

CHAPTER 7

ROLE OF THE PRA IN DECISION MAKING

7.0 INTRODUCTION

When deciding whether or not to remediate a hazardous waste site, the risk manager needs to know if an unacceptable risk is present, and if so, what cleanup level to apply to the contaminated media. For this information, the risk manager should turn to the risk assessor for help in interpreting the results of the risk assessment. This chapter provides guidance on how to interpret the results of a probabilistic risk assessment (PRA) to help determine if an unacceptable risk is present, and the criteria to consider when deriving a risk-based preliminary remediation goal (PRG) and a final remedial goal.

7.1 GENERAL PRINCIPLES OF RISK-BASED DECISION MAKING IN SUPERFUND

Under Agency policy, an individual with reasonable maximum exposure (RME) will generally be the principal basis for evaluating potential human health risks at Superfund sites (see *Risk Assessment Guidance for Superfund* (Section 6.1.2 of U.S. EPA, 1989) and the National Contingency Plan's (NCP) Preamble (U.S. EPA, 1990)). The RME is defined as the highest exposure that is reasonably expected to occur at a site, and is intended to estimate a conservative exposure case (i.e., well above the average case) that is still within the range of possible exposures. In general, where cumulative carcinogenic risk to the RME individual is less than $1E-04$, and the non-carcinogenic Hazard Index (HI) is less than or equal to 1, remedial action is not warranted under Superfund unless there are adverse environmental impacts, or the applicable or relevant and appropriate requirements (ARARs) are not met. As discussed in Section 7.2.4, the RME receptor is often (although not always) an appropriate basis for evaluation of risks to ecological receptors, as well.

Once a determination of unacceptable risk to humans and/or ecological receptors has been made, the risk managers will typically ask the risk assessor to develop site-specific PRGs. PRGs are generally defined as health-based chemical concentrations in an environmental media for which the risks (cancer or noncancer) to the RME receptor would not exceed some specified target level. For systemic or noncarcinogenic toxicants, the target risk level is generally a HI of unity (1). This is considered to be a threshold concentration to which the human population (including sensitive subgroups) and ecological receptors may be exposed without adverse effect during less-than-lifetime (i.e., chronic, subchronic, or short-term) exposures. For carcinogens, the target risk level used to derive the PRG typically represents a cumulative lifetime cancer risk to an individual of between $1E-06$ and $1E-04$ (equivalently expressed as 10^{-6} and 10^{-4}). For carcinogenic risks, less-than-lifetime exposures are converted to equivalent lifetime values (U.S. EPA, 1989). The $1E-06$ risk level is specified in the NCP as a point of departure for determining remediation goals when ARARs are not available or not sufficiently protective. It is important to remember that risk-based PRGs are initial guidelines and do not represent final cleanup or remediation levels. Remediation levels are finalized after appropriate analysis in the remedial investigation/feasibility study (RI/FS) and record of decision (ROD). A final cleanup level may differ from a PRG based on the risk manager's consideration of various uncertainties in the risk estimate, the technical feasibility of achieving the PRG, and the nine criteria outlined in the NCP (see Chapter 1, Exhibit 1-2).

EXHIBIT 7-1

DEFINITIONS FOR CHAPTER 7

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.

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.

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., 95th 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., 95th 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.

Hazard Index (HI) - The sum of more than one Hazard Quotient for multiple substances and/or multiple exposure pathways. The HI is calculated separately for chronic, subchronic, and shorter-duration exposures.

Hazard Quotient (HQ) - The ratio of a single substance exposure level over a specified time period (e.g., subchronic) to a reference dose (or concentration) for that substance derived from a similar exposure period.

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, 1991b).

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.

RME Range - The 90th to 99.9th percentiles of the risk distribution generated from a PRA, within which an RME risk value may be identified. The 95th percentile is generally recommended as the starting point for specifying the RME risk in a Superfund PRA.

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

7.2 INTERPRETING A RISK DISTRIBUTION

7.2.1 WHAT IS A DISTRIBUTION OF RISK AND WHAT DOES IT LOOK LIKE?

In the traditional point estimate risk assessment approach, risks to the RME individual are characterized as single point values (e.g., HI=2, or cancer risk=1E-05). In the PRA approach, the output of the risk assessment is an estimate of the distribution of risks across all members of the population. An example is shown in Figure 7-1.

