

APPENDIX E

DEFINITIONS OF TERMS RELEVANT TO PRA AND REFERENCES FOR FURTHER READING

E.0 DEFINITIONS OF TERMS

Definitions for the specialized terms pertaining to probabilistic analysis are presented in this appendix. Some of the same terms are also defined at the beginning of each chapter, sometimes with additional examples that are relevant to concepts presented in the chapter. The definitions in this guidance are intended to be consistent with definitions used in the National Contingency Plan (NCP) and other Environmental Protection Agency (EPA) guidance, including the definitions of variability, uncertainty, and Monte Carlo simulation found in EPA's *Guiding Principles for Monte Carlo Analysis* (U.S. EPA, 1997a). Note that if a definition uses a term that is defined elsewhere in the appendix, it is highlighted in bold text.

Definitions of Terms Used in PRA	
50th percentile	The number in a distribution such that half the values in the distribution are greater than the number and half the values are less. The 50 th percentile is equivalent to the median .
95th percentile	The number in a distribution such that 95% of the values in the distribution are less than or equal to the number and 5% of the values are greater than the number.
95% Upper Confidence Limit for a Mean	The 95 percent upper confidence limit (95% UCL) for a mean is defined as a value that, when repeatedly calculated for randomly drawn subsets of size <i>n</i> , equals or exceeds the true population mean 95% of the time. The 95% UCL provides a measure of uncertainty in the mean ; it is not a measure of variability and should not be confused with a 95 th percentile . As sample size increases, the difference between the UCL for the mean and the true mean decreases, while the 95 th percentile of the distribution remains relatively unchanged, at the upper end of the distribution. EPA's Superfund program has traditionally used the 1-sided 95% UCL for the mean as the concentration term in point estimates of reasonable maximum exposure (RME) for human health risk assessment (U.S. EPA, 1992, 1997b).
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 .
Arithmetic Mean (AM)	A number equal to the average value of a population or sample. Usually obtained by summing all the values in the sample and dividing by the number of values (i.e., sample size).
Assessment Endpoint	A term usually associated with ecological risk assessment ; an explicit expression of an environmental value (ecological resource) that is to be protected, operationally defined by risk managers and risk assessors as valuable attributes of an ecological entity. Examples include 1) sustained aquatic community structure, including species composition and relative abundance and trophic structure; 2) reductions in populations of fish-eating birds; and 3) reductions in survival, reproduction or species diversity of indigenous benthic communities (U.S. EPA, 1997c, 1999a).

Definitions of Terms Used in PRA

Backcalculation	A method of calculating a preliminary remediation goal (PRG) that involves algebraic rearrangement of the risk equation to solve for concentration as a function of risk, exposure, and toxicity.
Background Exposure	Exposures that are not related to the site. For example, exposure to chemicals at a different time or from locations other than the exposure unit (EU) of concern. Background sources may be either naturally occurring or anthropogenic (man-made).
Bayesian Analysis	Statistical analysis that describes the probability of an event as the degree of belief or confidence that a person has, given some state of knowledge, that the event will occur. Bayesian Monte Carlo combines a prior probability distribution and a likelihood function to yield a posterior distribution (see Appendix D for examples). Also called subjective view of probability, in contrast to the frequentist view of probability.
Bootstrap Methods	A method of sampling actual data at random, with replacement, to derive an estimate of a population parameter such as the arithmetic mean or the standard error of the mean . The sample size of each bootstrap sample is equal to the sample size of the original data set. Both parametric and nonparametric bootstrap methods have been developed.
Boxplot	Graphical representation showing the center and spread of a distribution, sometimes with a display of outliers (e.g., Figure 7-3). This guidance uses boxplots to represent the following percentiles : 5 th , 25 th , 50 th , 75 th , and 95 th .
Cancer Slope Factor (CSF)	A plausible upper-bound estimate of the probability of a response per unit dose of a chemical over a lifetime. The CSF is used to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.
Central Limit Theorem	If random samples of size <i>n</i> are repeatedly drawn from a population of any distribution, the distribution of sample means converges to the normal distribution. The approximation improves as <i>n</i> increases.
Central Tendency Exposure (CTE)	A risk descriptor representing the average or typical individual in the population, usually considered to be the arithmetic mean or median of the risk distribution.
CTE Risk	The estimated risk corresponding to the central tendency exposure .
Cleanup Level	A chemical concentration chosen by the risk manager after considering both RGs and the nine selection-of-remedy criteria of the NCP (U.S. EPA, 1990; 40CFR 300.430(e)(9)(iii)). Also referred to as Final Remediation Levels (U.S. EPA, 1991), chemical-specific cleanup levels are documented in the Record of Decision (ROD). A cleanup level may differ from a PRG for several reasons, including various uncertainties in the risk estimate, the technical feasibility of achieving the PRG , and application of the nine criteria outlined in the NCP.
Coefficient of Variation	Ratio of the standard deviation (SD) to the arithmetic mean (AM) ($CV=SD/AM$). Dimensionless measure of the spread of a distribution, therefore, useful for comparing probability density functions (PDFs) for different random variables .

