risk estimate. While the two main criteria for determining a cleanup level are: (1) protection of human health and the environment, and (2) compliance with applicable or relevant and appropriate requirements (ARARs), a cleanup level may differ from the RG because of modifying criteria, such as feasibility, permanence, state and community acceptance, and cost effectiveness. These and other factors are reflected in the nine evaluation criteria outlined in the NCP (U.S. EPA, 1990a; 40CFR §300.430(e)(9)(iii)) (see Chapter 1, Exhibit 1-2).

This chapter and Appendix C provide a comprehensive description of the issues associated with developing site-specific PRGs with both point estimate and probabilistic approaches, including the use of geostatistics. Because methods for calculating a 95% upper confidence limit for the mean (95% UCL) are discussed fully in the *Draft Guidance on Calculation of Upper Confidence Limits for Exposure Point Concentrations at Superfund Sites* (U.S. EPA, 2001a) and *Draft Guidance on Surface Soil Cleanup at Superfund Sites: Applying Cleanup Levels* (U.S. EPA, 2001b), they are covered only briefly in this guidance. In general, this chapter, Appendix C, and the Superfund guidance under development should be consulted by risk assessors when developing site-specific PRGs.

## 5.1 GENERAL CONCEPTS REGARDING EPCs AND PRGS

PRGs developed from point estimate risk assessments and PRAs will be discussed in this section to compare and contrast the two approaches. The PRG is a special case of the concentration term (or EPC) in the risk equation. The intent of the EPC is to represent the average chemical concentration in an environmental medium in an exposure unit (EU) (i.e., the area throughout which a receptor moves for the duration of exposure). The EPC should be determined for individual EUs within a site. Because an EPC is calculated from a sample, there is uncertainty that the sample mean equals the true mean concentration within the EU; therefore, to account for associated uncertainty, the 95% upper confidence limit for the mean (95% UCL) is generally used for Superfund risk assessments (U.S. EPA, 1992). For both point estimate and probabilistic approaches, the PRG is an assumed value of the EPC that yields a risk estimate that is at or below an acceptable risk level.

*☞ The EPC usually represents the average concentration within the EU estimated from a sample; the PRG usually represents the average concentration within the EU that corresponds to an acceptable level of risk.*

The PRG may be thought of as a goal for the post-remediation EPC (see Section 5.1.2). Specifically, after remediation is completed, the average concentration (or the 95% UCL used as a measure of uncertainty in the average) for the EU should be sufficiently low to be protective of human health and the ecosystem. While the methods used to calculate the pre- and post-remediation EPC may differ, the interpretation of the EPC remains constant. For example, if the 95% UCL is used to represent the EPC before remediation, then the EPC following remediation (e.g., the PRG) should also represent a 95% UCL (Bowers et al., 1996).

Risk assessors may consider both variability and uncertainty in the development of an EPC. The calculation of a 95% UCL generally requires knowledge of not only chemical concentration measurements within the EU but also the receptor's behavior. Relevant information may include the variability in concentrations in the given sample, the sampling locations, and variability in the movement and activity patterns of receptors within the EU. A discussion of spatial and temporal variability associated with characterizing contamination in different exposure media is presented in Appendix C, and important sources of uncertainty in the EPC are discussed in Section 5.1.1.

For all risk assessments, chemical concentration measurements should be collected in a manner that is consistent with an understanding of both the source of contamination and the definition of the exposure unit. An investment of time and resources should be made in planning, scoping, and problem formulation. Part of this investment is to follow the Data Quality Objectives (DQO) process to obtain samples appropriate for the risk assessment and sufficient to support the remedial decision (U.S. EPA, 1993, 1994, 2000). Using new methods of sample collection and analysis such as dynamic workplans and real-time analysis may enable risk managers to get the most "bang for the buck" from the resources available for site characterization. Information about these methods and the DQO process is available from EPA's Office of Emergency and Remedial Response (U.S. EPA,

2001c) and Technology Innovation Office (U.S. EPA, 2001d, 2001e). The world wide web address is [http://clu-in.org/char1\\_edu.cfm#syst\\_plan](http://clu-in.org/char1_edu.cfm#syst_plan).

### 5.1.1 SOURCES OF UNCERTAINTY IN THE EPC

The 95% UCL is generally used as the EPC to represent uncertainty in the mean concentration in both the central tendency exposure (CTE) and reasonable maximum exposure (RME) risk estimates for Superfund (U.S. EPA, 1992). Similarly, in PRA, a probability distribution for uncertainty may be used in a two-dimensional Monte Carlo analysis (2-D MCA) simulation (see Appendix D) to represent a source of uncertainty in the EPC. There are numerous potential sources of uncertainty in the estimate of the true mean concentration within the EU. The sources of uncertainty when the EPC is expressed as either a single number or a distribution are the same and can be grouped into the following four broad categories:

- (1) ***Uncertainty in the sample data.*** A limited number of measurements in the sample are used to make inferences about the EPC and the spatial distribution of concentrations at a site. Uncertainties may arise from many factors, including both sampling variability and measurement error. As the number of samples increases, the uncertainty generally decreases (e.g., more information will be available to characterize the spatial distribution and variation in concentration). In point estimate risk assessments, the 95% UCL is generally used as the EPC to account for the uncertainty in estimating the average concentration within an EU.
- (2) ***Uncertainty about the location of the EU.*** When the size of a receptor's EU is less than the size of the site, the placement of the EU may be a source of uncertainty, especially when the contamination is distributed unevenly across the site and the PRA includes exposure scenarios for future land uses.
- (3) ***Uncertainty in the behavior of the receptor.*** Even in the case of extremely well characterized sites, it remains uncertain whether the receptor will contact the environmental medium in a temporal and/or spatial distribution that can be adequately represented by the environmental samples collected.
- (4) ***Uncertainty in chemical concentrations over time.*** The concentration in a given medium may undergo temporal changes, which may introduce uncertainty in estimates of a long-term average. Examples include the movement or attenuation of a solvent plume in groundwater; aerobic or anaerobic degradation; the change in the average concentration in a fish population due to changes in population dynamics; and the mixing of surface and subsurface soil over time.

A lack of knowledge in all four categories may be considered when selecting approaches to quantify uncertainty in the concentration term. One of the first steps in quantifying uncertainty is to define the EU, or the geographical area in which individual receptors are randomly exposed for a relevant exposure duration. Depending on the receptor's movement and activities, an EU may be as small as a child's play area (e.g., sandbox) or as large as the foraging area of an upper trophic level animal predator (e.g., an entire military base). The relationship between the size of the EU, the movements of the target receptor, and health endpoint of concern (i.e., acute or chronic) may dictate the appropriate use of sample data in developing an EPC. One of the assumptions generally made for the concentration term in Superfund risk assessment is that receptors contact all parts of an EU at random, and that measurements are obtained from a simple (or stratified) random sample. If an individual is randomly exposed within the same EU over a long period of time, the most appropriate metric for the EPC would be the true (but unknown) population mean of the concentrations within the EU (e.g., 95% UCL).

Often, the scale of the EU will be different (smaller or larger) than the scale of the sample data. For example, an ecological receptor population may have a small home range relative to the size of the entire site, or the endpoint of concern may be acute toxicity, requiring an evaluation of a short-term exposure scenario. If the receptors are not expected to contact all parts of the site with equal probability, then the EU may be redefined so that only a subset of the data collected for site characterization are used to estimate the EPC. In addition, the location of the EU may be unspecified within the site because there may be multiple areas that provide suitable habitat for the receptor population. Departing from the assumption of random exposure within one unique geographic area presents an additional challenge to estimating an EPC. In some cases, it may be informative to develop multiple estimates of the EPC in a PRA. By treating the EPC as a random variable, risk assessors can explore the effect of uncertainty in the location of the EU. A variety of modeling approaches are available to calculate an EPC (e.g., arithmetic mean, or 95% UCL) based on the spatial variability in chemical concentrations measured over an area larger than the EU. Methods such as geostatistics (see Section 5.5.2 and Appendix D), Microexposure Event Modeling (MEE) (see Appendix D), and random walk scenarios (Hope, 2000, 2001) may be used to quantify both the spatial and temporal variability in exposure to varying concentrations. Using these methods, risk assessors may redefine the EU to be more representative of the random movement of the receptor during the period of exposure. Because these modeling approaches may be considered more advanced methods for quantifying the EPC, they are generally considered in Tier 3 of the PRA process (see Chapter 2).

### **5.1.2 PRE- AND POST-REMEDATION EXPOSURE POINT CONCENTRATIONS**

The differences between pre- and post-remediation EPCs are discussed below. In general, both estimates of the EPC are based on the same concepts regarding the exposed population and the definition of the EU. However, the post-remediation EPC will tend to yield lower estimates of (post-remediation) risk and can require more advanced methods for calculating uncertainty (e.g., 95% UCL).

The pre-remediation EPC is determined based on existing site sampling at the time of the remedial investigation, prior to remediation. By contrast, the post-remediation EPC generally is determined based on a prediction of site conditions after remediation. For example, in surface soil, the post-remediation EPC can be determined by substituting the nondetect level (generally, half the laboratory reporting limit) for some of the high concentrations in the sample and recalculating the EPC. The underlying assumption in calculating a post-remediation EPC is that remediation will have sufficiently reduced the chemical concentrations at the site, and the risk existing after remediation is complete will be equal to or less than the target risk level of concern.

The preceding discussion is most applicable to surface soil PRGs. In general, compared with other exposure media (e.g., groundwater, air), surface soil is stationary with relatively constant chemical concentrations within an EU. For other environmental media, more complex approaches may be needed to estimate the post-remediation EPC. Modeling of the remediation process may introduce additional uncertainty not encountered in risk estimates based on the pre-remediation EPC.

### **5.1.3 REMEDIATION ACTION LEVELS (RALs) AND 95% UCL CALCULATION METHODS**

The EPC should incorporate knowledge about the spatial distribution of contamination, the behavior of the receptor, the location of the EU, land use, and other factors. These factors affect both the numerical value of an EPC and uncertainty associated with this estimate. In many cases, it is presumed factors associated with land use will not change after remediation.

The remediation action level (RAL) is the maximum concentration that may be left in place at any location within an EU such that the average concentration (or 95% UCL as a measure of the average) will not

present a risk above levels of concern. This RAL may be considered a “not-to-exceed” threshold or action level for the purposes of site remediation. Using surface soil as an example, areas within the EU that have concentrations greater than the RAL may be excavated and replaced with clean fill (e.g., nondetect surrogate values). To obtain a post-remediation EPC, the 95% UCL is calculated after substituting the surrogate nondetect value for all measurements located within the EU that are greater than the RAL.

When appropriate, the same statistical method of uncertainty should be used to estimate UCLs for both the pre- and post-remediation EPCs. However, in some instances, the method used for calculating the pre-remediation EPC will be inappropriate for calculating the post-remediation EPC, because the distribution of contaminant concentration will have changed. For example, pre-remediation site sampling may suggest that variability in concentrations can be reasonably characterized by a lognormal distribution, which would support the use of the Land method for estimating the 95% UCL. The post-remediation site conditions, however, may reflect a mixture of clean fill and contamination, resulting in a poor fit to a lognormal distribution (see Figure 5-3, Section 5.5.3). In this case, the Land method would not be appropriate. Because of the difference in the statistical distribution of concentration measurements used to estimate the pre-remediation EPC and post-remediation EPC, a non-parametric (i.e., distribution free) method should be considered for calculating uncertainty in the average concentrations in both pre- and post-remediation scenarios. In general, when the method used to calculate the 95% UCL for a post-remediation scenario is different than that of the pre-remediation scenario, the 95% UCL for the pre-remediation scenario should be recalculated with the post-remediation method. Results of this change in methodology can be presented as part of a quantitative uncertainty analysis. Specifically, this recalculation will allow for an evaluation of the effect that a RAL has on the confidence interval for the mean. The discordance between pre- and post-remediation distributions can be expected to increase as the degree of remediation needed to achieve a target risk level of concern increases.

In general, risk assessors should be aware of the practical and statistical issues associated with the various methods of calculating the 95% UCL, and the application of these methods to both the pre- and post-remediation concentration distribution. Different methods can yield very different confidence intervals, some of which are expected to yield more accurate coverage (i.e., likelihood that the confidence interval includes the parameter) depending on characteristics of the underlying distribution of concentrations, such as distribution shape, sample size, and variance (Gilbert, 1987; Hall, 1988). Information about a variety of parametric and non-parametric methods, such as bootstrap resampling, can be found in *The Lognormal Distribution in Environmental Applications* (U.S. EPA, 1997), *Estimating EPCs When the Distribution is Neither Normal nor Lognormal* (Schulz and Griffin, 1999) and a Superfund guidance document currently under development, *Draft Guidance on Calculation of Upper Confidence Limits for Exposure Point Concentrations at Superfund Sites* (U.S. EPA, 2001a).

#### **5.1.4 CONSIDERATION OF RISK FROM ACUTE TOXICITY**

Sometimes a risk assessment will need to address more than one health endpoint of concern (e.g., cancer and noncancer). The RAL should be sufficiently low so that it is simultaneously protective of each endpoint of concern. Generally, when acute toxicity is a concern, the long-term average concentration across the entire EU may not be the appropriate metric for assessing risks. For example, a single episode of a child ingesting a handful of soil containing malathion may result in an acute toxic effect to that child. Therefore, the RAL must not only be low enough to reduce the post-remediation EPC to acceptable long-term average levels, but also low enough that acute toxicity will not be an issue. This consideration applies to both point estimate and probabilistic estimates of PRGs.