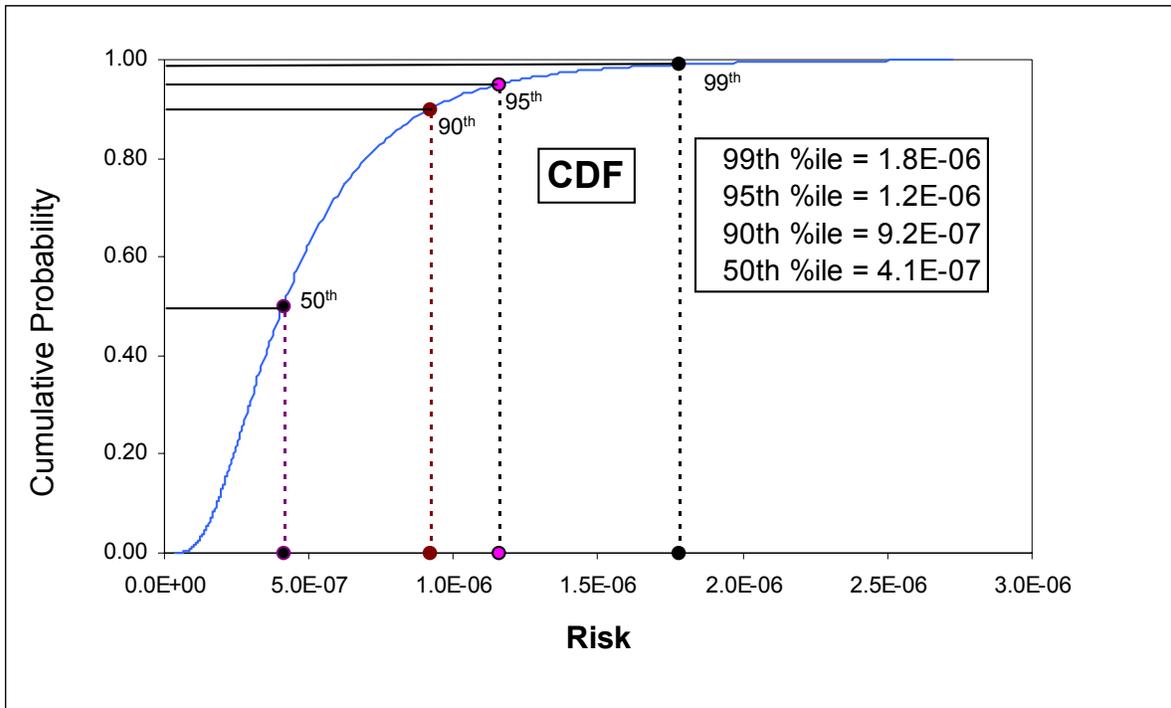


Figure 7-1. Hypothetical PRA results showing a cumulative distribution function (CDF) for lifetime excess cancer risk.

In this example, the x-axis of Figure 7-1 represents the excess lifetime cancer risk level and the y-axis represents the cumulative probability of the cancer risk level within the hypothetical population. The graph also shows various landmarks along the distribution curve such as the 50th percentile, the 90th, 95th, etc. In this illustration, the 95th percentile corresponds to a cancer risk of 1.2E-06.

7.2.2 WHAT IS THE RME RANGE?

Given a risk distribution such as shown in Figure 7-1, what part of the risk distribution should a risk manager be concerned about? As explained above, the risk to the RME receptor is a key factor in making decisions regarding the need for action at a Superfund site. EPA's *Guidelines for Exposure Assessment* (U.S. EPA, 1992) states that the "high-end" (or RME) of exposure for a population occurs between the 90th and 99.9th percentiles, with the 99.9th percentile considered a bounding estimate. Similarly, PRAs developed to support RME risk estimates for Superfund should reflect this approach.

☞ *In this guidance, the 90th to 99.9th percentiles of the risk distribution are collectively referred to as the **recommended RME range**.*

In utilizing PRA results to determine if an unacceptable risk is present and to develop a PRG which is sufficiently protective, risk managers should address two questions:

- (1) What percentile of the risk distribution will be selected to represent the RME receptor?
- (2) How will information on uncertainty in the high-end risk estimates be used in this process?

The risk manager may consider a number of factors in choosing a specific percentile to represent the RME individual. This may include both quantitative information and professional judgment. In particular, risk managers may need to understand what sources of variability and uncertainty are already explicitly accounted for by the modeling approach and inputs (i.e., point estimates and/or probability distributions) used to estimate the risk distribution, and what sources may be present but are not quantified. Approaches for selecting an appropriate percentile in human health and ecological risk assessments are described below.

7.2.3. RELATING THE RISK DISTRIBUTION TO THE RISK MANAGEMENT GOAL FOR HUMAN HEALTH

In most cases, a recommended starting point for risk management decisions regarding the RME is the 95th percentile of the risk distribution. The 95th percentile for the risk distribution is an appropriate description of high-end exposure as identified by the Presidential/Congressional Commission on Risk Assessment and Risk Management (1997).

☞ *In human health PRA, a recommended starting point for risk management decisions regarding the RME is the 95th percentile of the risk distribution.*

Figure 7-2 illustrates this approach for a site where cancer risks are the risk driver. Assume the risk manager has selected an excess cancer risk of 1E-05 as the risk management goal, and the 95th percentile as the definition of the RME. If line B on the graph represents a 1E-05 probability of cancer, a no-action decision may be warranted because the 95th percentile of the risk distribution is below the cancer risk level of concern. Conversely, if we were to assume that the 95th percentile is above the risk level of concern (i.e., line A on the graph represents 1E-05), remedial action may be warranted.