Definitions of Terms Used in PRA

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 Community Involvement Plan (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.
Concentration Term	The concentration variable used in exposure assessment . Concentration terms are expressed in units applicable to the media of concern (e.g., mg/L for water, $\mu\text{g}/\text{m}^3$ for air; mg/kg for soil and dust).
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.
Confidence Limit	The upper or lower value of a confidence interval .
Continuous Variable	A random variable that can assume any value within an interval of real numbers (e.g., concentration).
Countably Infinite	Used to describe some discrete random variables , this term refers to a set of numbers that can be counted with integers (e.g., one, two, three) and that has no upper limit. Examples include the number of tosses required for a coin to show a head—we can count each toss, but it is possible that at least one more toss is needed. The number of dust particles in a volume of air is another example. Countably finite implies there is an upper limit (e.g., days of work per year).
Correlation	A quantitative relationship between two or more input variables of a model (e.g., body weight, inhalation rate, skin surface area). In analyses involving time-dependent variables , a change in one variable is accompanied by a change in another time-dependent, correlated variable . Ignoring correlations in probabilistic risk assessment (PRA) may lead to unrealistic combinations of values in a risk calculation. Correlations can also be defined as relationships between inputs and outputs.

Definitions of Terms Used in PRA

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 .
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 .
Cumulative Distribution Function (CDF)	A graph that shows the cumulative probability of occurrence for a random independent variable (e.g., Fig. 6-1). The cumulative probability is typically given as the y-axis, ranging from 0 to 1.0. Each value <i>c</i> of the function is the probability that a random observation <i>x</i> will be less than or equal to <i>c</i> . Mathematically, the function that defines the CDF is obtained from the PDF by integration (in the case of a continuous random variable) or by summation (for discrete random variables).
Discrete Variable	A random variable that can assume any value within a finite set of values (e.g., number of rainfall events in one month) or at most a countably infinite set of values.
Empirical Distribution	A distribution obtained from actual data and possibly smoothed with interpolation techniques. Data are not fit to a particular parametric distribution (e.g., normal, lognormal), but are described by the percentile values.
Expected Value of Information (EVOI)	The expected increase in the value (or decrease in the loss) associated with obtaining more information about quantities relevant to the decision process. EVOI is a measure of the importance of uncertainty in risk and the potential for changing a risk management decision if uncertainty is reduced (see Appendix D).
Expert Judgment	An inferential opinion of a specialist or group of specialists within an area of their expertise. Expert judgment (alternatively referred to as professional judgment) may be based on an assessment of data, assumptions, criteria, models, and parameters in response to questions posed in the relevant area of expertise (see Appendix D).
Exposure Assessment	The qualitative or quantitative estimate (or measurement) of the magnitude, frequency, duration, and route of exposure. A process that integrates information on chemical fate and transport, environmental measurements, human behavior, and human physiology to estimate the average doses of chemicals received by individual receptors. For simplicity in this guidance, exposure encompasses concepts of absorbed dose (i.e., uptake and bioavailability).
Exposure Point Concentration (EPC)	The contaminant concentration within an exposure unit to which receptors are exposed. Estimates of the EPC represent the concentration term used in exposure assessment .

