



## U.S. Navy Human Health Risk Assessment Guidance

# Chapter 9 – Other Tools: Using Probabilistic Risk Assessment to Further Characterize Risks

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## 9.0 Introduction

This chapter presents a technique for more thoroughly evaluating risk, and evaluating and characterizing the uncertainty and variability associated with risks presented in a baseline risk assessment (BHHRAs). While a BHHRAs uses a single value or point estimate (also called a deterministic approach) to calculate risks, a probabilistic risk assessment (PRA) uses a range of estimates to calculate the risks. This results in a more detailed evaluation that determines a range of risks and highlights the predominant contributing factors (USEPA, 1999).

Performing a PRA is one way to accomplish the United States Environmental Protection Agency's (USEPA's) goal of using several descriptors of risk. Most BHHRAs use only a single descriptor of risk (usually the reasonable maximum exposure [RME] scenario) (USEPA, 1995). A variety of PRA modeling techniques can be used to characterize the variability and uncertainty in risk. Monte Carlo analysis (MCA), is one of the most common probabilistic methods used for human health risk assessment (HHRA) purposes. While a PRA can be a useful tool to characterize and quantify variability and uncertainty in risk assessments, it is not appropriate for every site (USEPA, 1999). Remedial Project Managers (RPMs) should consider the option of developing PRAs on a case-by-case basis.

## 9.1 Purpose and Objectives

### Introduction

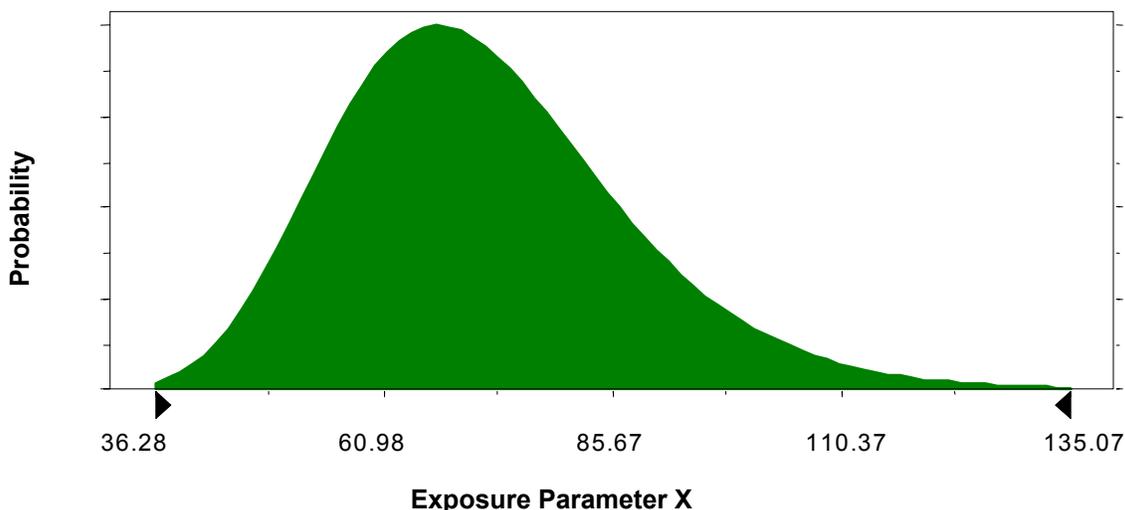
A risk assessment performed using probabilistic methods is very similar in concept and approach to the traditional deterministic method used in the BHHRAs, with the main difference being the methods used to incorporate uncertainty and variability into the risk estimate (USEPA, 1999). In the point estimate approach, a single numerical value (i.e., point estimate) is chosen for each variable. For example, point estimates may include a drinking water ingestion rate of 2 L/day and a body weight of 70 kg for an adult. Based on the choices that are made for each individual variable, a single estimate of risk is calculated. This differs from the probabilistic approach where a range of values is used as an input to the risk equation. Consequently, a range of risks is calculated based on various combinations of the input values.

### Goal of Probabilistic Risk Assessment

The primary goal of a PRA analysis is to characterize the uncertainty and variability in the estimates of exposure or risk. A secondary goal is to identify key sources of this uncertainty and variability, and to quantify their relative contribution to the overall variance of the BHHRAs results (USEPA, 1997). A PRA can also be used to determine risk.

### Probability Density Functions

PRA is a way to evaluate thousands of "what if" scenarios. The same calculation is performed over and over, with various combinations of input parameters. The input parameters are randomly selected from a range of values, also called a probability density function (PDF). PDFs are functions representing the distribution of a variable. The density (i.e., the height of the graph curve) at a point refers to the probability that the variable will have a specific value. [Figure 9.1](#) presents an example of a PDF.