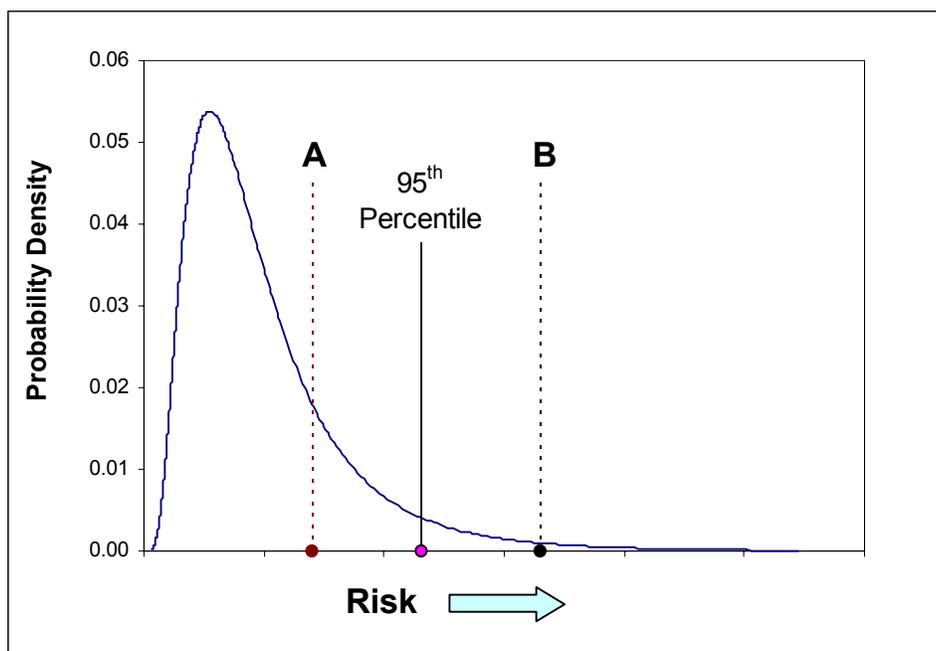


Figure 7-2. Example of a probability distribution for risk illustrating the 95th percentile and two different risk levels of concern (A and B). Assuming the 95th percentile corresponds to the RME, the need for remedial action depends on how the RME risk compares with the risk level of concern. For Case A (RME > level of concern), remedial action may be warranted. For Case B (RME < level of concern), remedial action may be unnecessary.

Although the 95th percentile is recommended as a starting point for defining the RME in the majority of human health risk assessments conducted within the Superfund program, the risk manager may use discretion in selecting a different percentile within the RME range (90th to 99.9th percentiles). In situations where the risk manager believes that a sufficient amount of site-specific information has been collected to indicate that the risk estimates are much more likely to be high (e.g., overestimated due to multiple health protective inputs), the risk manager may choose a lower percentile within the recommended RME risk range (e.g., the 90th) as the most representative of the RME estimate at the site. Conversely, when the risk manager believes that the risk estimates may tend to underestimate true risks, or if there is substantial uncertainty in the accuracy of the risk estimates, the risk manager may choose a percentile higher than the 95th in the recommended RME risk range (e.g., the 98th or the 99th). There are a variety of factors that can be considered when making this decision, such as the qualitative and quantitative uncertainty in the exposure assessment calculations, the uncertainty in the toxicity values, and the presence of biological or measured data (in contrast to modeled data). These factors are discussed below in Section 7.3. It is highly recommended that the risk manager consult with the site risk assessor when applying these factors to determine an appropriate percentile in the RME risk range.

7.2.4 RELATING THE RISK DISTRIBUTION TO THE RISK MANAGEMENT GOAL FOR ECOLOGICAL RISK ASSESSMENT

For ecological risk assessments, the choice of the percentile of the variability distribution for exposure or risk that will be protective depends on the receptor that is being considered as well as the nature of the endpoint used to establish the level of concern. For most species, the risk management objective will generally be to ensure population sustainability, even if some individual members of the population (those at the upper end of the exposure or risk distribution) may experience a higher risk of adverse effects. The risk management goal of population stability does not necessarily correspond to protection of the central tendency receptor at or below the regulatory level of concern.

As indicated in Chapter 4, without knowledge of the proportion of the local population that must survive and reproduce for the population to be stable, the choice of the central tendency exposure (CTE) receptor as the basis of the risk management goal may not be protective. Sustainability of a local population often depends upon the amount of “reserves” within that subpopulation to fill in ecological niches left voided by toxicologically impaired individuals. At a very small number of sites, a population biologist may be able to provide information about the level of effect associated with a decrease in population sustainability. At the majority of sites, the use of the CTE receptor by risk management as the basis for adequate protection of local populations of ecological receptors cannot be supported. Therefore, in the absence of such species-specific (trophic level) information, it is prudent and appropriate to base PRGs and cleanup levels on the upper end of the distribution of variability in the Hazard Quotient (HQ) to provide greater confidence that the receptor population of concern will be protected.

For threatened or endangered species, it will normally be appropriate to provide protection to as high a percentile of the distribution (i.e., the RME receptor) as is practicable (e.g., high-end of the RME range of 90th to 99.9th percentiles), since injury to even a single individual is undesirable.