*For consideration of acute toxicity, the risk assessor should consult, as appropriate, with a toxicologist in the development of RALs.*

For a small number of chemicals, toxicity values have been determined based on acute effects (e.g., nitrate in drinking water). However, at present, EPA does not have acute toxicity criteria or guidance on acute toxicity applied to the RAL. Hence, consultation with a toxicologist is vital.

### **5.1.5 CHARACTERIZATION OF UNCERTAINTY IN THE EPC: POINT ESTIMATES AND DISTRIBUTIONS**

In point estimate risk assessments, the 95% UCL is typically used to characterize uncertainty in the EPC (U.S. EPA, 1992). In PRA, either a point estimate (e.g., 95% UCL) or a probability distribution may be used to characterize uncertainty in the concentration term. The probability distribution may characterize either variability or uncertainty. The terms probability distribution for variability (PDF<sub>v</sub>) and probability distribution for uncertainty (PDF<sub>u</sub>) can be used to distinguish between probability distributions for variability and uncertainty, respectively.

The decision to use a point estimate, PDF<sub>v</sub>, or PDF<sub>u</sub>, as the input for the concentration term in a Monte Carlo model will depend on the goals of the Monte Carlo simulation, as determined by the tiered process (see Chapter 2). If the goal is to characterize variability in risk, in general, a one-dimensional Monte Carlo analysis (1-D MCA) will be used and the appropriate input for the concentration term will be a point estimate that characterizes uncertainty in the mean concentration within the EU. As explained in Section 5.1.1, risk assessors will need to consider the relationship between the size of the EU, the movements of the target receptor, and health endpoint of concern (i.e., acute or chronic) to determine how to use the available sample data to define the EPC. A PDF<sub>u</sub> is typically not an appropriate choice for the concentration term in a 1-D MCA when the goal is to characterize variability in risk. Mixing of a PDF<sub>u</sub> for the concentration term with PDF<sub>v</sub>'s for other exposure variables in 1-D MCA would yield a single risk distribution from which the relative contributions of variability and uncertainty could not be evaluated. Use of a PDF<sub>u</sub> for the concentration term may be considered in 2-D MCA simulations (see Appendix D), where the goal may be to characterize both variability and uncertainty in risk.

When the sample size is small and the variance is large, the 95% UCL may exceed the maximum detected concentration (MDC). In such a case, the MDC is generally used to estimate the EPC, although the true mean may still be higher than this maximum value (U.S. EPA, 1992). For poorly characterized sites, there may be considerable uncertainty that site remediation will be sufficient to reduce the 95% UCL to a health-protective level. Poor site characterization may provide an impetus for the risk manager to opt for a more health-protective remedial alternative or to collect additional data.

To ensure that actual cleanup based on a RAL is protective generally requires post-remediation confirmation sampling. This step in the risk management process is emphasized further in Section 5.8 on measurement of attainment.

### **5.1.6 MULTIPLE CHEMICALS**

Developing PRGs for multiple chemicals in one or more environmental media is particularly challenging. When multiple chemicals are present, the total risk level should be considered for regulatory purposes with each chemical contributing a portion of the total risk. This issue is quite complex and usually will affect both the calculation of the risk and development of site-specific PRGs. Chemicals may exhibit different spatial and temporal variability within the EU. Fate and transport characteristics may vary between chemicals as well as between different areas of the site. Co-located sampling, or geostatistical techniques (e.g., co-kriging) may

provide insights regarding relationships in spatial patterns for different chemicals (see Appendices C and D) and the corresponding exposures for receptors.

## 5.2 WHEN TO USE PRA FOR DEVELOPING PRGs

Because point estimate risk assessments and PRA employ different approaches to characterize variability and uncertainty, the resulting RME risk estimates and calculations of PRGs are often different. The magnitude of the difference can depend on many factors, including the number of input variables described with probability distributions in the PRA, the choice of distributions used to characterize variability or uncertainty (especially for those variables that are highly ranked in a sensitivity analysis), the percentile of the probability distribution that corresponds with RME point estimate for each input variable, and the choice of percentile from the PRA used to represent the RME risk (e.g., 95<sup>th</sup> percentile). Since the results of a point estimate approach and PRA can be expected to differ, but the magnitude of the difference is not known *a priori*, this can present a challenge in deciding whether or not to conduct a PRA to develop a PRG. The potential advantages and disadvantages of both the point estimate approach and the PRA can be factored into the decision (see Chapter 1, Exhibits 1-6 and 1-7).

In general, PRA may be appropriate for developing site-specific PRGs in cases where PRA has also been used to estimate site-specific risks. As indicated by the tiered approach (see Chapter 2), if the risk manager determines that quantifying variability and uncertainty may enhance risk management decision making, PRA may be warranted. If a PRA is feasible, the risk manager should proceed to Tier 2 and employ PRA to complete the RI/FS process. Usually, embedded in a site-specific PRG are all of the exposure assumptions and toxicity metrics used in the risk assessment. Hence, introducing the use of PRA for PRGs in the feasibility study (or any time after the remedial investigation and baseline risk assessment are complete) would, in effect, undermine the tiered approach.

*☞ If only point estimates were used in the risk assessment, probabilistic methods should not be used for PRG development.*

If additional data have been collected to conduct PRA, the point estimate risk assessment should be revisited with the new data as well. As discussed in Chapter 2, a point estimate risk assessment (Tier 1) should always accompany a PRA. PRA is intended to enhance risk management decision making, and should not be viewed as a substitute for point estimate approaches. Using the tiered approach, a risk assessor can determine the appropriate level of complexity that is supported by the available information to conduct the risk assessment and to calculate a PRG.

## 5.3 METHODS FOR DEVELOPING PRGs

Risk assessors may use PRA to quantify sources of uncertainty and variability in the calculation of PRGs as well as risks. Two of the common methods for calculating PRGs in PRA include: (1) backcalculation (see Section 5.4), which is equivalent in concept to the point estimate calculation of a PRG; and (2) iterative forward calculation methods, including iterative reduction and iterative truncation (see Section 5.5). Backcalculation can be used in PRA when the target risk and concentration terms are expressed as point estimates. Iterative methods can be more involved, but unlike backcalculation, there are no constraints on their application to PRA. The two approaches yield the same result when the same assumptions are used in the risk assessment.

## 5.4 BACKCALCULATION

Traditionally, risk is calculated as a function of multiple exposure variables, including the concentration term, and toxicity value (Equation 5-1). If one or more of the exposure variables is described by a PDF, a Monte Carlo simulation will yield a distribution for risk (see Chapter 1).

Backcalculation methods can be envisioned as setting a target risk level (e.g., RME risk equal to  $10^{-6}$  or Hazard Index equal to 1) and then algebraically reversing the risk equation to solve for the concentration term (Equation 5-2). A Monte Carlo simulation using Equation 5-2 will yield a distribution of concentrations that reflects the combination of distributions from all other exposure variables.

$$\frac{C \times IR \times EF \times ED}{BW \times AT} = Intake$$

$$Intake \times Toxicity = Risk$$

$$C \times V = Risk$$

Equation 5-1

$$C = Risk \times V^{-1}$$

Equation 5-2

where,

<i>Toxicity</i>	=	toxicity term representing either the cancer slope factor (CSF) or reference dose (1/RfD) for the chemical in the exposure medium
<i>C</i>	=	concentration term
<i>V</i>	=	algebraic combination of the toxicity term with all exposure variables except <i>C</i>
<i>IR</i>	=	ingestion or inhalation rate
<i>AT</i>	=	averaging time
<i>BW</i>	=	body weight
<i>ED</i>	=	exposure duration
<i>EF</i>	=	exposure frequency

This calculation produces a distribution of PRGs that represents the same sources of variability as a forward calculation of risk. Each percentile of the PRG distribution (i.e., the  $\alpha$  percentile) corresponds to the  $1-\alpha$  percentile from the distribution of risk estimates. For example, if the 95<sup>th</sup> percentile of the distribution of risk estimates was chosen to represent the RME individual, the 5<sup>th</sup> percentile ( $1-0.95=0.05$ ) would be the corresponding concentration value from the distribution of PRGs (Bowers, 1999). The correspondence between the risk distribution and the PRG distribution is intuitive—just as selecting a higher percentile on the risk distribution is more protective, a lower percentile on the PRG distribution is more protective. The RME range for the risk distribution 90<sup>th</sup> to 99.9<sup>th</sup> percentile is analogous to an RME range for the PRG distribution of 0.1<sup>st</sup> to 10<sup>th</sup> percentile.

Backcalculation has been a familiar method of developing PRGs and may be appropriate in some situations for the sake of clarity and transparency due to the general understanding of this method among risk assessment practitioners. Once a backcalculation has been performed to determine a PRG, the PRG should be used as the concentration term in a forward calculation to ensure that the risk at the PRG is acceptable.

### 5.4.1 DIFFICULTIES WITH BACKCALCULATION

There are limitations in the use of backcalculation in PRA (Ferson, 1996). Simple rearrangement of Equation 5-1 does not suffice when the variable (i.e., the concentration or risk term) that is backcalculated is represented by a probability distribution (Burmester et al., 1995; Ferson, 1996). The difficulty for PRA arises because each risk estimate from an MCA that uses the familiar “forward-facing” risk equation represents a combination of random values selected from the input distributions. Therefore, the output can be considered conditional on all of the inputs. Rearranging the risk equation does not maintain the same conditional probabilities; therefore, the distribution for risk estimated as a function of the distribution for concentration in Equation 5-1 does not return the same distribution for concentration when applied in Equation 5-2. While there are techniques that can maintain the dependencies and correlations between exposure factors when the risk equation is rearranged (e.g., deconvolution), they are complex and beyond the scope of this guidance.

Backcalculation methods may also be difficult to implement in situations in which complex fate-and-transport considerations are present. Leaching of soil contamination to groundwater, bioconcentration of chemicals at higher trophic levels, and other multimedia processes that result in exposure via several environmental media are situations in which backcalculation may not be useful. Note that these difficulties are not unique to backcalculation. Uncertainty in fate-and-transport considerations makes any type of PRG determination challenging.

Further, the backcalculation approach only provides information on the EPC that corresponds to a risk level of concern; it does not specify an RAL that would achieve this EPC. For example, when a risk equation is algebraically solved for concentration (see Equation 5-2), a PRG is developed without a corresponding RAL. Thus, there is no information associated with the PRG value to indicate the highest concentration in the EU that must be removed so that the average concentration (or 95% UCL) within the EU is at or below the PRG. Hence, additional efforts are needed. In addition, post-remediation concentrations may need to satisfy more than one regulatory constraint. For example, the average (or 95% UCL) concentration within an EU may need to be less than a concentration associated with chronic toxicity or cancer and simultaneously, the RAL concentration may need to be less than a concentration that might cause acute toxicity.

In spite of these caveats, backcalculation methods may be appropriate for some sites. For example, when the target risk is specified by a single numerical value and the risk manager has chosen a percentile of variability to represent the RME individual, then a backcalculated PRG can be derived from a PRA.

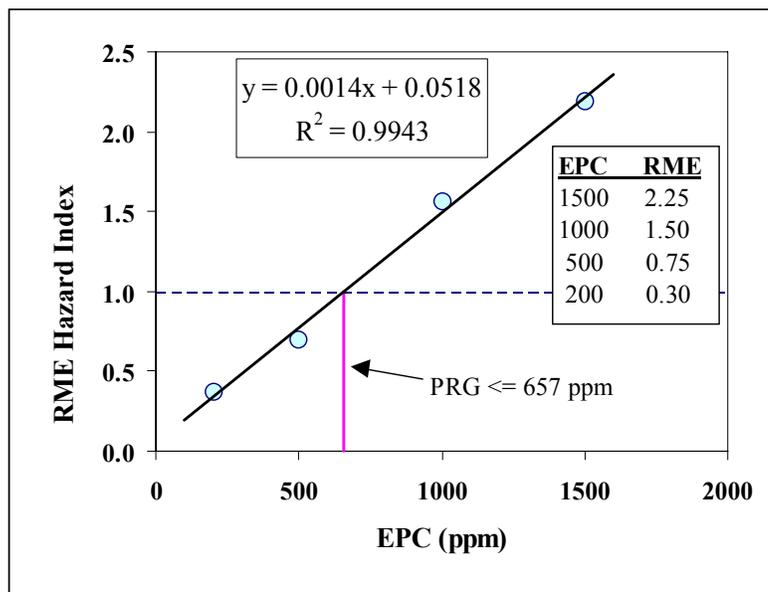
Although backcalculation methods may be appropriate for some sites, risk assessors should be familiar with their limitations. Because of these limitations, this guidance recommends iterative forward calculations as the primary method for calculating PRGs when performing a PRA. Iterative methods avoid difficulties associated with applying MCA to a backcalculation, and can provide more information for the risk manager.

## 5.5 ITERATIVE METHODS

Iterative methods simply involve calculating risk with the “forward-facing” equation (see Equation 5-1) a number of times (iteratively) using progressively lower values for the concentration term until the risk is sufficiently protective. This iterative method has also been called the “repeated runs” method. Note that iterative methods for calculating a PRG are not uniquely applicable to PRA. Iterative methods also may be used to develop PRGs in point estimate risk assessments.

EPA recommends iterative simulations as a general approach for calculating PRGs from probabilistic risk assessments.