**Figure 9.1 – Example Probability Density Function**

**Explanatory Text for Figure 9-1.** In an exposure calculation that includes exposure parameter X, a single value is randomly selected from the distribution. This process occurs for each parameter for which there is a distribution (each calculation is called an iteration). Each iteration of a PRA analysis represents a combination of exposure and toxicity variables. A convenient aid to understanding the PRA approach for quantifying variability is to visualize each iteration as representing a single individual and the collection of all iterations as representing a population. In general, each iteration should represent a plausible combination of input values, which may require using bounded or truncated probability distributions (USEPA, 1999).

### Uncertainty and Variability

An essential concept in a PRA is the distinction between “uncertainty” and “variability.” Efforts to clearly distinguish between uncertainty and variability are important for both risk assessment and risk communication (USEPA, 1999). Uncertainty occurs because of a lack of knowledge. In other words, uncertainty is an expression of the confidence we have that a parameter accurately reflects the population. For example, the uncertainty associated with a study of body weights that included 100 individuals is much higher than that from a study that includes 10,000 individuals. Consequently, a risk assessment conducted using a body weight value based on the 10,000-individual study would have less uncertainty than using a body weight value from the 100-person study. Generally, larger numbers of individuals included in the study result in more confidence in the findings. Theoretically, it is possible to eliminate uncertainty by expanding the study to include all members of a population.

Variability, on the other hand, is an expression of the range of differences between individuals observed for a given population. For example, the mean body weight of a study of 10,000 individuals might be 71.7 kg but the range (i.e., variability) might be from 37 – 135 kg with a standard deviation of 15.9 kg. It is not possible to eliminate variability in heterogeneous populations even if there is no uncertainty.

## 9.2 Differences Between Deterministic Baseline Risk Assessments and Probabilistic Risk Assessments

The risks from a single chemical in a BHHRA are determined by combining a number of different values to result in a single estimate of exposure or risk. Probabilistic risk assessment differs from the point estimate approach by allowing a value to be chosen from a distribution of plausible values for each exposure variable. Thus, the output of a PRA is a range or distribution of risks experienced by the various



members of the population of concern (USEPA, 1999). The advantages and disadvantages of deterministic and probabilistic risk assessments are presented in [Table 9.1](#).

**Table 9.1 – Advantages and Disadvantages of Deterministic and Probabilistic Risk Assessments (USEPA, 1999)**

Type of Risk Assessment	Advantages	Disadvantages
Deterministic Risk Assessment	<ul style="list-style-type: none"> <li>◆ Uses upper-bound assumptions to ensure protection of human health.</li> <li>◆ Employs a consistent approach and standard reporting methods.</li> <li>◆ Requires less time to complete (than a PRA).</li> <li>◆ Can be easily understood and communicated.</li> <li>◆ Is based on standard equations and exposure assumptions.</li> <li>◆ Is consistent with historical risk assessment practice.</li> <li>◆ Can be used as a screening tool.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Results in a single-point estimate of risk, which may be viewed as a “bright line.”</li> <li>◆ Provides little insight into the range of risks.</li> <li>◆ Lacks information about variability in the potentially exposed population.</li> <li>◆ Addresses uncertainty in a qualitative manner.</li> </ul>
Probabilistic Risk Assessment	<ul style="list-style-type: none"> <li>◆ Provides a range of risk estimates.</li> <li>◆ Provides quantitative information on variability and uncertainty.</li> <li>◆ Identifies the drivers of risk and exposure by quantitative sensitivity analysis.</li> <li>◆ Provides more information to decision makers than deterministic method.</li> <li>◆ Can help to identify data gaps.</li> <li>◆ Provide confidence limits on the risk estimates.</li> <li>◆ Uses a wide variety of site-specific information.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Requires investment of time and resources for additional data collection and review.</li> <li>◆ Requires good information on PDFs.</li> <li>◆ Possesses less transparency and clarity than BHHRA.</li> <li>◆ May convey false sense of accuracy unless distributions accurately reflect site.</li> <li>◆ Makes risk management decision more challenging.</li> <li>◆ Possesses the potential for lack of consistency among different sites.</li> <li>◆ Requires extensive use of statistics, possibly limited by available software.</li> <li>◆ Must conform to limitations on the interpretation and application of results.</li> <li>◆ More difficult to communicate the results to regulators, stakeholders, and risk managers.</li> </ul>

A key step when performing a PRA is the involvement of regulators and stakeholders early in the process. People who should be involved in the PRA process include USEPA risk assessors and managers, members of the public, representatives from state or county environmental or health agencies, other federal agencies (i.e., health agencies, Natural Resource Damage Assessment trustees, etc.), tribal government representatives, and representatives from federal facilities (Department of Defense, Department of Energy, etc.). PRAs are not routinely performed at sites. Therefore, it is important to determine why a PRA would be beneficial and how the information that is generated from the PRA will be used to help make risk management decisions.