7.3 FACTORS TO CONSIDER IN CHOOSING THE PERCENTILE FOR THE RME

Risk assessments (both point estimate and PRA) should be based on the best quality data available. A key component of the risk management process is a careful review and evaluation of the potential limitations in the quality and relevance of the data that are used in the risk assessment (i.e., qualitative and quantitative uncertainties) in order to evaluate the strengths and weaknesses of the assessment (U.S. EPA, 1993). Communication between risk managers, risk assessors, and other technical team members is vital at this stage. The main question to be answered is, “How well do the inputs to the risk assessment represent exposure pathways and behaviors at a given site?” The answer to this question can be expressed qualitatively (e.g., high, medium, or low) or quantitatively (e.g., confidence intervals or credible intervals). Some examples of these types of evaluation are illustrated below.

Use of Default Exposure Distributions

When site-specific data are not available, the best available information on some exposure parameters most likely will be from studies at other sites (e.g., in other parts of the country). In both point estimate risk assessment and PRA, the use of surrogate data to support input parameters raises questions about representativeness for both current and future land use scenarios. A specific example of potentially poor representativeness would be the use of national data for estimating the exposure frequency of adult workers when the receptor of concern is a railroad worker. Railroad workers may typically be on the site for only 100 days/year. If the risk assessment were based on the national default assumption of 250 days/year, this choice would give a high bias to the risk estimate.

Another example of a site-specific exposure factor that may vary considerably among different locations is fish ingestion rates. At sites where ingestion of fish contaminated with metals poses a concern, tissue concentrations from fish fillets collected on site are often used to determine the concentration term. However, a cultural practice of people harvesting fish on site may include consuming some of the internal organs of the fish in addition to the fillets. If the metal contaminants selectively accumulate in the internal organs instead of the fillet tissues, use of data only on fillets contaminants would give a low bias to the risk estimate.

Other Factors that Influence Site-Specific Exposures

Exhibits 7-2 and 7-3 list other types of factors that may be important to consider when evaluating the representativeness of an exposure or risk model. Given the source of the available data, the risk assessor should identify potential uncertainties and discuss the likelihood that the values used may under- or overestimate actual site-specific exposures. The risk manager should consider this information in decision making throughout the tiered process for PRA (see Chapter 2).

EXHIBIT 7-2

EXAMPLES OF DEMOGRAPHIC, CULTURAL, AND BEHAVIORAL FACTORS THAT CAN AFFECT EXPOSURE

- Subsistence fishing, hunting, or ingestion of home-grown produce
- Exposures to cultural foods or medicines that contain contaminants
- Preparation of foods in containers that contain contaminants that may leach out into food or beverage
- Hobbies and other personal practices resulting in exposure to contaminants
- Age of the population (e.g., children may have greater exposure and susceptibility than adults (U.S. EPA, 1995b, 1996))

EXHIBIT 7-3

EXAMPLES OF PHYSICAL OR GEOGRAPHICAL FACTORS THAT CAN AFFECT EXPOSURE

- Geographical features that limit or enhance accessibility (e.g., slopes, valleys, mountains)
- Land use, including where exposure occurs within the exposure unit, and the current or future manner in which the receptor contacts the contaminated media
- Availability of contaminated medium for exposure (e.g., grass vs. bare soil)
- Depth of contamination (e.g., surface soil is of greatest concern for direct contact)
- Bioavailability of contaminant from media or water (e.g., physiochemical factors that enhance or reduce absorption)
- Water quality and distribution systems, including water hardness and use of lead-soldered pipes
- Temporary barriers (e.g., fences, ground cover, and concrete) that affect current (but not necessarily future) exposures

For example, the features of a potentially exposed population and the physical and geographical factors at a site can increase or decrease exposure to contaminated media. These factors should be considered in defining exposure pathways and characterizing exposure variables in the risk assessment. Such site-specific information may support a decision to evaluate the entire RME range (90th to 99.9th percentile) before selecting the percentile that represents RME risk. A departure from the 95th percentile would depend on whether or not qualitative or quantitative factors suggest an increased or decreased exposure, and hence, risk. In practice, multiple and sometimes competing factors may need to be balanced in order to determine an appropriate percentile for the RME risk (see hypothetical example in Section 7.5).

Subpopulations may be at increased risk from chemical exposures due to increased sensitivity, behavior patterns that result in high exposures, and/or current or past exposures from other sources. Environmental health threats to children are a particular concern (U.S. EPA, 1995b, 1996). Once identified, a subgroup can be treated as a population in itself, and characterized in the same way as the larger population using similar descriptors for population and individual risk (U.S. EPA, 1995a). This principle applies to both point estimate risk assessments and PRA.

Use of Biological Data

Biological monitoring data and/or other biomarker data can be useful sources of information for evaluating uncertainty in an exposure or risk assessment. These data can provide an indication of the magnitude of current or past exposures and the degree to which the exposures are correlated with contaminated site media. Examples of biological data that are useful in human health assessments include lead in blood, trichloroethylene and its metabolites in blood or urine, arsenic or methyl parathion metabolites in urine, and polychlorinated biphenyls (PCBs) or dioxins in blood or fat tissue. Tissue burdens of contaminants are also widely useful as biomarkers of exposure in ecological risk assessments. Just as air or groundwater monitoring data can provide increased (or decreased) confidence in the results of predictive air or groundwater models, biomarkers can be used in a similar manner to evaluate how much confidence should be placed in predictive exposure assessment models. Biological data can be subject to the same shortcomings as other exposure data in terms of data quality and representativeness. The design and performance of the biological data collection effort generally should be carefully evaluated for these factors (e.g., low, medium, and high quality or confidence; low or high bias, etc.) before using the results in the risk decision. Currently, collection of biological monitoring data is limited at Superfund sites and requires coordination with appropriate agencies outside of EPA.