Most often, iterative forward calculations are performed using a systematic trial-and-error method until the percentile of variability in risk chosen to represent the RME individual is at or below acceptable risk levels. Sometimes, a short cut can be used to reduce the number of simulations needed with the trial-and-error method. If successive “guesses” of the EPC are plotted with the corresponding risk estimate, the exact solution can be determined from the best-fit line, thereby significantly reducing the effort required to implement this method. An example is given in Figure 5-1. For many risk equations, the relationship between the EPC and the RME risk will be approximately linear. Nevertheless, the final estimate of the EPC should be checked by running another simulation for risk with this estimate.



**Figure 5-1.** A hypothetical example of the use of iterative methods to determine the EPC that corresponds with a target RME Hazard Index (HI) of 1.0. Assume that the EPC is represented by the 95% UCL and the RME HI is the 95<sup>th</sup> percentile of the output distribution. In this case, four separate Monte Carlo simulations were run with iteratively decreasing values for the EPC. The least-squares, best-fit line to these four data points suggests that a reasonable PRG would be approximately 660 ppm.

A possible and significant advantage of iterative forward calculations over back-calculations is that the method is intuitive and yields a distribution of risks rather than a distribution of PRGs (as with a back-calculation method). The distribution of risks will be more familiar to the public and other stakeholders, and thus, both the method and the resulting output may be easier to communicate to senior level managers and stakeholders (see Chapter 6).

Two general types of iterative methods are described in more detail in Sections 5.5.1 and 5.5.2. The main difference between the methods is in the interpretation of the concentration term that is being reduced. With iterative reduction, the concentration is assumed to be the post-remediation EPC, whereas with iterative truncation, it represents the RAL needed to achieve a post-remediation EPC.

### 5.5.1 ITERATIVE REDUCTION

Iterative reduction can be applied to any medium. Generally, a point estimate representing the EPC (e.g., 95% UCL) is successively lowered, each time repeating the Monte Carlo simulation of variability in risk. When the EPC is reduced until the endpoint of concern (e.g., RME risk corresponding to the 95<sup>th</sup> percentile) is at or below an acceptable level of risk, the PRG is set at the corresponding EPC. The goal is to identify the point estimate that corresponds to a target risk level. Note that the PRG is not the same as the RAL. The RAL is the maximum concentration that may be left in place within an EU to achieve the PRG.

The concentration at which the risk is acceptable defines the PRG. Therefore, the PRG bears the same uncertainties as the EPC. For example, assume that a risk assessor examined the carcinogenic effects from

chronic consumption of a chemical in groundwater, then the exposure unit may be determined by the long-term average concentration at any well that potentially draws drinking water from the contaminated groundwater. Uncertainty in the long-term average concentration can reflect a number of factors that contribute to spatial and temporal variability, including the direction of groundwater flow, natural attenuation, and other fate and transport variables. Remediation by a pump-and-treat system for a prolonged period of time may be used to lower the concentrations at the wells. Even though the remediation strategy may be complicated by spatial and temporal variability, iterative reduction can be used to establish a PRG. A remediation strategy may be considered a potential candidate if it can achieve the PRG by reducing the average concentration at each of the well locations. The concept of “hot-spot” removal, or truncation of the highest concentrations first, would not be an option under this scenario (see Section 5.5.2).

### 5.5.2 ITERATIVE TRUNCATION

Iterative truncation is a method of calculating a PRG that involves developing an expression for the concentration term in which higher values of concentration are removed or “truncated” to reduce the maximum concentration. These higher values are replaced by the surrogate nondetect value. The risk is recalculated for each successive reduction in the highest value. The method is repeated with consecutively lower truncation limits until risk is acceptable.

Iterative truncation is most applicable to surface soil cleanup as the spatial variability over time is minimal compared to other media (e.g., surface water). With each iteration of the risk equation (e.g., Equation 5-1), the highest concentration value is truncated corresponding to a different RAL. In this way a “not-to-exceed” level is specified and the PRG is recalculated the same way in each iteration. The process continues until the risk distribution yields risk estimates at or below the level of concern.

Iterative truncation can be applied to either the empirical distribution function (EDF) for the concentration term, or a fitted distribution for variability in concentrations within the EU. Applied to the EDF, the maximum detected concentration within the EU is replaced with a surrogate value for a nondetect (e.g., half the reporting limit or the background value for some chemicals), and the EPC (e.g., 95% UCL) is recalculated for this altered data set. If this new EPC yields unacceptable risk, then the two highest detected concentrations are replaced by the nondetect value and the EPC is recalculated. In the third iteration, the three highest detections are replaced, and so on, until the target risk level is achieved. Alternatively, the sample data may be fit to a probability distribution for variability, and the process would be repeated with decreasing values in the high-end tail of the continuous distribution.

When the concentration term is a distribution representing uncertainty in the mean concentration, then, similar to the recalculation of the point estimate 95% UCL described above, this distribution of uncertainty in the mean concentration should be determined anew each time a datum is replaced with the nondetect value.

When a distribution of variability in concentration is used for the EPC, for example, in an ecological risk assessment where sampling may be sparse relative to the foraging area of a small home range receptor (see Appendix C), then the distribution developed in an identical way with the high values replaced by the surrogate nondetect value should be used in the iterative determination of a PRG.

The decision to apply iterative truncation should be made after considering a variety of characteristics of the sample data and post-remediation scenario (see Exhibit 5-3). For example, small sample size may result in high uncertainty in the 95% UCL, thereby limiting the use of iterative truncation. Quantitative criteria regarding these factors are not provided in this guidance given that the level of certainty required for decision making will

vary on a case-by-case basis. Use of geostatistical methods (Appendices C and D) may aid in interpreting site data or improving sampling design. Geostatistics is capable of describing the spatial distribution of a contaminant in a quantitative fashion. These methods establish a correspondence between the actual sampling locations and the locations a receptor would be expected to frequent. Additionally, it enables the estimation of concentrations in unsampled locations. Hence, for determination of concentrations at specific locations at a site or within EUs of various sizes and shapes, geostatistics may provide an invaluable tool. Geostatistics has applications both to developing the EPC and PRG and has been recommended and used at some sites for characterization of soil and groundwater contamination (U.S. EPA, 1990b, 1991c).

Although the consideration and use of geostatistics is encouraged, a full consideration of geostatistics is beyond the scope of this guidance. Those interested in greater detail than provided in Appendices C and D are urged to consult the Superfund guidance document currently under development, *Draft Guidance on Surface Soil Cleanup at Superfund Sites: Applying Cleanup Levels* (U.S. EPA, 2001b), for additional discussion of how geostatistics can be used to quantify the concentration term or the PRG.

Generally, iterative truncation methods fail to produce adequate cleanup strategies when site characterization is incomplete. This problem, however, is not specific to PRA. Both point estimate and probabilistic methods are sensitive to poor site characterization.

Risk assessors should realize that application of iterative truncation may result in areas on-site that have concentrations higher than the PRG. This is because the PRG will reflect an average concentration (or 95% UCL) from a distribution of concentrations in which the maximum is truncated at the RAL. For example, Figure 5-3 (see Section 5.5.3) shows how the concentration distribution can be truncated at an RAL, while still leaving behind concentrations greater than the PRG.

### 5.5.3 EXAMPLE OF ITERATIVE METHODS

The iterative truncation method is easiest to think about with regard to soil cleanup when contaminated soil is removed and replaced with clean fill soil. This replacement would reduce both the mean and 95% UCL. In most cases, risk assessors may assume that the concentrations of chemicals in clean fill soil can be represented by the surrogate nondetect value (e.g., half the detection limit). Alternatively, the fill may be sampled so that the measured concentrations in the fill dirt may be used to calculate the post-remediation

#### EXHIBIT 5-3

##### CRITERIA FOR ITERATIVE TRUNCATION

- 1. Sample size ( $n$ ) is sufficient.** Small sample sizes lead to large estimates of uncertainty in the concentration term. Small sample size may cause the risk assessor to overlook some sources of uncertainty.
- 2. Concentration distribution is not highly skewed.** A highly skewed distribution may yield unreliable estimates of uncertainty, especially for small sample sizes.
- 3. Sampling design yields a representative distribution of measurements within the exposure unit.** Simple random sampling may fail to represent a patchy spatial distribution of contaminants. Similarly, hotspot (e.g., cluster) sampling may fail to represent random movement of receptors. To evaluate potential biases in sampling, analyses with both standard statistical methods and geostatistical methods may be required.
- 4. Assumptions about the post-remedial distribution of concentration are reasonable.** If these assumptions are shown to be incorrect by subsequent sampling events, the process for developing a PRG may need to be repeated and additional remedial activities may be required.

concentration term. Generally, metals and other inorganic chemicals will be present in clean fill, albeit at lower concentrations than on site.

A simple example using the 95% UCL as a point estimate for the EPC is given in Exhibit 5-4. In this example, background concentrations of chemical X were very low and hence, the fill was assumed to have a concentration of half the detection limit. The risk management objective is to identify a PRG in which the 95<sup>th</sup> percentile risk estimate is below 1E-04 and to determine the RAL necessary to achieve this PRG. This example illustrates how iterative truncation is applied to the empirical distribution function, rather than fitting the concentrations to a parametric distribution.

Assume that iterative reduction of the 95% UCL demonstrated that a post-remediation EPC of no greater than 33 mg/kg is needed to achieve a RME risk of 1E-04. What is the RAL that yields this EPC? The risk assessor recognizes that the post-remediation concentration distribution is very often a mixed distribution, consisting of a group of nondetect values and a truncated parametric distribution. Because of the complex nature of mixed distributions (Roeder, 1994), non-parametric methods for calculating the 95% UCL of the arithmetic mean (e.g., bootstrap resampling) were determined to be appropriate (U.S. EPA, 1997; Section 5.1.3).

**EXHIBIT 5-4**

**EXAMPLE OF ITERATIVE METHODS**

**Scoping and Problem Formulation**

Chromium contamination was present at a 12-acre industrial facility. In scoping and problem formulation, all stakeholders agreed that the facility would maintain itself and the current land use would continue into the foreseeable future. Most of the facility area was maintained as green space and as a buffer with the surrounding community. Surrounding the facility to the fence line were lawns and ornamental shrubs tended by landscape workers. These landscape workers were considered to be the high risk group as they would move freely and randomly over the entire area of the facility outside the buildings. Hence, the landscape workers would be exposed to an average concentration over the entire area of the facility outside the buildings. The management of the facility was very cooperative and concerned about their workers. Nonetheless, the facility management did not wish to bear more cost than necessary.

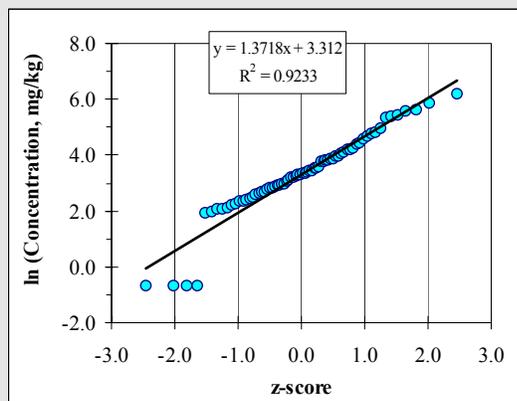
**Site Characterization - Soil Sample (n=70)**

Seventy surface soil samples were obtained using a sampling grid placed over all 12 acres. Five or six sampling locations were placed in each acre. None of the samples was composited. The grid-based sampling permits a rough estimation of the percentage of the site that would need active remediation. The detection limit for the chromium was 1 mg/kg. Four of the samples were nondetects. Sampling results are shown in Table 5-1. Although the samples from the site appeared to occur in a lognormal distribution (Figure 5-2), the presumed post-remediation distribution would be a mixed distribution, consisting of a truncated lognormal distribution and a group of data at the surrogate nondetect value.

**Table 5-1.** Soil sample (n=70) (mg/kg).

0.5	9.7	16.2	25.1	34.0	54.1	120.6
0.5	10.6	17.1	25.4	34.0	57.8	122.2
0.5	10.8	17.4	26.4	36.5	60.2	140.7
0.5	11.0	17.9	26.9	43.3	65.7	211.9
6.8	11.8	18.4	27.1	43.3	66.1	224.1
7.2	12.0	18.6	28.2	45.3	71.8	235.6
7.8	13.7	19.7	28.3	46.4	82.7	266.8
8.0	13.9	19.8	30.3	48.2	84.7	284.0
8.2	14.7	22.0	30.9	49.3	98.1	361.2
9.3	15.0	22.8	31.1	52.6	107.7	486.6

**Figure 5-2.** Lognormal probability plot of soil concentrations, including 4 nondetects.



In this example, a series of iterative truncations showed that removal of all sample results greater than 100 mg/kg (n=11) and replacement of these with the nondetect surrogate of 0.5 mg/kg yielded a 95% UCL of 33 mg/kg and RME risk below 1E-04. Table 5-2 summarizes the results of the calculations for the three conditions: (1) pre-remediation concentrations; (2) post-remediation concentrations using iterative truncation to achieve an RAL of 100 mg/kg; and (3) post-remediation concentrations assuming the 95% UCL calculated is used as the RAL. Note that if the PRG of 33 mg/kg was applied as a “not-to-exceed” level (i.e., RAL), the resulting remediation effort would increase from 15 to 40% of the site, yielding a 95% UCL of 14 mg/kg. While this would be a protective decision, other information was used to support the selection of the second scenario instead. A toxicologist was consulted, who indicated that acute exposure to the workers at levels of 100 mg/kg would not present a health risk. To build additional protectiveness into the remedy, the management also indicated scheduling for the landscape workers would be performed so the areas tended would be rotated among all the workers.