## 9.3 When Should Probabilistic Risk Assessments be Performed?

There is no discrete set of criteria for determining when a PRA should be performed at a site. PRAs generally require more time, resources, and expertise on the part of the risk assessor, reviewer, and risk manager than traditional point estimate risk assessments. In general, PRAs should only be considered at sites where the remediation costs are high and the savings offered by performing a PRA are significant. Factors that should be considered to determine if a PRA is warranted or feasible at a site are explained below.

- ◆ **Cost of Remediation** – If the remediation costs are high, then the level of effort required to perform a PRA might be appropriate.
- ◆ **Results of the BHHRA** – The results of the BHHRA should be evaluated to determine if a PRA will provide regulators, stakeholders, and risk managers with more information about the uncertainty and variability associated with the risks presented in the BHHRA. For example, if a few chemicals and exposure pathways drive the risks presented in the BHHRA, then it might be appropriate to develop a PRA to specifically evaluate the uncertainty and variability associated with these risks.
- ◆ **Availability of Site-Specific Exposure Data** – If site-specific exposure data (e.g., frequency of exposure, ingestion rates, etc.) are available, then PDFs could be incorporated into the evaluation which would increase the likelihood of acceptance by regulators and stakeholders.
- ◆ **Regulators and Stakeholders** – The views of regulators and stakeholders on PRAs should be considered when determining whether or not a PRA should be performed. If regulators or stakeholders are firmly against the use of a PRA, then its value in the risk assessment process may be diminished.

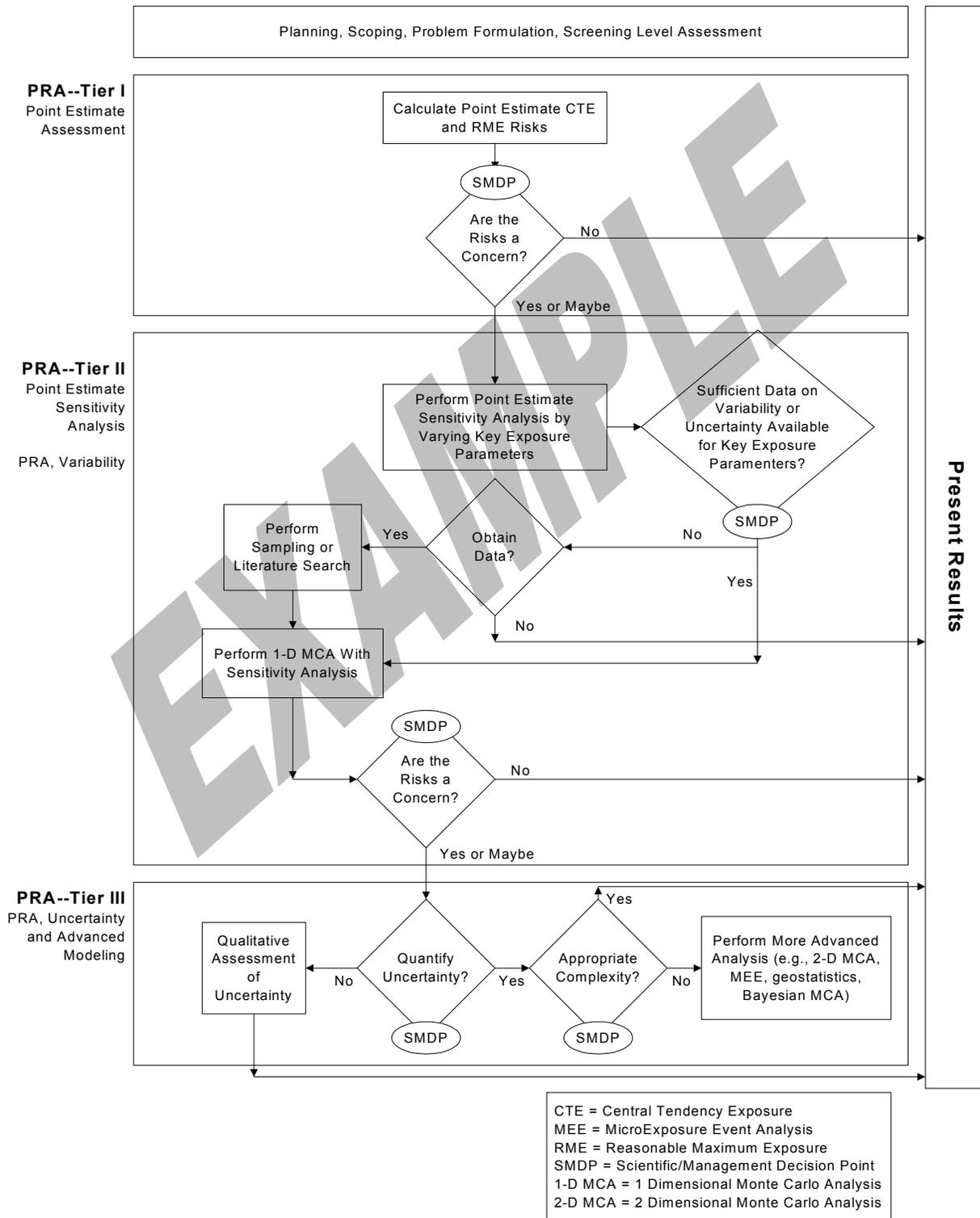
## 9.4 USEPA Policy on Probabilistic Risk Assessment