Issues Related to Toxicity Factors

A variety of factors may affect the magnitude of adverse responses expected to occur in similarly exposed individuals such as age, physiological status, nutritional status, and genotype. In general, these sources of inter-individual variability, and related uncertainties, are taken into account in the derivation of toxicity values (e.g., reference concentration (RfC), reference dose (RfD), and carcinogenic slope factor (CSF)) used in human health risk assessments. Thus, human health toxicity values usually are derived to be health-protective for the most sensitive populations.

☞ Sources of variability or uncertainty are often accounted for in the derivation of toxicity values. The level of protectiveness afforded by the toxicity value may be an important factor in deciding on the appropriate RME risk percentile to use.

Risk managers, in collaboration with risk assessors, should carefully consider whether the toxicity value is representative of the population of concern. For example, the toxicity value may be based on oral exposures to drinking water, whereas exposure to a site population being evaluated may be via soil ingestion. Similarly, the toxicity value could be based on effects in a healthy worker population, whereas the site population encompasses all ages and a range of individual health conditions. Uncertainty in toxicity values may reflect insufficient data to evaluate developmental toxicity concerns or to account for *in utero* exposures. Also, it may be unclear whether the population of concern has similar characteristics to the sensitive population accounted for in the derivation of the toxicity value. This determination may require coordination with a toxicologist to review the basis for the derivation of the toxicity values in question. Even then, in most cases, the determination will be very difficult, because our understanding of human variability in toxicologic responses is very limited for many chemicals. When data are insufficient to support a more quantitative representation of these sources of inter-individual variability an uncertainty factor may be used in the derivation of non-cancer human health toxicity values (RfD, RfC).

Some of the same factors that should be considered when employing toxicity values to estimate risk are also relevant to the use of toxicokinetic and toxicodynamic modeling in risk assessment. For example, a toxicity assessment for methylmercury used a technique called benchmark dose modeling (BMD) to relate the levels in maternal blood to adverse developmental effects, based on data from a large epidemiology study of Faroes Islanders (Grandjean et al., 1997; Budtz-Jørgensen et al., 2000). The RfD determined is well-supported by the other large human studies from the Seychelles (Davidson et al., 1995, 1998) and New Zealand (Kjellstrom et al., 1986, 1989) as well as a physiologically-based pharmacokinetic (PBPK) model based on the Seychelles data (Clewell et al., 1999). The RfD obtained with benchmark dose modeling (BMD) was 1E-04 mg/kg-day. The PBPK model incorporated variability in toxicokinetics to obtain a range of acceptable intakes of methylmercury between 1E-04 and 3E-04 mg/kg-day. Although the PBPK model was not used in the derivation of the benchmark dose value, it was used to support the choice of uncertainty factors in the derivation of the RfD.

At the time this guidance was finalized, the understanding of this type of toxicity information (i.e., human variability) was not well developed. Although such information was not used to characterize variability in human health risks, the estimates of variability from the PBPK model did provide additional information on uncertainty. For decision makers, the toxicity data and the choice of the endpoint (e.g, neurodevelopmental effects in the case of methylmercury) can guide qualitative risk management choices regarding the percentile representing the RME (within the 90th to 99.9th percentile range) and/or the appropriate level of confidence in the RME estimate. Exhibit 7-4 lists some of the issues to consider when evaluating the uncertainty in a toxicity value.

EXHIBIT 7-4

EXAMPLES OF TOXICITY CONSIDERATIONS

- How severe is the effect?
- Is the effect reversible?
- How steep is the slope of the dose-response curve at low dose?
- Is the contaminant persistent in the environment or in receptors?
- Does the contaminant bioconcentrate as it moves through the food chain?
- How bioavailable is the contaminant?

Use of Quantitative Uncertainty Estimates

PRA methods such as a two-dimensional Monte Carlo analysis (2-D MCA) may be used to quantify the uncertainty or confidence surrounding risk estimates, and this information may be helpful in selecting the RME risk percentile. Figure 7-3 provides hypothetical results of a 2-D MCA where a credible interval has been quantified for a 95th percentile of variability in noncancer HI. In exposure units (EU) 1 and 3, the credible intervals for the 95th percentile are fairly narrow, which suggests a high degree of confidence that the risks in EU1 are negligible and that the risks in EU3 are unacceptable. Conversely, the relatively wide credible intervals in EU2 and EU4 give less confidence in the results, but suggest that the 95th percentiles likely exceed a target HI of 1 in both cases. Further efforts to reduce or characterize uncertainties may affect the risk management decision in these two areas.