Definitions of Terms Used in PRA

Exposure Unit (EU)	A geographic area where exposures occur to the receptor of concern during the time of interest. Receptors may be human or ecological (e.g., plants, birds, fish, mammals). For purposes of PRA , probability distributions for exposure and toxicity variables apply equally to all members of a population at a given exposure unit. Ecological exposure units often consider habitat and seasonality factors that enhance exposure in a spatial area usually related to home ranges.
Forward Calculations	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.
Frequency Distribution	A graph or plot that shows the number of observations that occur within a given interval; usually presented as a histogram showing the relative probabilities for each value. It conveys the range of values and the count (or proportion of the sample) that was observed across that range.
Frequentist	A term referring to classical statistics in which the probability of an event occurring is defined as the frequency of occurrence measured in an observed series of repeated trials.
Geometric Mean (GM)	The n^{th} root of the product of n observations. For lognormal distributions, the GM is equal to the median and is less than the arithmetic mean . For normal distributions, all three measures of central tendency (GM, AM , median) are equal.
Geostatistics	Branch of statistics that focuses on data that have a spatial or geographic components. In risk assessment, geostatistics is a general term for a variety of techniques that are typically applied to chemical concentrations in soil or groundwater in which the sampling locations are considered in quantifying the exposure point concentration .
Goodness-of-Fit (GoF) Test	A method for examining how well (or poorly) a sample of data can be described by a hypothesized probability distribution for the population. Generally involves an hypothesis test in which the null hypothesis H_0 is that a random variable X follows a specific probability distribution F_0 . That is, $H_0: F = F_0$ and $H_a: F \neq F_0$.
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 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).
High-end Risk	A risk descriptor representing the high-end, or upper tail of the risk distribution, usually considered to be equal to or greater than the 90 th percentile .

Definitions of Terms Used in PRA

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.
Hypothesis Testing	Statistical test of an assumption about a characteristic of a population. The goal of the statistical inference is to decide which of two complementary hypotheses is likely to be true.
Image Analysis	A technique in geostatistics used to restore a degraded image or interpret images that have been contaminated by noise or possibly some nonlinear transformation.
Independence	Two events A and B are independent if knowing whether or not A occurs does not change the probability that B occurs. Two random variables X and Y are independent if the joint probability distribution of X and Y can be expressed as the product of the individual marginal probability distributions . That is, $f(X, Y) = f(X) \cdot f(Y)$. Independence of X and Y is <i>not</i> synonymous with zero correlation (i.e., $\text{Cor}(X, Y) = 0$). If X and Y are independent, then $\text{Cor}(X, Y) = 0$; however, the converse is not necessarily true because X and Y may be related in a nonlinear fashion but still maintain zero correlation (Law and Kelton, 1991).
Independent and Identically Distributed (IID)	Random variables that are independent and have the same probability distribution of occurrence.
Individual-Level Effect	An assessment endpoint that focuses on protecting a hypothetical or real individual in a population. Individual-based models may account for unique exposure and toxicological response to chemicals among individual receptors.
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	A method of calculating a PRG that involves developing an expression for the concentration term in which high-end values are “truncated” to reduce the maximum concentration, and calculating risks associated with the reduced concentration. The method may be repeated with consecutively lower truncation limits until risk is acceptable. Iterative truncation methods avoid difficulties associated with applying Monte Carlo analysis to a backcalculation .
Kriging	A statistical interpolation method that selects the best linear unbiased estimate of the parameter in question. Often used as a geostatistical method of spatial statistics for predicting values at unobserved locations based on data from the surrounding area. Information on fate and transport of chemicals within the area lacking data can be incorporated into kriged estimates.
Kurtosis	The measure of peakedness of a distribution. A uniform distribution has a lower kurtosis than a peaked distribution such as the normal and lognormal distribution. Kurtosis is referred to as the 4 th central moment of a distribution .

Definitions of Terms Used in PRA

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).
Latin Hypercube Sampling (LHS)	A variant of the Monte Carlo sampling method that ensures selection of equal numbers of values from all segments of the distribution. LHS divides the distribution into regions of equal sampling coverage . Hence, the values obtained will be forced to cover the entire distribution. It is more efficient than simple random sampling, i.e., it requires fewer iterations to generate the distribution sufficiently.
Likelihood Function	A term from Bayesian statistics referring to a probability distribution that expresses the probability of observing new information given that a particular belief is true.
Local Sensitivity Analysis	Evaluation of the model sensitivity at some nominal points within the range of values of input variable(s).
Location Tag	The spatial coordinates of a sampling location (e.g., longitude, latitude).
Low-end Risk	A risk descriptor representing the low-end, or lower tail of the risk distribution, such as the 5 th or 25 th percentile .
Maximum Detected Concentration (MDC)	The maximum concentration detected in a sample.
Mean	Arithmetic mean or average; the sum of all observations divided by the number of observations. Referred to as the first central moment of a distribution .
Microexposure Event (MEE) Analysis	A method of assessing risk based on an aggregate sum of a receptor's contact with a contaminated medium. MEE analysis simulates lifetime exposure as the sum of many short-term, or "micro" exposures (see Appendix D). MEE approaches can be used to explore uncertainty associated with the model time step in PRA (e.g., use of a single value to represent a long-term average phenomenon, seasonal patterns in exposure, or intra-individual variability).
Mode	The most probable value of a random variable ; a value with the largest probability or highest probability density (or mass for discrete random variable). The second parameter of a triangular distribution.
Moments of a Distribution	Similar to a parameter ; constant that represents a mathematical description of a random variable . Central moments are defined with respect to the mean . Mean , variance , skewness , and kurtosis are the first, second, third, and fourth central moments of a probability distribution .