**Table 5-2.** Pre- and Post-Remediation EPCs (95% UCLs) for Chemical X in Surface Soil Samples.

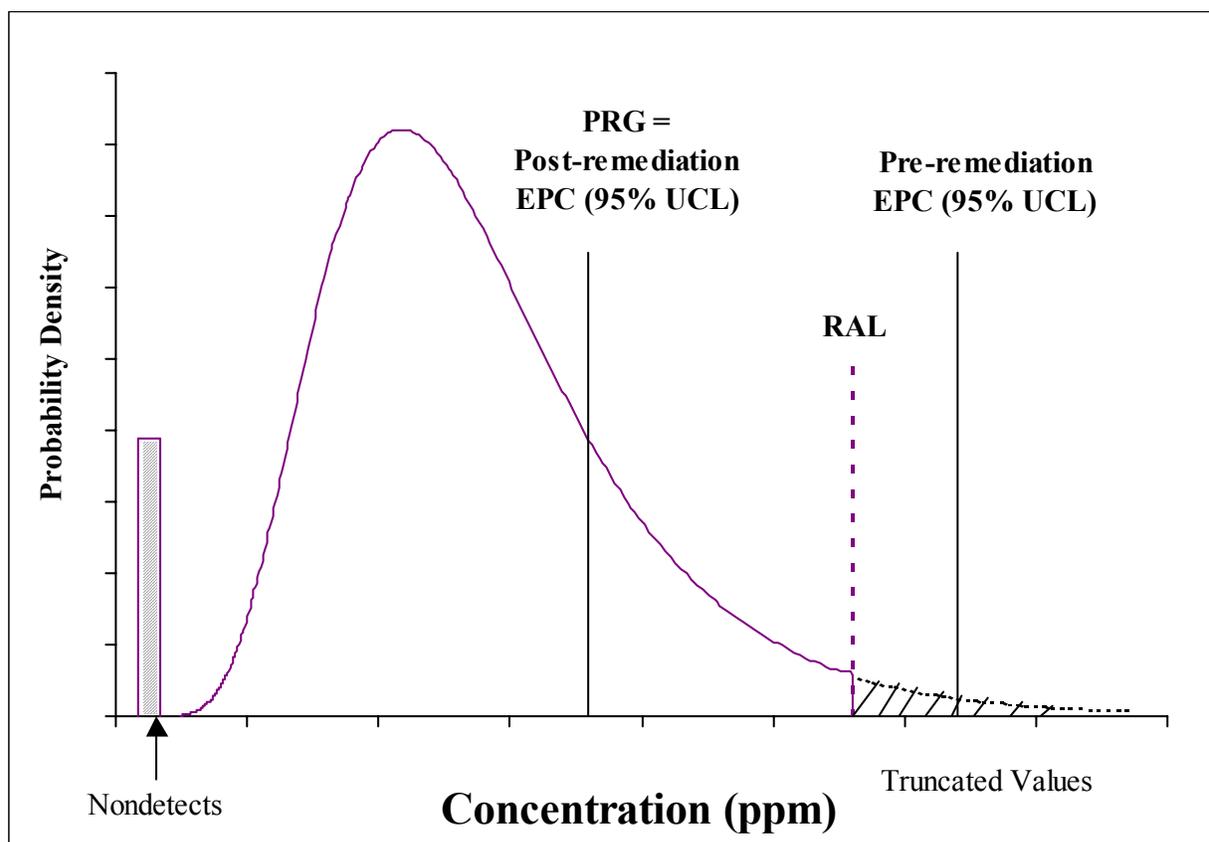
Remediation Scenario	RAL (mg/kg)	EPC (mg/kg) 95% UCL	Percent of Site to be Remediated
1. Pre-remediation	NA	93	NA
2. Post-remediation using the PRG as the 95% UCL	100	33	15%
3. Post-remediation using the PRG as the RAL (i.e., “not-to-exceed”)	33	14	40%

NA=not applicable for a pre-remediation scenario.

Figure 5-3 shows a conceptual framework for considering the post-remediation distribution as a mixture between a group of nondetects and a distribution of contamination truncated at the RAL. Prior to remediation, the EPC exceeds a level that would be protective of human health and ecosystems. If the high-end soil concentrations are removed and the soil is replaced with clean fill, the resulting distribution will be bimodal, with one peak occurring at the nondetect concentration, and the second occurring near the mean of the post-remediation distribution.

#### 5.5.4 MULTIPLE EXPOSURE UNITS AND ITERATIVE METHODS

When multiple EUs are present at the site, there may be a small number of samples within a given EU and the uncertainty in the concentration term generally will be large. It may be possible to use knowledge of the mechanism of how the contamination occurred along with spatial patterns in the sampling results in other nearby EUs to quantify uncertainty. Geostatistical techniques for estimating the mean concentration may provide useful insights into the importance of accounting for spatial relationships among the sample data. Appendix C also provides a discussion of the situation of multiple EUs within a larger site.



**Figure 5-3.** Hypothetical example of a mixed, bimodal distribution that represents a combination of the pre-remediation distribution truncated at the remediation action level (RAL) and a uniform distribution representing clean fill at the surrogate nondetect concentration. Shaded portions represent equal areas. In this example, the PRG is defined by the post-remediation EPC (95% UCL).

## 5.6 PRGs FOR GROUNDWATER

For some chemicals encountered at hazardous waste sites, chemical-specific ARARs may exist, and may be considered as PRGs. ARARs may be selected as site-specific cleanup levels. The maximum contaminant levels of the Safe Drinking Water Act are examples of ARARs.

*For groundwater contamination, ARARs should be applied as RALs if they are protective.*

Of course, for cases in which an ARAR is less protective than a remediation goal determined from a risk assessment, then a risk-based PRG may be developed in accordance with the NCP (U.S. EPA, 1990a).

As an exposure medium, groundwater is the opposite of soil in that groundwater is not static, and receptors are usually exposed at one location (i.e., the well head). Often, a single well can be considered the EU when assessing risks associated with either the residential or industrial/occupational scenarios. The EPC may still reflect the concept of averaging over a long time period (e.g., years) due to potential changes in concentrations in

well water over time. For example, chemical fate and transport modeling may suggest that concentrations are decreasing over time. Similarly, there may be temporal and spatial variability depending on the seasonal fluctuations of the water table. Ideally, the risk assessment would focus on individuals who may be exposed at locations nearest to the center of the contaminant plume, where concentrations are likely to be highest (Freeze and Cherry, 1979; Sposito, et al., 1986).

Because of the uncertainty in the movement of groundwater and the necessity of sampling the medium at fixed locations, identifying a meaningful RAL needed to achieve a given PRG is difficult. In most cases, ARARs will be applicable as RALs or “not-to-exceed” levels.

## **5.7 PRGs FOR OTHER CONTAMINATED MEDIA**

Iterative truncation techniques are generally applied to a static medium, such as soil, rather than dynamic or fluid media such as water and air. This is simply because it is difficult to design a method that will selectively remove high concentrations from a fluid medium. Iterative reduction may be more relevant than iterative truncation when an RAL cannot be developed. These issues are discussed below with respect to sediment, surface water, and fish.

### ***Sediment***

Sediment may be transported over time more readily than soils. If it can be assumed that the sediment remains in place, then iterative truncation techniques may be applied. However, at some sites, sediment may be considered a fluid medium. For example, sediment may be resuspended by the movement of water craft, waves, changing tides, or erosion. Similarly, the depth of the contaminated sediment may change over time as new layers of sediment are deposited above more contaminated sediment.

Exhibit 5-5 gives an example of the use of iterative truncation to evaluate alternative RALs for sediment of a lake contaminated by pesticide runoff. In this example, the RAL is related to both the ecological endpoint of concern (i.e., reduction in reproductive success of mammalian omnivores at the lake) and the fraction of areal extent of the lake that would require remediation at that RAL.

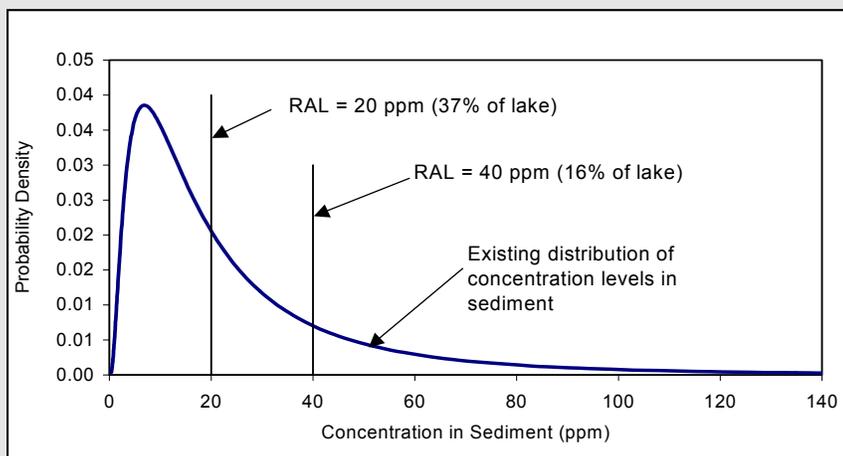
**EXHIBIT 5-5**

**EVALUATION OF ALTERNATIVE RALS USING ITERATIVE TRUNCATION**

Risks to a population of mammalian omnivores residing near a lake contaminated with pesticide "X" were judged to be sufficiently high that a reduction in population number over time was expected (see Chapter 4, Exhibit 4-12). The primary reservoir of pesticide X in the lake is sediment. The BTAG committee decided to use the iterative truncation method to estimate the beneficial effects of a series of different Remedial Action Levels (RALs). PRA was used to predict the distribution of responses (percent reduction in population success) and the areal extent of the lake requiring remediation as a function of RAL. The results are summarized below.

RAL in Sediment	Reduction in Reproductive Success			Fraction of Lake
	Mean	90th	95th	
None	8.9%	31%	59%	0%
100 ppm	7.6%	24%	48%	3%
80 ppm	7.0%	27%	45%	5%
60 ppm	5.9%	18%	36%	8%
40 ppm	4.4%	12%	26%	16%
20 ppm	1.9%	4.7%	10%	37%

The BTAG reviewed these results and concluded that while an RAL of 20 ppm would be needed to provide nearly complete protection of the exposed population, an RAL of 40 ppm would provide a good reduction in effect level while tending to minimize the areal extent of the lake that required remediation, which in turn would tend to minimize disturbance of the ecosystem during remediation. Based on this, the risk manager identified 40 ppm as the RAL and initiated a feasibility study to investigate ways of achieving this objective.



### ***Biota (Fish, Aquatic Invertebrates, Plants)***

Biota, such as fish, aquatic invertebrates, and plants can serve as bioindicators or indirect estimators of contamination in other exposure media that would be targets for remediation. The concentration of chemicals fish may reflect a combination of exposures via sediment, the water column, and food source (e.g., prey). Therefore, the use of bioindicators to develop PRGs in other media introduces a sources of uncertainty. If there is a high correlation between concentrations in fish and sediment, then sediment concentrations may be considered when developing PRGs to protect the receptor population. The EU, in this case, is the area where the angler population, or ecological predator population, harvests fish. However, in risk assessments that include a fish ingestion exposure pathway, there may be high uncertainty about the true concentration term. Concentrations may be affected by many factors, including changes in the fish population and changes in fish preferences, which may be difficult to address in risk assessments. The choice of fish species consumed by a given individual may also affect the concentration term.

Fish population studies and fate and transport considerations of the contaminants may indicate if and when a fish population will reach a calculated cleanup level. For many sites, it may be difficult to obtain this level of site-specific data due to resource and time constraints.

Although remediation may not immediately reduce contaminant concentrations in biota, the determination of a cleanup level can serve as a target for any future decline in concentrations. In general, iterative reduction methods are applicable for developing PRGs to protect aquatic ecosystems; however, under some conditions iterative truncation may also be used. For example, if contamination is correlated to relatively static sediment, and the home-range of the fish is relatively small (e.g., nonmigratory) then iterative truncation may be applicable.

### ***Surface Water***

The development of PRGs for surface water is also difficult with iterative truncation. For fluid media (e.g., groundwater or surface water), iterative reduction can be performed using a range of EPCs to determine a PRG with acceptable risk at the target RME percentile.

## **5.8 MEASUREMENT OF ATTAINMENT**

The NCP (U.S. EPA, 1990a) provides for continued monitoring for groundwater cleanups to ensure attainment of the remedial action objectives. In addition, it is common practice among remedial project managers to conduct confirmation sampling after completing a remedy for soil contamination. However, completion of the remedial action according to this strategy does not necessarily mean that risks within EUs at the site have been reduced to levels specified in the ROD. The degree of uncertainty about whether the remedial action at the site has achieved the cleanup level should determine whether confirmation sampling is warranted. In general, confirmation sampling following cleanup activities is recommended. Sampling after the remedial investigation is complete may show additional areas needing remediation (i.e., where additional contamination exists).

If additional sampling is conducted after the remedial investigation, the concentration term and corresponding estimates of risk should be recalculated. The PRG developed in the remedial investigation may not be health-protective in light of the additional contamination. The same concepts that relate the concentration term to the PRG should be applied in this situation.