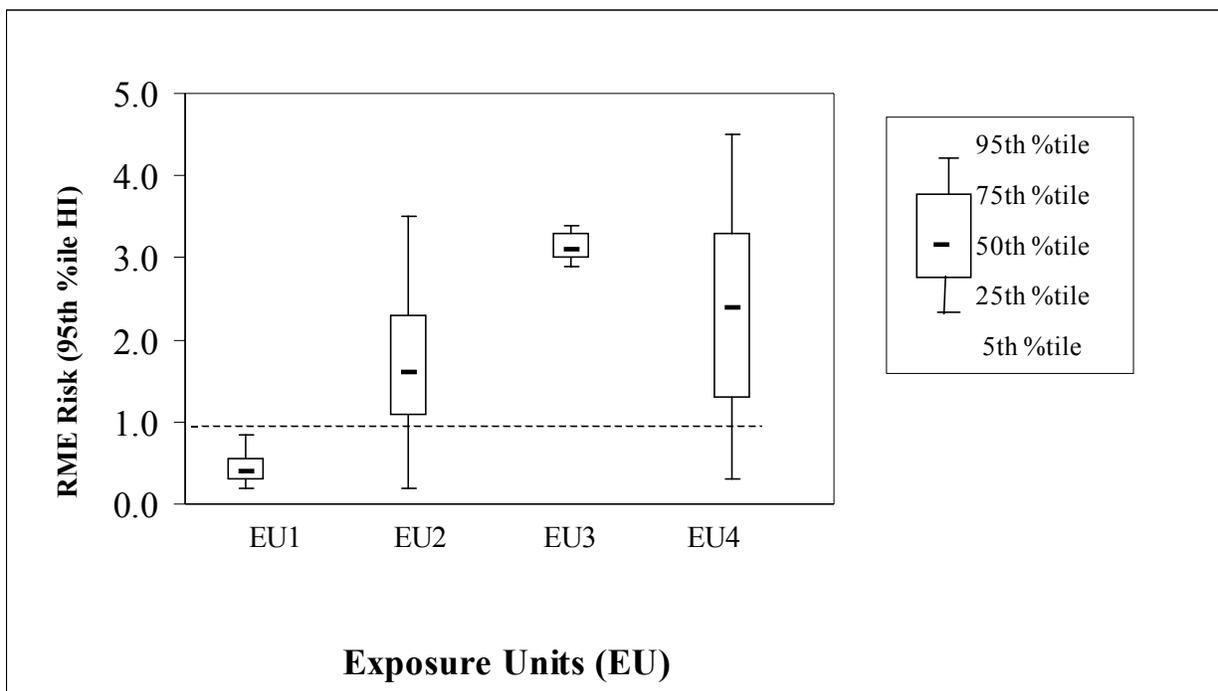


Figure 7-3. Box and whisker plots characterizing uncertainty in the RME risk estimates (95th percentile of the Hazard Index) at four locations. The box represents the inter-quartile range (25th to 75th percentiles) while the whiskers represent the 90% credible interval (5th to 95th percentiles).

Summary: Multiple Criteria Form the Basis of the Remedial Decision

Final risk management decisions should be based on a weighted consideration of all of the relevant factors that influence confidence in the risk distribution. For example, a risk manager may be presented with a risk assessment for a heavy metal in residential soil in which the distribution of cancer risk estimates in the RME range (i.e., 90th to 99.9th percentiles) overlaps the risk range of concern (1E-06 to 1E-04). The risk manager then should proceed with the site technical team to evaluate the data available to define inputs for the risk assessment, as well as the site-specific factors, and the available biological monitoring data. Assume that several factors that are likely to increase the confidence in the risk estimates were noted: (1) the soil collection and analysis effort was well-designed; (2) the predominant chemical and physical forms of the metal in the soil are characterized by relatively low bioavailability; (3) all of the yards in the residential neighborhood are covered with grass lawns, a feature generally expected to reduce direct exposure to soil; and (4) biomonitoring data from the site are all within normal physiological ranges, suggesting little, if any, excess contaminant exposure occurred at the site. In addition, generic national data were used in the absence of site-specific information on two input variables that ranked highest in the sensitivity analysis, thereby reducing confidence in the risk estimates. In this example, the consideration of these factors collectively suggests that the results of the risk assessment are likely biased towards an overestimate of risk, and this information may be used in a risk management selection of a percentile of the risk distribution to represent the RME receptor (e.g., less than or equal to the 95th percentile).

7.4 UNCERTAINTY ASSOCIATED WITH THE USE OF THE 99.9TH PERCENTILE

As previously stated, this guidance adopts the 90th to 99.9th percentiles of the risk distribution as the recommended RME risk range for decision-making purposes, consistent with EPA's *Guidelines for Exposure Assessment* (U.S. EPA, 1992). A cautionary note should be added about the selection of the higher percentiles within that range, especially the 99.9th percentile. The extreme percentiles ("tails") of an input distribution are understandably the most uncertain part of a PDF, since the number of data values in these ranges are less abundant than in the center of the range. This uncertainty in the tails of the input distributions leads in turn to greater uncertainty in the tails of the calculated exposure or risk distribution, and the magnitude of this uncertainty increases rapidly at the very high percentiles. In many cases, estimates at the extreme tails, such as the 99.9th percentile, may be neither accurate nor plausible. For that reason, great care should be taken when evaluating an RME risk in the upper percentiles of the risk range.