Definitions of Terms Used in PRA

Monte Carlo Analysis (MCA) or 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.
Monte Carlo Sampling	A method of simple random sampling used to obtain a distribution of values which may serve as an input to a PRA . The probability of obtaining any given sample is similar to the probability of a sample occurring within the distribution. Hence, for a given sample size, simple random sampling tends to produce values clustered around the mean of the distribution.
Multiple Regression Analysis	A statistical method that describes the extent, direction, and strength of the relationship between several (usually continuous) independent variables (e.g., exposure duration, ingestion rate) and a single continuous dependent variable (e.g., risk).
Nonparametric Method	A procedure for making statistical inferences without assuming that the population distribution has any specific form such as normal or lognormal. Sometimes referred to as <i>distribution-free</i> methods. Common examples are the sign test, Spearman rank correlation , and the bootstrap-t approach.
Numerical Stability	The property of a probabilistic simulation such that the a parameter value of the output distribution (e.g., percentile , mean , variance , etc.) remains sufficiently constant for a specified number of Monte Carlo iterations. Numerical stability is a measure of the precision of the output from a simulation; the tails of the distribution are typically less stable than the center. Sufficient precision is determined by professional judgment.
One-dimensional Monte Carlo Analysis (1-D MCA)	A method of simulating a distribution for an endpoint of concern as a function of probability distributions that characterize variability or uncertainty . In this guidance, distributions used to characterize variability may be abbreviated PDF_v , whereas distributions used to characterize uncertainty may be abbreviated PDF_u . It is good practice <i>not</i> to combine PDFs for variability and uncertainty in 1-D MCA.
Parameter	A value that characterizes the probability distribution of a random variable . For example, a normal probability distribution may be defined by two parameters (e.g., AM and SD). It is important to distinguish between this definition, and a second popular use of the term parameter when referring to an input variable in a mathematical equation or model. For this guidance, the term variable will be used to describe inputs to a model. For example, if body weight is a variable in the exposure assessment that we define with a probability distribution (e.g., normal) we would state that the variable is body weight and the parameters are the arithmetic mean and standard deviation values that characterize the normal distribution
Parametric Distribution	A theoretical distribution defined by one or more parameters . Examples are the normal distribution, the lognormal distribution, the triangular distribution, and the beta distribution.

Definitions of Terms Used in PRA

Percentile	The p^{th} <i>percentile</i> of the distribution is the value such that p percent of the observations fall at or below it. Also called <i>quantiles</i> or <i>fractiles</i> ; percentiles are expressed as a percent, ranging from 0 to 100, whereas quantiles or fractiles range from 0 to 1.
Point Estimate	A quantity calculated from values in a sample to represent an unknown population parameter . Point estimates typically represent central tendency or upper bound estimate of variability .
Point Estimate Risk Assessment	The familiar risk assessment methodology in which a single estimate of risk is calculated from a set of point estimates . The results provide point estimates of risk for the CTE and RME exposed individuals. Variability and uncertainty are discussed in a qualitative manner.
Point Pattern Analysis	A technique in geostatistics of restricting the analysis to location information, ignoring attribute information, addresses two location problems: (1) describing points according to spacing, and (2) describing points according to density.
Population-Level Effect	An ecological term for an assessment endpoint that focuses on protecting a group of individuals within a specified exposure unit and time that have similar exposures and toxicological responses to chemicals.
Posterior Distribution	A term from Bayesian statistics referring to a probability distribution that has been updated with new information.
Potentially Responsible Party (PRP)	Individuals, companies, or any other party that is potentially liable for Superfund cleanup costs.
Power	The probability that a test procedure detects a false null hypothesis ; Power equals $(1-\beta)$, where β is the probability of a Type II error (i.e., accepting H_0 when H_a is true). Power curves are a function of a fixed significance level (α), sample size, and variability (SD) .
Preliminary Remediation Goal (PRG)	A chemical concentration in an environmental medium associated with a particular exposure scenario that is expected to be protective of human health and ecosystems. PRGs may be developed based on (ARARs), or exposure scenarios evaluated prior to a risk assessment (e.g., generic PRG) or as a result of the baseline risk assessment (site-specific PRG). Exhibit 5-1 provides further detail on generic and site-specific PRGs.
Prior Distribution	A Bayesian term referring to the hypothesized, expected, or calculated probability distribution for an event prior to the collection of new information.
Probabilistic Risk Assessment (PRA)	A risk assessment that uses probabilistic methods to derive a distribution of risk or hazard based on multiple sets of values sampled for random variables .