Confirmation sampling activities are included in remedial design/remedial action plans to ensure the remedy is successful. In addition, the five-year review presents a second opportunity to ensure that any contamination left on site does not pose an unacceptable risk.

*☞ If confirmation sampling indicates an insufficient reduction in risk, a more extensive remediation effort may be needed. Possible reasons for not achieving remedial action objectives can include inadequate site characterization or the discovery of unknown contamination.*

For post-remediation sampling, the DQO process should generally be followed. If the post-remediation risk associated with the confirmation sample indicates risk exceeds a level of concern, then additional remediation may be warranted.

## 5.9 SUMMARY OF RECOMMENDED METHODS

Table 5-3 summarizes the possible methods for developing PRGs for various environmental media. It should be noted that iterative reduction (IR) can be used in all cases, whereas iterative truncation (IT) is limited to situations where the highest concentrations can be identified and removed. Backcalculation may be applicable in all cases, but because of caveats noted in Section 5.4.1, iterative approaches are generally recommended in this document.

**Table 5-3.** Summary of Potential Methods for PRG Development by Environmental Medium.

Potential Exposure Medium	Back-calculation	Iterative Reduction (IR)	Iterative Truncation (IT)	Explanations for IT
Soil	X	X	X	Applicable if soil is relatively fixed.
Sediment	X	X	X	Applicable if sediment is relatively fixed. In some situations, sediment transport may be a better assumption due to current velocity, tides, resuspension, etc.
Biota (Fish, Aquatic Invertebrates, Plants) - bioindicators of contamination in sediment	X	X	SA	Depends on home-range of fish relative to the scale of the sampling design. If contamination is correlated to relatively static sediment, and the home-range of the fish is relatively small (e.g., non-migratory) then IT may be applicable.
Surface Water	X	X	NA	Not applicable as surface water is a fluid medium.
Groundwater (GW)	X	X	NA	Not applicable as GW is a fluid medium. Generally, ARARs must also be satisfied.
Home-grown produce, milk, livestock, other food items	X	X	SA	Depends on relative contributions of soil uptake (applicable) vs. foliar deposition (not applicable).

X=applicable  
NA=not applicable  
SA=sometimes applicable

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## CHAPTER 6

### COMMUNICATING RISKS AND UNCERTAINTIES IN PROBABILISTIC RISK ASSESSMENTS

#### 6.0 INTRODUCTION

The Environmental Protection Agency (EPA) has developed a guidance document, *Risk Assessment Guidance for Superfund: Volume I—Human Health Evaluation Manual, Supplement to Part A: Community Involvement in Superfund Risk Assessments* (U.S. EPA, 1999a) and two videotapes, “*Superfund Risk Assessment and How You Can Help, An Overview*” (10 minutes) (U.S. EPA, 1999b) and “*Superfund Risk Assessment and How You Can Help*” (40 minutes) (U.S. EPA, 2000b), to improve community involvement in the Superfund risk assessment process. The videotapes (available in both English and Spanish) show examples of how regions have involved communities in the risk assessment process at several Superfund sites. The guidance document and videotapes, along with the *Superfund Community Involvement Handbook and Toolkit* (U.S. EPA, 1998), should serve as a primary community involvement resource for risk assessors and remedial project managers (RPMs). The *Handbook and Toolkit* offers the following specific guidance:

- Provides suggestions for how Superfund staff and community members can work together during the early stages of Superfund remedial investigation and feasibility study (RI/FS) and later cleanup
- Identifies where, within the framework of the human health risk assessment methodology, community input can augment and improve EPA’s estimates of exposure and risk.
- Recommends questions the site team (risk assessor, RPM, and community involvement coordinator [CIC]) should ask the community.
- Illustrates why community involvement is valuable during the human health risk assessment at Superfund sites.

This chapter provides guidance and suggestions on how to deal with risk communication issues that arise during a probabilistic risk assessment (PRA). Specifically, the concepts of uncertainty and variability may present additional communication challenges for PRA. For example, whereas discussions of uncertainty for point estimate risk assessments are often qualitative in nature, PRA opens the floor for discussion and presentation of quantitative uncertainty analysis. Concepts associated with quantitative characterizations of uncertainty may be more difficult to communicate and may not be well received due to stakeholder desires for certainty (Slovic et al., 1979). As such, this chapter highlights appropriate stakeholder involvement and principal risk communication skills that are effective for communicating PRA concepts and risk information. Key factors for successful communication of PRA include early and continuous involvement of stakeholders, a well-developed communication plan, good graphics, a working knowledge of the factors that may influence perceptions of risk and uncertainty, and a foundation of trust and credibility.

**EXHIBIT 6-1**

**DEFINITIONS FOR CHAPTER 6**

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.

Community Advisory Group (CAG) - A group formed to provide a public forum for community members to present and discuss their needs and concerns related to the Superfund decision-making process. A CAG serves as the focal point for the exchange of information among the local community, EPA, State regulatory agency, and other pertinent Federal agencies involved in the cleanup of a Superfund site.

Community Involvement Coordinator (CIC) - As a member of the CAG and site team, the CIC coordinates communication plans (i.e., the CIP) and addresses site-specific CAG organizational issues.

Community Involvement Plan (CIP) - A plan that identifies community concerns and the preferences of the community for the communication of site-related issues.

Confidence Interval - A range of values that are likely to include a population parameter. Confidence intervals may describe a parameter of an input variable (e.g., mean ingestion rate) or output variable (e.g., 95<sup>th</sup> percentile risk). When used to characterize uncertainty in a risk estimate, it is assumed that methods used to quantify uncertainty in the model inputs are based on statistical principles such as sampling distributions or Bayesian approaches. For example, given a randomly sampled data set, a 95% confidence interval for the mean can be estimated by deriving a sampling distribution from a Student's t distribution.

Credible Interval - A range of values that represent plausible bounds on a population parameter. Credible intervals may describe a parameter of an input variable (e.g., mean ingestion rate) or output variable (e.g., 95<sup>th</sup> percentile risk). The term is introduced as an alternative to the term confidence interval when the methods used to quantify uncertainty are not based entirely on statistical principles such as sampling distributions or Bayesian approaches. For example, multiple estimates of an arithmetic mean may be available from different studies reported in the literature—using professional judgment, these estimates may support a decision to describe a range of possible values for the arithmetic mean.

Cumulative Distribution Function (CDF) - Obtained by integrating the PDF, gives the cumulative probability of occurrence for a random independent variable. Each value  $c$  of the function is the probability that a random observation  $x$  will be less than or equal to  $c$ .

Hazard Quotient (HQ) - The ratio of estimated site-specific exposure to a single chemical from a site over a specified period to the estimated daily exposure level, at which no adverse health effects are likely to occur.

Hazardous Substance Research Centers (HSRC) - Research centers providing free technical assistance to communities with environmental contamination programs through two distinct outreach programs: Technical Outreach Services for Communities (TOSC) and Technical Assistance to Brownfields Community (TAB).

Histogram - A graphing technique which groups the data into intervals and displays the count of the observations within each interval. It conveys the range of values and the relative frequency (or proportion of the sample) that was observed across that range.

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 distribution of risk values. A set of iterations or calculations from Monte Carlo sampling is a simulation. For example, a single iteration for risk from ingestion of water may represent a hypothetical individual who drinks 2 L/day and weighs 65 kg; another iteration may represent a hypothetical individual who drinks 1 L/day and weighs 72 kg.

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).

Percentile - A number in a distribution such that X % of the values are less than the number and 1-X % are greater. For example, the 95<sup>th</sup> percentile is a number in a distribution such that 95% of the values are less than the number and 5% are greater.

EXHIBIT 6-1

DEFINITIONS FOR CHAPTER 6—Continued

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 or RME, depending on the choice of inputs.

Potentially Responsible Party (PRP) - Individuals, companies, or any other party that is potentially liable for 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 function or graph representing the probability distribution of a continuous random variable. The density at a point refers to the probability that the variable will have a value in a narrow range about that point.

Rank Correlation (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.

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.

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  $r^2$ .

Stakeholder - Any individual or group who has an interest in or may be affected by EPA’s site decision-making process.

Technical Assistance Grant (TAG) A federal grant that is intended to provide a community with the opportunity to hire independent experts to help evaluate and explain the results of a risk assessment.

Technical Outreach Services for Communities (TOSC) - A service of the HSRC with the aim to provide independent technical information and assistance to help communities with hazardous substance pollution problems.

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.

Variable - A quantity that can assume many values.

Section 6.1 discusses the need for early and continuing stakeholder involvement. Section 6.2 recommends a seven-step process for communicating PRA results to stakeholders, and Sections 6.3 and 6.4 provide guidance on specific techniques for communicating information. The success of risk communication efforts will depend on the extent to which the communication strategy addresses the needs of a diverse audience, with different perceptions of risk and uncertainty (Section 6.5), and the degree of trust and credibility that is established from the outset of the process (Section 6.6). Section 6.7 provides a discussion of risk communication issues that are uniquely relevant to RPMs.

## 6.1 STAKEHOLDER INVOLVEMENT

Many stakeholders may be interested in a risk assessment (see Exhibit 6-2). It is generally important to *involve and engage interested stakeholders early and continuously* throughout the decision-making process (U.S. EPA, 2001).

Public involvement activities should be tailored to the needs of the community and described in the site communications strategy. The CIC should coordinate these first steps through the development of a Community Involvement Plan (CIP). Coordination between the RPM, risk assessor, and CIC is needed to determine the appropriate points in the RI/FS process to communicate with the community, and plan for the appropriate level of communication. The CIP should identify community concerns and the preferences of the community for the communication of site-related issues. The CIP may be updated during the RI/FS as needed.

Examples of outreach activities include giving oral presentations and poster sessions at public meetings, coordinating group meetings or focused workshops, conducting interviews with community members on specific issues, and distributing fact sheets.

Ideally, the public and other interested stakeholders would be involved early in the site-specific decision-making process. If the community has not been previously involved, efforts should be made, in coordination with the CIC, to identify and communicate with the appropriate individuals in the community prior to the Agency's receipt of the PRA workplan. The public and other stakeholders should be given the opportunity to provide input to the workplan for a PRA (see Chapter 2, Section 2.1).

The initial community meeting can serve to establish a rapport between EPA and the community and facilitate the exchange of information needed to support a PRA. This information may include policy decisions associated with both point estimate and probabilistic approaches, as well as technical details regarding the conceptual exposure model and the selection of distributions. A discussion of these topics may increase certainty about the assumptions made in the risk assessment. For example, the community may be able to offer insights regarding site-specific activities and sources of exposure data not readily

### EXHIBIT 6-2

#### STAKEHOLDERS POTENTIALLY INVOLVED IN THE 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 Resources Damage Assessment (NRDA), trustees, etc.)
- Tribal government representatives
- Potentially responsible parties (PRPs) and their representatives
- Representatives from federal facilities (e.g., Department of Defense, Department of Energy, etc.)

available to the risk assessor. This type of discussion should allow for the free exchange of information with the public and sets the stage for future discussions. It is important that an appropriate level of detail be presented at the first meeting. Instead of overloading the audience with information, it is generally better to coordinate several meetings so that complex policy and technical concepts can be broken down into smaller discussion topics.

Following the approval of the PRA workplan, the public and other interested stakeholders should be involved in various stages of the PRA development, including providing and/or reviewing data, reviewing the selected distributions (e.g., selected creel survey) and commenting on PRA documents as appropriate during public comment periods. On-going community involvement may require consideration of EPA's resources including the availability of personnel and contractor support. Other considerations include EPA's compliance with provision in the National Contingency Plan (NCP) for involving the community. The appropriate level of community involvement in the PRA should be based on a number of factors including the nature and extent of contamination at the site, the expressed interests of the community members, the complexity of the PRA, and the role of PRA in site-specific remediation or cleanup decisions.

## **6.2 COMMUNICATION AND PRESENTATION**

Communication is a two-way process that should involve the transfer of information between the Agency and the stakeholders, as well as active listening by the Agency to the stakeholder's ideas and concerns. The goals of risk communication are to present risk information in an understandable manner through an open, honest, frank, and transparent presentation and discussion of risks, including uncertainties. In meeting these goals, it is important that the RPMs and risk assessors be sincere and direct in their presentation of the results of the PRA, accept the public and other interested stakeholders as valuable contributors to the process, and listen to the concerns and ideas that are raised.

One goal of communication should be to respect the stakeholder's concerns. The public and other interested stakeholders should have the opportunity to understand the PRA and its effects on the decision-making process. Technical Assistance Grants (TAGs) may be one way to advance this goal by providing the community the opportunity to hire independent experts to help evaluate and explain the results of the PRA. Alternatively, the RPM and risk assessor may use the tools outlined in Sections 6.3 to 6.6 to present PRA concepts and the results of the PRA to the community in a manner that is easily understood. This may require significant up-front planning, testing, and post-evaluation to identify the appropriate messages to communicate and to determine how well this information was communicated.

The site-specific PRA communication plan should be consistent with the NCP's provisions on community involvement. It is important to recognize that community involvement is part of a regulatory process and that EPA generally will consider all timely public input, but may not implement all of it. Ultimately, EPA must meet the legal requirements of the Superfund law in making decisions regarding remedial actions.

A vast body of literature exists regarding risk communication. Since the early 1980's, a number of researchers have developed models for communicating risk to the public. These models are available in the scientific literature, and a list of supplemental references is provided at the end of this chapter.