7.5 MOVING FROM A PRG TO A REMEDIAL GOAL

As discussed above, where an unacceptable risk is identified, the risk assessor is typically asked to develop site-specific PRGs (see Chapter 5 for discussion on derivation of PRGs). PRGs may be developed using a probabilistic approach much in the same manner as they are developed using a point estimate approach. The target risk level should be set for a specified percentile (corresponding to the RME receptor), and the concentration in contaminated media which corresponds with that target risk level should be calculated. It is important to understand that the PRG is an early step, not the last step, in the selection of a final cleanup level. During the RI/FS, the risk manager should evaluate the remedial alternatives using the nine criteria described in the NCP (U.S. EPA, 1990) (Chapter 1, Exhibit 1-2). Achieving a target level of protection for human and/or ecological receptors is one of the primary factors, but this objective should be balanced by criteria such as feasibility, permanence, state and community acceptance, and cost. Indeed, there may be times when a purely risk-based PRG may be impracticable as a final cleanup goal. In cases such as this, it is important to remember that the RME is not a single, fixed percentile on the risk distribution, but instead represents the portion of the risk distribution curve between

the 90th and 99.9th percentiles. Depending on the specific exposure and toxicity information available at a site, a PRG developed using the 90th percentile of risk may be sufficient to protect the reasonably maximum exposed individual. Alternatively, at some sites, the risk manager may feel that a PRG developed using even the 95th percentile of risk is not sufficiently protective of the RME individual and thus may choose to develop a PRG using a higher percentile.

☞ Selection of final remediation or cleanup levels during the RI/FS and ROD may be an iterative process, and may consider a range of factors in addition to the initial PRG estimate.

For example, at a former nuclear energy site, a PRG of 200 picocuries/gram (pCi/g) was developed for plutonium in soil based on a one-dimensional Monte Carlo analysis (1-D MCA) and the recommended starting point of the 95th percentile for the RME individual. At this particular site, the surrounding communities were strongly opposed to this PRG as a cleanup level. They felt it was not adequately protective, and as a result, limited progress occurred in remediating the site over the years. The communities pointed out to the risk manager that many of the exposure assumptions used in the PRA were not site-specific, and some members of the community felt that exposures occurred more often (i.e., with higher frequency) and for a longer period of time (i.e., for a greater duration) than were assumed. Based on the exposure parameters recommended by the community, the PRG would have been 75 pCi/g. At this point, the risk manager could have chosen to either go back and collect sufficient site-specific demographic and exposure data to refine the risk calculations and the PRG derivation, or evaluate the feasibility of a PRG associated with higher percentiles on the risk distribution curve (e.g., 99th percentile). In this particular example, the risk manager compared the costs associated with the cleanup that would be required to satisfy the community concerns with the costs associated with collection of additional data and recalculation of the risk and PRG. The risk manager decided that the additional cost of cleanup was manageable and expected that the PRG based on the 99th percentile would be accepted by the community. In addition, remedial activity could begin quickly without more investigation. When the risk manager presented these findings to the community, the citizens quickly agreed with this approach and remediation activities moved forward.

How does Variability and Uncertainty in Risk Relate to the Choice of a PRG?

An effective approach for communicating the results of a probabilistic analysis to risk managers is to develop graphics that relate variability and uncertainty in risk to the choice of a PRG. Two graphics are illustrated in Figures 7-4 and 7-5, based on the concept of iterative simulations presented in Chapter 5 (Section 5.5). Continuing the PRG example discussed above, assume that multiple 1-D MCA simulations are run with PRGs for plutonium ranging from 25 pCi/g to 250 pCi/g in increments of 25 pCi/g. As the concentration term is changed to correspond with a PRG, each Monte Carlo simulation yields a different distribution of risk. Figure 7-4 focuses on the RME range of percentiles from the risk distribution (i.e., 90th - 99.9th percentiles). A risk manager might use this graphic to evaluate how the PRG could change based on the choice of the percentile used to represent the RME. A hypothetical risk level of concern of 1E-05 corresponds with the 90th percentile at a PRG of approximately 125 pCi/g, whereas 1E-05 intersects the 95th percentile line at a PRG of approximately 75 pCi/g. Therefore, when variability in risk is the focus of the decision, the difference between an RME set at the 95th percentile instead of the 90th percentile is 50 pCi/g.

Figure 7-5 presents information on uncertainty, rather than variability. This graphic could be used to summarize results of a 2-D MCA (see Appendix D), or a series of 1-D MCA simulations (see

Chapter 3, Section 3.4) applied to the same range of PRGs evaluated in Figure 7-4. In this case, the results yield a 90% credible interval (CI) for the risk distribution. Figure 7-5 highlights the 90% CI for the 95th percentile, assuming that a risk manager selects the 95th percentile to represent the RME risk, and she is interested in the uncertainty in the risk estimates. Using the same hypothetical risk level of concern (1E-05), the 90% upper CI for the 95th percentile corresponds with 1E-05 at a PRG of approximately 25 pCi/g. The risk manager may need to consider the cost and feasibility of achieving a PRG as low as 25 pCi/g. In addition, the 90% lower CI corresponds to a PRG of 250 pCi/g. The risk manager may determine that this range of uncertainty (i.e., an order of magnitude) is too wide to set a PRG, and that further steps are needed to reduce identify the major sources (i.e., sensitivity analysis).