Definitions of Terms Used in PRA

Probability Density Function (PDF)	A graph that shows the probability of occurrence of an unknown or variable quantity. A PDF is used to characterize a continuous random variable ; the integral of all possible values is equal to 1.0 (i.e., the area under the curve). In PRA, PDFs can be used to display the shape of the distribution for an input variable (e.g., normal distribution for ingestion rate) as well as the output from a Monte Carlo simulation (e.g., risk distribution).
Probability Distribution	A function that associates probabilities with the values taken by a random variable . A probability distribution can be displayed in a graph (e.g., PDF or CDF), summarized in a table that gives the distribution name and parameters, or expressed as a mathematical equation. In PRA, the process of selecting or fitting a distribution that characterizes variability or uncertainty can also be referred to as applying a <i>probability model</i> to characterize variability or uncertainty . In this guidance, the probability model is considered to be one source of model uncertainty.
Probability Mass Function (PMF)	A histogram that shows the probability of occurrence of an unknown or variable quantity. A PMF is used to characterize a discrete random variable ; similar to the PDF , the sum of all possible values of a PMF is equal to 1.0. The mass at a point refers to the probability that the variable will have a value at that point.
Random Variable	A variable that may assume any value from a set of values according to chance. Discrete random variables can assume only a finite or countably infinite number of values (e.g., number of rainfall events per year). A random value is continuous if its set of possible values is an entire interval of numbers (e.g., quantity of rain in a year) variable that may assume any of a set of values. The likelihood of each value is described by a probability distribution .
Range Sensitivity Analysis	Evaluation of the model sensitivity across the entire range of values of the input variable(s).
Rank	If a set of values is sorted in ascending order (smallest to largest), the rank corresponds to the relative position of a number in the sequence. For example, the set {7, 5, 9, 12} when sorted gives the following sequence {5, 7, 9, 12} with ranks ranging from 1 to 4 (i.e., rank of 5 is 1, rank of 7 is 2, rank of 9 is 3, and rank of 12 is 4).
Rank Correlation (Spearman Rank Order Correlation Coefficient)	A “distribution free” or nonparametric statistic <i>r</i> that measures the strength and direction of association between the ranks of the values (not the values themselves) of two quantitative variables .
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.
Reasonable Maximum Exposure (RME)	The highest exposure that is reasonably expected to occur at a site (U.S. EPA, 1989, 1990). 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.
RME Risk	The estimated risk corresponding to the reasonable maximum exposure .

Definitions of Terms Used in PRA

Reference Dose (RfD)	An estimate of an exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime. Chronic RfDs are specifically developed to be protective for a long-term exposure to a chemical (e.g., >7 years) and account for uncertainty spanning perhaps an order of magnitude or greater.
Remediation Action Level (RAL)	Generally, a concentration such that remediation of all concentrations above this level in an exposure unit will result in the 95% UCL being reduced to a level that does not pose an unacceptable risk to an individual experiencing random exposures. The RAL will depend on the mean, variance , and sample size of the concentrations within an exposure unit as well as considerations of acute toxicity of the chemicals of concern.
Remediation Goal	Generally, a health-based chemical concentration in an environmental medium chosen by the risk manager as appropriate for a likely land use scenario.
Risk Assessment	The use of available information to make inferences about the health effects associated with exposure of individuals or populations to hazardous materials or situations. Components of risk assessment include: hazard identification, dose-response assessment, exposure assessment , and risk characterization (NRC, 1983).
Risk Characterization	A component of risk assessment that describes the nature and magnitude of risk, including uncertainty . In assessments of Superfund sites, it includes the summary and interpretation of information gathered from previous steps in the site risk assessment (e.g., data evaluation, exposure assessment , toxicity assessment), including the results of a probabilistic analysis.
Risk Descriptor	A statistic (e.g., arithmetic mean , 95th percentile) that describes the risk to the assessment endpoint .
Risk Management	The process by which regulatory decisions are made using all available risk assessment information (including, but not limited to, the results of the PRA). The NCP provides nine criteria for remedial decisions (e.g., protection of human health, compliance with ARARs , etc.). Risk managers may include the Remedial Project Manager (RPM), section and branch chiefs, etc.
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 .
Scientific/Management Decision Point (SMDP)	A point during the risk assessment process when the risk assessor communicates results of the assessment at that stage to the risk manager. At this point, the risk manager determines whether the information is sufficient to arrive at a decision regarding risk management strategies and/or if additional information is needed to characterize risk.