### **6.2.1 COMMUNICATION OF PRA WITH CONCERNED CITIZENS, OTHER STAKEHOLDERS, AND MANAGERS: AN OVERVIEW**

Before the decision to conduct a PRA is made, a CIP should be in place. Generally, when a decision is made to conduct a PRA, an important step should be to work with citizens to develop a communication strategy for PRA and its application within the Superfund process (see Chapter 1). The initial introduction of the community to the RI/FS process should include a discussion of the principles of risk assessment. This discussion may be best presented in an informal setting such as a public availability session. Because of the potentially complex nature of PRA and quantitative uncertainty analysis, a small group meeting may be an appropriate forum in which to discuss issues and facilitate an exchange of ideas. If there is interest among a large group of stakeholders, multiple small group sessions may be scheduled. Such meetings may provide the foundation for building trust and credibility (see Section 6.6).

In general, it is important to identify whether a Community Advisory Group (CAG) should be formed. The purpose of a CAG is to provide a public forum for community members to present and discuss their needs and concerns related to the Superfund decision-making process. The CIC is an important member of the team and may coordinate communication plans, hand-out materials, and address site-specific organizational issues.

A number of resources may be available to the community to aid in understanding technical material in a PRA. In addition to the TAG program, which provides funds for qualified citizens' groups affected by a Superfund site to hire independent technical advisors, another program is the Technical Outreach Services for Communities (TOSC), which uses university educational and technical resources to help communities understand the technical issues involved in hazardous waste sites in their communities. This is a no-cost, non-advocate, technical assistance program supported by the Hazardous Substance Research Centers.

The tiered approach for PRA presented in Chapter 2 (Figures 2-1 and 2-2) encourages risk assessors and RPMs to participate in discussions with stakeholders early in the process of developing point estimate and probabilistic approaches. If a decision is made to perform a PRA, a continuing dialogue should be useful to evaluate interim results of the PRA and determine if additional activities are warranted (e.g., data collection, further modeling). These on-going discussions should help assure that RPMs are aware of the details of the PRA analysis and are comfortable with the material that will be shared with the community, other interested stakeholders, and senior managers.

## 6.2.2 STEPS FOR COMMUNICATION OF THE RESULTS OF THE PRA

The complexity of a PRA will vary depending on the site-specific nature of the assessment performed. For example, PRAs may include an analysis of variability, uncertainty, or both. Some analyses may involve simulations to evaluate temporal variability (e.g., Microexposure Event analysis) and spatial variability (e.g., geostatistics). The challenge for presenters is to *identify the critical information and level of detail to be presented to various audiences that may be involved in the Superfund decision-making process* (e.g., senior risk managers, concerned citizens, congressional staff, and PRPs).

The 7-step process, described below (and summarized in Exhibit 6-3), may be repeated many times during the performance of a PRA. For communication purposes, a PRA normally will involve more interaction with stakeholders than a point estimate risk assessment because PRA concepts and results are often more difficult to communicate.

### (1) *Identify the Audience*

The first step should be to identify the audience of potentially interested stakeholders. Strategies for presenting PRA information normally will be tailored to the audience. Participants in the audience may change during the tiered process depending on the complexity of the PRA (see Chapter 2) and the specific site-management decisions being made.

### (2) *Identify the Needs of the Audience*

The second step should be to identify the needs of the audience. The relevant information and the appropriate level of detail will vary depending on the audience. For example, some participants may be well informed about PRA concepts and will not need much introductory PRA information. For other audiences, PRA concepts may be new, so it may be beneficial to hold an informal meeting to discuss the general objectives and methods used to conduct a PRA. Once introductory PRA concepts have been discussed and are understood by the audience, more advanced discussions may be warranted on topics such as the sources of data used in the PRA, the most critical variables in the PRA (identified during the sensitivity analysis), the selection of distributions, and the level of characterization of uncertainty (see also Section 6.5). The risk assessor should select the key information for each topic and discuss the significance of this information based on the intended audience.

#### EXHIBIT 6-3

##### IMPORTANT STEPS FOR COMMUNICATING PRA RESULTS

- (1) Identify the audience
- (2) Identify the needs of the audience
- (3) Develop a communication plan
- (4) Practice to assure clarity of presentation
- (5) Present information
- (6) Post-meeting review of presentation and community feedback
- (7) Update information as needed for future assessments and presentations

**(3) Develop a Communication Plan**

The third step should be to develop a plan to communicate significant information to the public in an easily understandable format (Exhibit 6-4). Adequate planning in the presentation of PRA information is essential. A thorough understanding of the design and results of the PRA will help to place the information in proper context and understandable format (U.S. EPA, 1994). Even more importantly, the risk assessors and RPMs should clearly identify the main messages to be presented.

**EXHIBIT 6-4**

**KEY CONSIDERATIONS IN DEVELOPING UNDERSTANDABLE MATERIAL**

- Identify main messages
- Place information in appropriate context
- Use clear formats
- Use examples and graphs
- Provide handouts and glossaries
- Present information with minimum jargon

Section 6.4 provides examples of graphics that may be useful in presentations of PRA. Handouts, glossaries, and other materials may complement a presentation and provide information for discussion following the meetings. In addition, examples designed to help demonstrate concepts unique to PRA (e.g., using one probability distribution to describe variability and a second distribution to describe parameter uncertainty) may help facilitate the flow of communication and increase the level of understanding. One useful technique in public meetings is to involve members of the audience to illustrate a concept. For example, the topic of discussion may be the method used to select and fit a probability distribution used to characterize variability in a PRA. To demonstrate this concept, a risk assessor can draw a bell-shaped curve on a flip chart and label the *x-axis*, “number of liters of water consumed per day”, and the *y-axis*, “number of people who consume a specific amount of water in a day”. Next, each meeting participant can be asked to identify their own consumption pattern, perhaps by holding up a 0.5 liter bottle and asking how many such bottles are consumed on an average day. This community-specific information can then be plotted on a new graph in the form of a histogram and the bars can be connected to form a curve or distribution similar to the one first drawn. The resulting distribution (for an example, see Figure 6-1) can then be used to discuss the following PRA concepts in more detail:

- Variability (between individuals)
- Shape of the distribution and plausible range of values
- Central tendency exposure (CTE) and reasonable maximum exposure (RME) estimation
- Uncertainty in the distribution (sample size, potential response bias, differences in activity patterns)
- Uncertainty in a parameter estimate (difference between the 95% upper confidence limit (UCL) for a mean and the 95<sup>th</sup> percentile)

Using this information as a basis, the risk assessor can compare the results from the community analysis with data from various geographic areas in the U.S. where water consumption patterns may differ. The risk assessor can then lead a discussion with the community regarding the various sources of uncertainty in selecting and fitting exposure distributions, including:

- (a) **Extent of Representation** - Are the available data representative of the target population? For example, would the data on water consumption collected during the meeting be representative for various population groups?

- (b) **Data Quantity** - What sample size is needed to develop a distribution? This discussion will introduce the concept that uncertainty in both point estimates and probability distributions may be reduced by increasing the sample size
- (c) **Data Quality** - Are the data collected using acceptable study protocols? Is the information available from the peer-reviewed literature? An example can be made of the data collected during the meeting to highlight issues associated with survey design, and methods for controlling for potential bias or error. For example, if the survey data were to be used in a risk assessment for a drinking water scenario, the data quality may be improved by repeat sampling over time

Other exposure variables that can be used in this distribution example include: fish consumption rates, chemical concentrations in soil, and fraction of time spent indoors. In general, examples should focus on variables that may be of interest, are easily illustrated, and are unlikely to make participants uncomfortable divulging personal information such as age.

#### **(4) Practice to Assure Clarity of Presentation**

The fourth step should be to practice the presentation to assure that the information is presented clearly to the intended audience. Staff from communication groups or public information offices within EPA regional offices may help to determine whether or not the presentation addresses the needs of various audiences. Also, practicing the presentation with co-workers who are unfamiliar with the site can help assure that the appropriate messages are being conveyed, and will help the team prepare for potential questions that will arise during the meeting.

#### **(5) Present Information**

A number of factors should be considered when developing a plan to present the PRA in a meeting. Although the size of the public meeting can sometimes be unpredictable, typically individuals will feel more comfortable asking questions and expressing opinions in small, informal settings. For any audience, it is usually helpful to have general fact sheets on PRA available for distribution. The fact sheets may contain information that describes the PRA process, how information from the PRA will be used at the site, and how the community may comment on the PRA report. The meeting team should usually include the CIC, RPM, Risk Assessor, and additional support as necessary.

Audio-visual materials and equipment should be checked prior to the start of the meeting. For example, overheads should be viewed from the audience seating to assure that information is accessible and readable. Presentations using portable computers can be effective for showing how the results of the PRA may differ with changes in modeling assumptions.

#### **(6) Post-meeting Review of Presentation and Community Feedback**

At the end of a meeting, it can be helpful to encourage participants to provide feedback regarding effective and ineffective communication techniques. Not only can this information be used to improve presentations offered to similar audiences in the future, it also provides a sense for how well the main messages and specific technical issues were communicated.

*(7) Update Information as Needed for Future Assessments and Presentations*

Shortly after the meeting or briefing, modifications should be made to the materials for future presentations where appropriate. In addition, if information is obtained that is relevant to the risk assessment, this information may be included in a subsequent analysis, and the process would be repeated.

### **6.3 COMMUNICATING DIFFERENCES BETWEEN POINT ESTIMATE AND PRA**

One method for effectively explaining the PRA approach to quantifying variability and uncertainty is to employ comparisons to the more easily understood point estimate methodology. These comparisons can focus on either the inputs or the outputs associated with the two approaches. The communicator may focus on a specific input variable, such as drinking water intake, and explain that with the point estimate methodology, a single average or high-end value (e.g., 2 liters per day for adults) normally is used to quantify exposure, whereas with PRA, a probability distribution (e.g., lognormal) is used to characterize variability in exposure among a population. In addition, the outcomes (e.g., cancer risk estimates) can be compared by showing where the point estimate(s) of risk fall within the distribution of risks generated with PRA.

When communicating results from point estimate and PRA models, an important concept to keep in mind is that both methods yield risk estimates with varying degrees of uncertainty. Continuing with the above example, concepts associated with uncertainty (e.g., representativeness, data quantity, and data quality) can be introduced by asking the audience if their estimate of water consumption on a specific day would be equal to their average daily consumption rate over a 1-year period. This example highlights a common source of uncertainty in exposure data (i.e., using short-term survey data to estimate long-term behavior). Section 6.5 discusses different perceptions of uncertainty.

It is common to accept output from quantitative models without fully understanding or appreciating the corresponding uncertainties and underlying assumptions. One challenge in presenting PRA results is to determine the most effective way to communicate sources of uncertainty without undermining the credibility of the assessment (see Section 6.6). For example, it may be counterintuitive that the more sources of uncertainty that are accounted for in a PRA, the wider the confidence intervals tend to be in the risk estimates (see Section 6.4.2). The audience may question the utility of a method that appears to introduce more complexity in a risk management decision. It may be useful to point out that many sources of uncertainty are present, and methods available to acknowledge and quantify them may differ in point estimate and probabilistic risk assessments.

The basic concepts of PRAs described in Chapter 1 may be used in developing presentations. Exhibits 1-5 and 1-6 in Chapter 1 summarize some of the advantages and disadvantages of point estimates and probabilistic approaches that should be considered when evaluating differences in the risk estimates of the two approaches. For example, point estimates of risk do not specify the proportion of the population that may experience unacceptable risks. In contrast, PRA methods allow statements to be made regarding both the probability of exceeding a target risk, and the level of confidence in the risk estimate.

When summarizing results of PRA, graphs and tables generally should include the results of the point estimates of risk (e.g., CTE and RME). It may be informative to note where on the risk distribution each of the point estimates lies. By understanding the assumptions regarding the inputs and modeling

approaches used to derive point estimates and probabilistic estimates of risk, a communicator will be better prepared to explain the significant differences in risk estimates that may occur. Special emphasis should be given to the model and parameter assumptions that have the most influence on the risk estimates, as determined from the sensitivity analysis (see Appendix A).

## 6.4 GRAPHICAL PRESENTATION OF PRA RESULTS TO VARIOUS AUDIENCES

Graphics can be an effective tool for communicating concepts in PRA. As the old adage goes, “A picture is worth a thousand words.” A graphic usually can be most easily understood by a diverse audience when it conveys a single message. It is generally a good idea to keep the graphics simple so that the message is clear. In general, each graphic should be developed and modified depending on the type of presentation and the intended audience.