The USEPA guidance for performing PRAs states that:

- ◆ the USEPA will not evaluate probabilistic analysis without review and approval of a work plan;
- ◆ a tiered approach should be used to determine the level of complexity appropriate for the risk assessment and whether or not a PRA should be performed (see Figure 9.2 for an example of a tiered PRA approach);
- ◆ PRAs should include single-point (deterministic) RME estimates, and central tendency estimates; and
- ◆ PDFs should not be used to represent toxicity values in the Monte Carlo simulation (USEPA, 1999).



Figure 9.2 – Example Tiered Approach for Conducting Probabilistic Risk Assessments (USEPA, 1999)





In the *Guiding Principles for Monte Carlo Analysis* the USEPA has also established the following conditions for Agency review and evaluation of PRAs.

- ◆ The purpose and scope of the assessment should be clearly articulated in a "problem formulation" section that includes a full discussion of any highly exposed or highly susceptible subpopulations evaluated (e.g., children, the elderly). The questions the assessment attempts to answer should be discussed and the assessment endpoints should be well defined.
- ◆ The methods used for the analysis (including all models used, all data upon which the assessment is based, and all assumptions that have a significant impact upon the results) should be documented and easily located in the report. This documentation should include a discussion of the degree to which the data used are representative of the population under study. Also, this documentation should include the names of the models and software used to generate the analysis. Sufficient information should be provided to allow the results of the analysis to be independently reproduced.
- ◆ The results of sensitivity analyses should be presented and discussed in the report. Probabilistic techniques should be applied to the compounds, pathways, and factors of importance to the assessment, as determined by sensitivity analyses or other basic requirements of the assessment.
- ◆ The presence or absence of moderate to strong correlations or dependencies between the input variables should be discussed and accounted for in the analysis, along with the effects these have on the output distribution.
- ◆ Information for each input and output distribution should be provided in the report. This includes tabular and graphical representations of the distributions (e.g., PDF and cumulative distribution function plots) that indicate the location of any point estimates of interest (e.g., mean, median, 95th percentile). The selection of distributions should be explained and justified. For both the input and output distributions, variability and uncertainty should be differentiated where possible.
- ◆ The numerical stability of the central tendency and the higher end (i.e., tail) of the output distributions should be presented and discussed.
- ◆ Calculations of exposures and risks using deterministic (i.e., point estimate) methods should be reported. Providing these values will allow comparisons between the probabilistic analysis and previous risk assessments. Further, deterministic estimates may be used to answer scenario specific questions and to facilitate risk communication. When comparisons are made, it is important to explain the similarities and differences in the underlying data, assumptions, and models.
- ◆ Since fixed exposure assumptions (e.g., exposure duration, body weight) are sometimes embedded in the toxicity values (e.g., reference doses and cancer slope factors), the exposure estimates from the probabilistic output distribution should be aligned with the toxicity values (USEPA, 1997).

These conditions reflect the good scientific practices of clarity, consistency, transparency, reproducibility, and the use of sound methods in risk assessment.

## 9.5 References

USEPA. 1995. Guidance for Risk Characterization. U.S. Environmental Protection Agency Science Policy Council. <http://www.epa.gov/ord/spc/rcguide.htm>.



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USEPA. 1999. Risk Assessment Guidance for Superfund: Volume 3 - (Part A, Process for Conducting Probabilistic Risk Assessment). Draft. Office of Solid Waste and Emergency Response. Washington, DC. EPA 000-0-99-000. <http://www.epa.gov/superfund/programs/risk/rags3adt/>.