Variations on Figures 7-4 and 7-5 can be developed to focus on different percentiles of the risk range. This information, together with the results of the sensitivity analysis which highlights the major sources of variability and uncertainty, should help to guide the selection of final remediation or cleanup levels, or continued data collection and analysis following the tiered process for PRA.

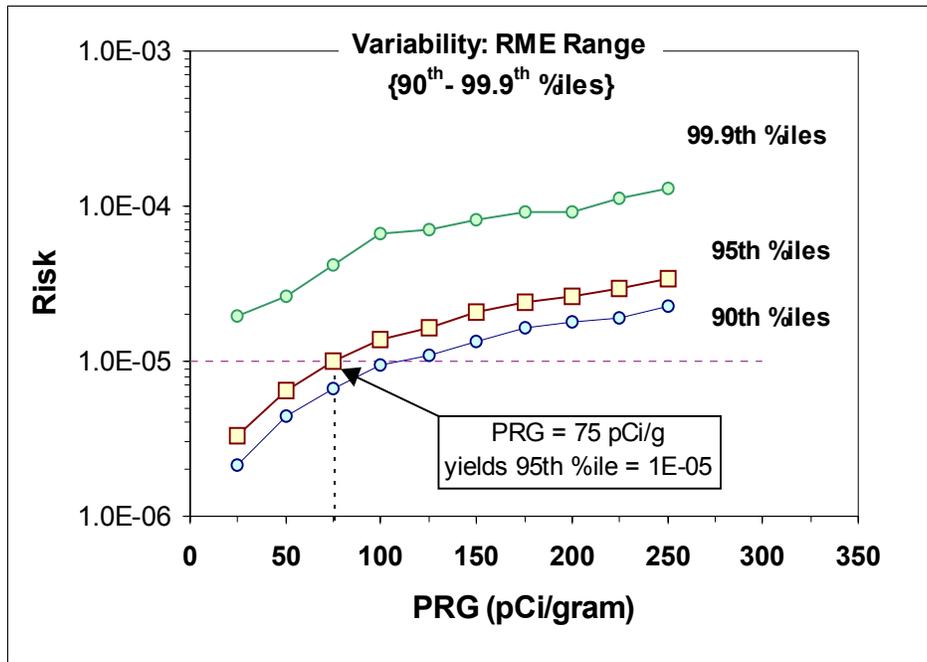


Figure 7-4. Example of graphic showing variability in risk (i.e., RME range, or 90th to 99.9th percentiles) associated with different choices of PRG for plutonium in soil (pCi/g). The hypothetical risk level of concern (1E-05) corresponds to a 90th percentile risk at a PRG of ~ 100 pCi/g, and a 95th percentile at a PRG of ~ 75 pCi/g. In this example, all of the 99.9th percentiles exceed 1E-05, leaving no choices for PRG at the high end of the RME range.

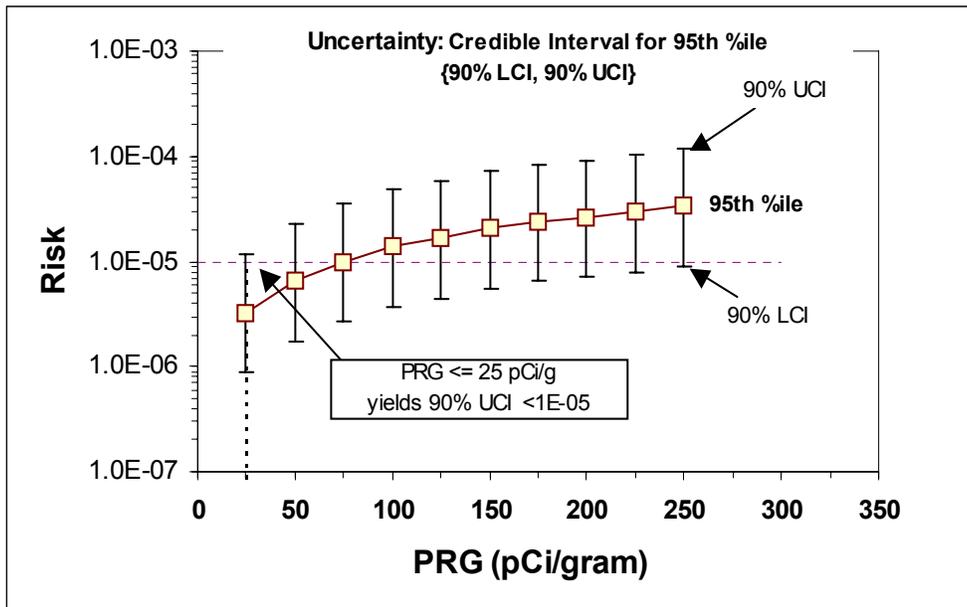


Figure 7-5. Example of graphic showing uncertainty in 95th percentile risk associated with the same choices of PRGs given in Figure 7-4. Uncertainty is given by the 90% upper and lower credible interval (CI). The hypothetical risk level of concern (1E-05) corresponds with the 90% upper CI at a PRG of ~ 25 pCi/g, and the 90% lower CI at a PRG of ~ 250 pCi/g.

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