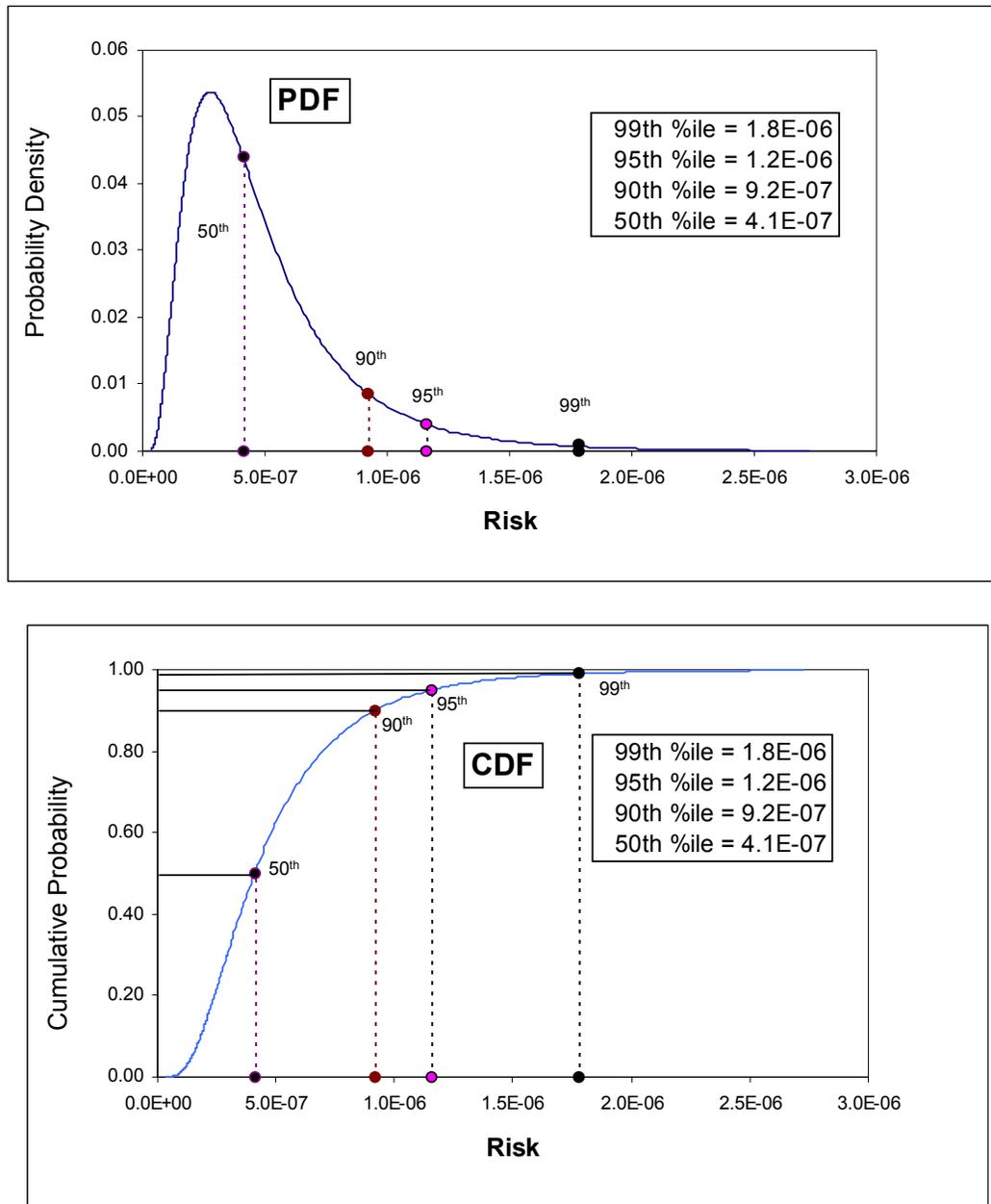
*☞ The key to presenting graphics in PRA effectively is to select a relatively small number of appropriate messages, and to find a balance between meaningful information and overwhelming detail.*

Points to consider when developing graphics for public meetings, senior staff, and the press are presented below. Certainly, recommendations for presenting clear and informative graphics are applicable to all three forums. Practical recommendations for graphical analysis techniques and tips for successful visual displays of quantitative information are given by Tufte (1983) and Helsel and Hirsch (1993).

### 6.4.1 PUBLIC MEETING

For a public availability session (or meeting), care should be taken to assure that the graphics are of appropriate size and the lettering is easy to read. For example, a graphic on an 8 ½ x 11 inch sheet of paper, or a font size smaller than 18 pt in a computer presentation, may not be easily seen from the back of a large auditorium. It may be appropriate to present information using large posters, spaced so that the audience may move among them and discuss the posted results with the risk assessor or RPM. Handouts and a glossary of terms may also be used. Using slides with too much text should be avoided, since the information may be difficult to read and understand. Pre-planning and pilot testing the graphics before the presentation may be helpful in assuring that the message is accurately portrayed to the community.

Consistent with EPA’s guidance on risk characterization, the CTE and RME cancer risks and noncancer hazards, and EPA’s decision point should be highlighted on graphics. The discussions accompanying the graph should emphasize that these values represent risks to the average and high-end individuals, respectively, and serve as a point of reference to EPA’s decision point. The distribution of risks should be characterized as representing variability among the population based on differences in exposure. Similarly, graphics that show uncertainty in risk can be described using terms such as “confidence interval”, “credible interval”, or plausible range. The graphics need not highlight all percentiles. Instead, selected percentiles that may inform risk management decisions (such as the 5<sup>th</sup>, 50<sup>th</sup>, 90<sup>th</sup>, 95<sup>th</sup>, and 99<sup>th</sup> percentiles) should be the focus. Figure 6-1 shows an example of a PDF for variability in risk with an associated text box for identifying key risk percentiles.



**Figure 6-1.** Hypothetical PRA results showing a probability density function (PDF) (top panel) for cancer risk with selected summary statistics for central tendency and high-end percentiles. This view of a distribution is useful for illustrating the shape of the distribution (e.g., slightly right-skewed) and explaining the concept of probability as the area under a curve (e.g., most of the area is below 1E-06, but there is a small chance of 2E-06). Although percentiles can also be overlaid on this graphic, a cumulative distribution function (CDF) (bottom panel) may be preferable for explaining the concept of a percentile.

Figure 6-2 gives two examples of graphics that can be used to display results of a sensitivity analysis from a Monte Carlo Analysis (MCA). While both graphics are likely to be understood by non-technical audiences, the pie chart may be more familiar. The pie chart (Figure 6-2A) suggests that the results should sum to 1.0, which may not be true if there are correlations among one or more variables, or if only a subset of the variables are displayed (e.g., those that contribute at least 1%). The available data can be normalized so that the squared correlation coefficients do sum to 100%, and this approach has been adopted by some commercial software available to run Monte Carlo simulations (e.g., *Crystal Ball*® by Decisioneering, [www.decisioneering.com](http://www.decisioneering.com)). The benefit of showing the squared correlation coefficient ( $r^2$  or *r-square*, also called the coefficient of determination), rather than the correlation coefficient ( $r$ ) is that *r-square* is proportional to the total variation in risk associated with specified input variable. Therefore, one can use the *r-square* to describe, in quantitative terms, the contribution of the input variable to the total variance in the risk distribution. In this example, exposure duration (ED) contributes approximately two-thirds (64%) to the total variance in risk.

A more technical graphic is the tornado plot (Figure 6-2B). In addition to showing the relative magnitude of the correlations (*r-square*), it illustrates the direction of influence a specific variable has on the final risk estimate. Bars that extend to the right indicate a positive correlation (e.g., high risk estimates correspond with high values for the variable), whereas bars that extend to the left indicate a negative correlation (e.g., high risk estimates correspond with low values for the variable.) In this example, the exposure duration (ED) has the largest positive correlation with risk, while body weight (BW) has the largest negative correlation with risk.

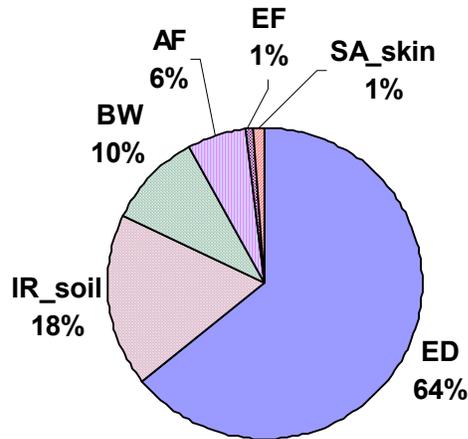
The graphics shown in this chapter are a small fraction of the graphics that might be used to communicate concepts related to PRA. Numerous additional examples are given throughout this guidance document. Table 6-1 provides a summary of cross references to other figures that were developed for this guidance document to convey specific concepts regarding variability and uncertainty.

**Table 6-1.** Examples of Graphics for Communicating PRA Concepts in this Guidance Document.

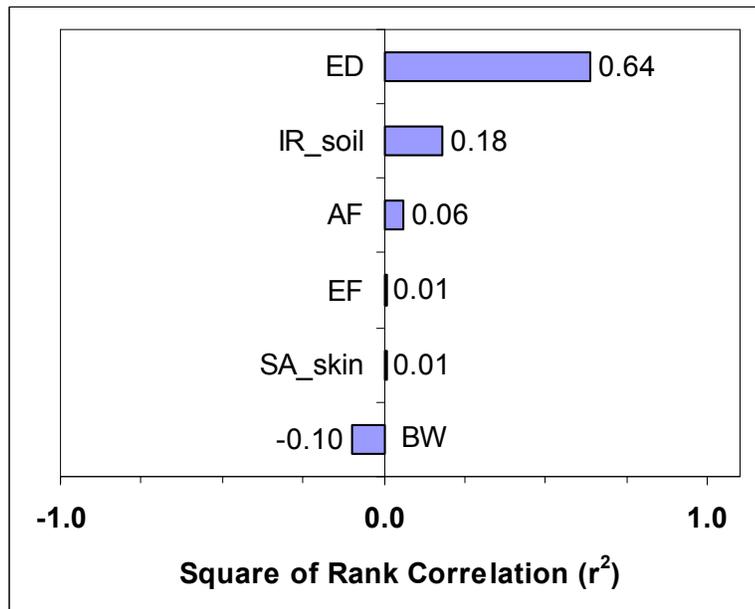
General PRA Topic Area	Location	Variability	Uncertainty
<b>Conceptual Diagrams for Fundamental Concepts</b>			
Monte Carlo Analysis	Figure 1-2	X	
Tiered process for PRA	Figure 2-1, 2-2	X	X
<b>PDFs and CDFs</b>			
Input variable(s)	Figure 1-1, 4-4, 4-5, 4-6	X	
Risk distribution with selected percentiles highlighted	Figure 6-1		X
Comparing RME risk (e.g., 95 <sup>th</sup> percentile) with risk level of concern	Figure 1-3, 4-3, 7-2,	X	
<b>Selecting and Fitting Probability Distributions</b>			
Fitting distributions - frequency distribution overlaid by a PDF	Figure 3-1	X	
Lognormal probability plot	Figure 5-2	X	
<b>Sensitivity Analysis</b>			
Sensitivity analysis - tornado plot of Spearman rank correlations	Figure 3-6, 6-2b	X	
Sensitivity analysis - pie chart	Figure 6-2a	X	
Joint probability curve	Figure 4-8	X	
<b>Variability in toxicity</b>			
Species sensitivity distribution	Figure 4-7	X	
<b>Iterative Simulations</b>			
CDFs from multiple 1-D MCA simulations to convey uncertainty in the risk distribution	Figure 3-3		X
<b>PRG Selection</b>			
Estimation from best-fit line for RME risk and EPC	Figure 5-1	X	
RME risk ranges corresponding to alternative choices of PRG	Figure 7-4	X	
90% credible interval for RME risk (95 <sup>th</sup> percentile) corresponding to alternative choices of PRG	Figure 7-5		X

Bi-model distribution for concentration showing pre-remediation EPC, post-remediation EPC, remediation action level, and uniform distribution for clean fill	Figure 5-3	X	X
<b>2-D MCA Results</b>			
Illustration of tabular and graphic outputs of a 2-D MCA	Figure 4-9		X
Confidence intervals (or credible intervals) on a risk distribution	Figure 1-4, 4-10, 4-11, 4-12		X
Box-and-whisker plot for results of 2-D MCA	Figure 3-4, 7-3		X
Horizontal box-and-whisker plots with multiple CDFs	Figure 6-3	X	X

A. Pie Chart



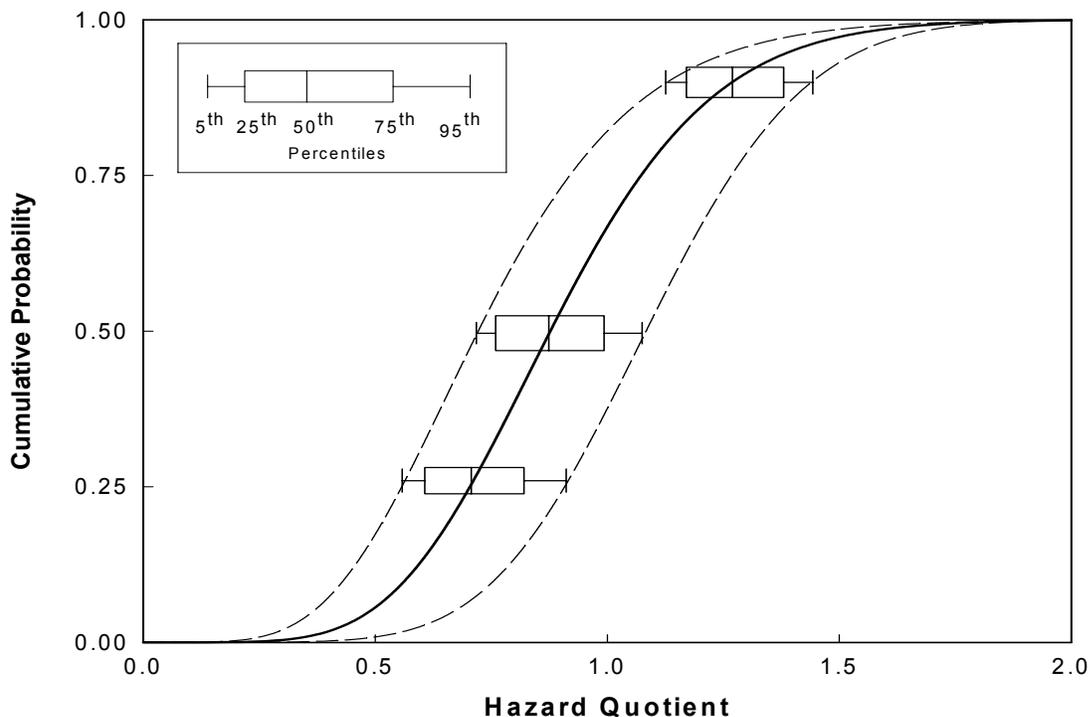
B. Tornado Plot



**Figure 6-2.** Results of a sensitivity analysis shown as a pie chart (A) and tornado plot (B). Both graphics illustrate the concept of the relative contribution to variance for exposure variables that contribute at least 1% to the variance in risk. The pie chart suggests that the sum of the squared rank correlations equals 1.0, which is true only if the results are normalized to 100%. The tornado plot gives both the magnitude and direction (positive or negative) of the correlation. ED=exposure duration, IR\_soil=soil ingestion rate, AF=absorption fraction, EF=exposure frequency, SA\_skin=surface area of skin, and BW=body weight.

### 6.4.2 EPA SENIOR STAFF

For communicating PRA with EPA's senior risk managers (e.g., EPA Section Chiefs, EPA Branch Chiefs, or EPA Division Directors), an executive summary or executive briefing package may be appropriate. This presentation should highlight major findings, compare point estimate and probabilistic results, provide sensitivity analysis results, and state uncertainties addressed in the PRA.



**Figure 6-3.** The results of a 2-D MCA. The graphic shows a method of presenting variability as a cumulative distribution function and uncertainty as box plots at the 25<sup>th</sup>, 50<sup>th</sup>, and 95<sup>th</sup> percentiles of variability. The CDF of the 50<sup>th</sup> percentile is represented by the solid line and the CDFs given by the dotted lines represent the 5<sup>th</sup> and 95<sup>th</sup> percentiles of uncertainty for each percentile of variability.

EPA senior level risk managers would generally be most interested in the risk estimates at the 50<sup>th</sup>, 90<sup>th</sup>, 95<sup>th</sup>, and 99.9<sup>th</sup> percentiles (i.e., a CTE risk estimate and the RME risk range). EPA senior managers may also wish to know the uncertainty surrounding each of the percentiles of risk. This uncertainty can be described in a table (e.g., confidence intervals around the 95<sup>th</sup> percentile risk) or a graphic (e.g., box-and-whisker plots). It is advisable for the risk assessor to have this information on hand during the briefing to respond to questions. Presenting distributions of uncertainty along with distributions of variability can create a very busy figure or table—it is best to keep things simple.

Figure 6-3 shows cumulative distribution functions (CDFs) for the Hazard Quotient (HQ) for a single chemical, representing variability in HQ. One method of displaying uncertainty is to use box-and-whisker plots. In this example, the horizontal box and whiskers represent uncertainty around selected percentile estimates of variability. Specifically, the three box-and-whisker plots correspond to the 25<sup>th</sup>, 50<sup>th</sup>, and 95<sup>th</sup> percentiles of the distribution for variability in HQ. The box shows the 25<sup>th</sup> and 75<sup>th</sup> percentiles (i.e., interquartile range) of uncertainty, whereas the whiskers show the 5<sup>th</sup> and 95<sup>th</sup> percentiles of uncertainty. In this example, uncertainty in the 95<sup>th</sup> percentile HQ is quantified by the box-and-whiskers plot in which the 5<sup>th</sup> percentile of uncertainty is 1.1, the 50<sup>th</sup> percentile is 1.3, and the 95<sup>th</sup> percentile is 1.4. This suggests that despite the uncertainty in the estimate of the 95<sup>th</sup> percentile of variability, an HQ of 1.0 is likely to be exceeded. Sometimes such results are said to describe the 90% *confidence interval* in the 95<sup>th</sup> percentile HQ. The term “confidence interval” is used loosely in this context to convey information about uncertainty; however, it is not the same as a statistical confidence limit that one might obtain by estimating a population parameter from a sample. An alternative term that may be more appropriate in this case is “credible interval”.

The three curves represent similar information on uncertainty across the complete range of percentiles for variability. The solid line shows the CDF for all of the 50<sup>th</sup> percentiles of uncertainty, whereas the dotted lines show the 5<sup>th</sup> and 95<sup>th</sup> percentiles of uncertainty.

The box-and-whisker plot is simple to produce, conveys information about the symmetry and width of the confidence interval, and is easy to interpret (Tufté, 1983). In general, box-and-whisker plots are useful for summarizing results from two-dimensional Monte Carlo (2-D MCA) simulations. The methods and inferences associated with 2-D MCAs are discussed further in Appendix D. The results of a 2-D Monte Carlo simulation represent a range of possible estimates for the percentile given one or more sources of uncertainty that were included in the simulation. If the target audience for this graphic has a greater understanding of statistics, it may be less confusing if alternative phrases are used to describe the results, such as “credible interval” or “probability band”.

Graphics that show probability density functions for uncertainty (PDFu’s) are generally more meaningful to a technical audience of risk assessors and uncertainty analysts. Alternative graphics may be needed to communicate other sources of uncertainty in risk estimates (e.g., use of alternative probability models for exposure variables, effect of changes in the model time step, application of spatial weighting to concentration data, etc.). Additional information on communicating risks to senior EPA managers is given by Bloom et al. (1993).

The results from the sensitivity analysis may be useful to the senior managers in deciding whether additional sampling is necessary. One issue that may be important to address with risk managers and senior staff is that the width of the credible interval (e.g., 5<sup>th</sup> to 95<sup>th</sup> percentiles of uncertainty) will be determined in part by the number of sources of uncertainty that are quantified. As additional sources of uncertainty are quantified and included in the model, the interval around the risk distribution will tend to widen. This situation may appear to be counterintuitive for those managers who expect confidence to increase as uncertainty is quantified. However, by uncovering and quantifying the sources of uncertainty, the benefits in the risk communication and decision-making process should become clear. The results of the sensitivity analysis should help to focus discussions, data collection efforts, and analyses on the more significant sources of uncertainty. In addition, by developing estimates of credible intervals of uncertainty in risk estimates, the decision-making process using the tiered approach may become more transparent.

### 6.4.3 PRESS RELEASES

For a press briefing presentation, care should be given to identify messages and develop publication quality graphics with clear descriptions that can be provided in press packages. It is usually a good idea to provide the graphics in both color and black and white so that the press can choose the most appropriate presentation style for the story. The RPMs generally should work with the CIC, the press staff in the Communication Division, and senior managers to develop press materials. Adequate time should be left for the preparation of materials and internal Agency review and approval before information is released.

### 6.5 PERCEPTION OF RISK AND UNCERTAINTY

The purpose of this section is to present current thinking about how people view risk and uncertainty. This section should provide useful information for planning risk communication and addresses the first step in the seven step process (Section 6.2.2), "Identify the Audience."

There are many individual differences in the way people regard the risks and hazards that are present in modern life. These differences have their roots in the differences in perception of risk and uncertainty of the individual human mind (Slovic, 1986). The risk assessor and/or risk communicator should keep in mind the general perceptions about risk held by different groups. Communications should be tailored to the specific audience. This section summarizes some of the criteria used to judge risks in the absence of scientific data and the direction of the potential bias that may be expected by applying these criteria. Additional publications on this issue are identified in the reference section at the end of this chapter.

In the absence of scientific data, the general public evaluates risks using inferences of judgment as described below (Slovic et al., 1979):

- **Availability:** People tend to judge risks as more likely if they are easy to recall.
- **Overconfidence:** People tend to be overconfident about the judgments they make based on the use of heuristics.
- **Desire for Certainty:** People tend to misgauge risk/benefit conflicts in favor of the benefits as a result of a desire for certainty and anxiety about uncertainty.

Slovic et al. (1979) identified nine characteristics of risk that may influence perceptions. These nine dimensions may provide a perspective on whether a health risk is perceived as “more risky” or “less risky”, as described in the table below.

<b>Dimension of Risk</b>	<b>More Risky</b>	<b>Less Risky</b>
Voluntariness	Involuntary	Voluntary
Immediacy of the effect	Delayed	Immediate
Exposed persons’ knowledge about risk	Low	High
Sciences’ knowledge about risk	Low	High
Control over risk	Low	High
Newness	Unfamiliar or New	Familiar
Chronic/Catastrophic	Catastrophic	Chronic
Common/Dread	Dreaded	Common
Severity of the consequences	High	Low

The presentation of uncertainty in a risk estimate can be interpreted with vastly different conclusions depending on the audience and their perceptions. For example, a thorough scientific account of multiple sources of uncertainty presented to a group of interested risk assessors and environmental scientists may be clearly understood. Such a group will likely conclude that the assumptions made in the risk assessment were appropriate and that the results can be used with confidence as a decision support tool. In contrast, a similar scientific presentation given to the community may be misunderstood, and the perceived risk may be greater. Citizens are often more concerned about the potential impact to their personal situation, than to the uncertainty in the risk estimate. Consequently, the community may react negatively to a long, highly scientific presentation on uncertainty. A good rule of thumb is to limit the presentation to no more than 15 minutes.

Focusing heavily on uncertainty may cause citizens to conclude that the risk must be high. They may also conclude that the presenter is incompetent because he or she is not sure of anything, or that the presenter is trying to hide something by cloaking the information in technical jargon, or even that the presenter is intentionally avoiding the public’s issues of concern. To the extent possible, technical jargon during the presentation should be avoided or explained.

A helpful presentation generally should incorporate the following steps: (1) present information about the conclusions that can be drawn from the risk assessment; it is extremely frustrating for decision-makers to receive detailed information on uncertainty without conclusions (Chun, 1996); (2) describe the certainty of the information that supports these conclusions; (3) address the uncertainty and its implications for the conclusions; and (4) present the information without jargon and in a frank and open manner. Section 6.4 provides examples of graphics that may be useful in presentations of PRA.

## 6.6 TRUST AND CREDIBILITY

The single most important quality a presenter may need to possess in order to communicate to others is a sense of trust and credibility. Trust and credibility are based on working with the community and providing thoughtful, accurate responses to questions and concerns raised by the community. Building trust and credibility is important, whether communicating to a high-level technical audience, a RPM/decision-maker who wishes to have the "big picture," or the public.

Credibility can best be established through a long history of frank and open discussions with the community. In addition, a presenter can gain credibility if he or she has the ability to restate the available information so that it addresses the concerns and interests of an audience. The ability to garner trust and credibility comes from knowing the audience, respecting their opinion, and communicating at an appropriate level (U.S. EPA, 1994).

## 6.7 COMMUNICATION ISSUES FOR RPMs

Following the RPM's decision to conduct a site-specific PRA, the level of stakeholder involvement in the development and review of the PRA should be evaluated. Establishing the appropriate level of stakeholder involvement may include input from the CIC, risk assessor and appropriate senior managers (e.g., Section Chief, Branch Chief, etc.). The level of stakeholder involvement may vary depending on the site complexity and the interest of the community. As an initial step, it may be appropriate to conduct an exploratory session where letters are sent to various stakeholders (e.g., environmental groups, CAG, etc.) inviting their participation in a general meeting on the topic of PRA. If there is a strong interest among the stakeholders, then a more involved communication plan may be appropriate including, but not limited to the following steps:

- Providing stakeholders with an introduction to the principles of PRA in an informal session (e.g., public availability session).
- Providing a draft Scope of Work (SOW) to interested stakeholders followed shortly thereafter by an availability session to discuss comments on the document.
- Providing a period of time for the stakeholders to review and comment on the selected distributions, including an availability session for discussions with EPA staff where the community may help to identify key site-specific information such as exposure factors and receptor behavior.
- Providing the opportunity for EPA risk assessor to meet with the TAG grantee (if appropriate) and stakeholders to ask questions regarding the SOW.
- Providing a revised SOW including a response to stakeholder comments.

- Providing an overview of the final PRA at a public meeting and providing appropriate supporting PRA documents in the repositories for stakeholder review and comment. This session may be part of the general session regarding the remedial investigation when the risk assessment is discussed. Based on the complexity of the PRA, it may be appropriate to hold a public availability session where the stakeholders (including the TAG grantee), if appropriate, are able to meet with EPA staff to ask questions and offer suggestions regarding the document.
  
- Providing a response to comments from stakeholders regarding the PRA.

If the level of interest is low, then a less extensive CIP may be appropriate. In this case, fact sheets (in plain language) describing the general principles of PRA to the stakeholders and the key findings of the PRA may be provided (U.S. EPA, 2000a). At public meetings where the risk assessment is discussed, a short discussion of the PRA findings and their significance may be appropriate. The PRA document should be made available in the repositories for review and comment by the stakeholders.

For sites with medium interest, a combination of the activities identified above may be appropriate. For example, it may be appropriate to have a public availability session on the principles of PRA and then make the documents available for review and comment.

The RPM should consider a number of administrative issues in developing the plan for involving the stakeholders in the PRA. Issues to consider include: staff resources, funds for obtaining meeting space, availability of contractor support, significance of PRA in decision making, and the length of time required to complete the RI/FS. To aid in reducing costs, it may be appropriate to combine meetings regarding PRA and point estimate risk assessment based on the close links between the documents.

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