Definitions of Terms Used in PRA

Sensitivity Analysis	Process for identifying the important sources of variability and uncertainty in a model's output. Different techniques can be used in each of the 3 tiers of the tiered process for PRA (see Chapter 2). In Tier 1, sensitivity ratios are used to quantify the effects of changes in one or more model inputs on the model output. In Tiers 2 and 3, correlation analysis can be used to rank inputs based on their relative contribution to variance in risk. Local sensitivity refers to nominal changes in inputs within a plausible range, whereas range sensitivity refers to changes in inputs across the minimum and maximum values of the plausible range. Further explanations of the different methods for sensitivity analysis are given in Appendix A.
Sensitivity Ratio	Ratio of the change in model output per unit change in an input variable ; also called <i>elasticity</i> .
Skewness	The measure of asymmetry of a distribution. Coefficients of skewness are zero for symmetric distributions (e.g., normal), positive for right-skewed distributions (e.g., lognormal), and negative for left-skewed distributions (e.g., specific forms of beta). Referred to as the third central moment of a distribution .
Spatial Autocorrelation	The tendency of data from locations that are relatively close together to be geographically correlated.
Stakeholder	Any individual or group who has an interest in or may be affected by EPA's site decision-making process.
Stability	Stochastic variability , or "wobble" associated with random sampling, calculated as the average percent change in the model output after rerunning Monte Carlo simulations with the same set of input assumptions. Used as a metric for evaluating the adequacy of the number of iterations in a MCA .
Standard Deviation, Arithmetic and Geometric	Standard deviation (or arithmetic standard deviation, SD) is a common measure of the spread of a distribution. Calculated as the square root of the variance . The geometric standard deviation (GSD) is the anti-log of the standard deviation of the logarithms of each value. The GSD is a unitless quantity that gives a measure of the ratio of the variance to the mean, similar in concept to the coefficient of variation .
Step Function	A mathematical function that remains constant within each of a series of adjacent intervals but changes in value from one interval to the next. Cumulative distribution functions for discrete random variables are step functions.
Stochastic Dominance	Implies no intersection between the CDFs ; distribution A stochastically dominates distribution B if, for every percentile of the CDF , $A > B$. This characteristic may not be apparent from the PDFs of the distributions, which may overlap.
Stochastic Process	A process involving random variables , and characterized by variability in space or time.
Target Population	The set of all receptors that are potentially at risk. Sometimes referred to as the "population of concern". A sample population is selected for statistical sampling in order to make inferences regarding the target population (see Appendix B, Section B.3.1, Concepts of Populations and Sampling).

Definitions of Terms Used in PRA

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.
Thiessen (Voronoi) Polygon Analysis	A method of spatial statistics in which an area is subdivided into subregions, or polygons, in order to predict values at unobserved locations.
Time Step	A variable in all exposure models that refers to the unit of time for which a random value is considered representative of intra-individual variability (e.g., average daily ingestion rates for an individual from one year to the next). A time step may be equal to an entire exposure duration (e.g., 30 years), or a fraction of the exposure duration during which changes in input variables may be expected (e.g., one year). Time steps need not be identical for all exposure variables , and should address the most rapidly changing variable in the risk equation. Time step can be an important consideration for MEE analysis .
Toxicity Reference Value (TRV)	A numerical expression of a chemical's dose-response relationship that is used in ecological risk assessment .
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 .
Truncation	The process of setting lower and upper limits on the range of a distribution, in order to avoid unrealistic values for exposure variables (e.g., > 100% bioavailability). Most often used for continuous, unbounded probability distributions (e.g., normal).
Two-dimensional Monte Carlo Analysis (2-D MCA)	An advanced modeling technique that uses two stages of random sampling, also called nested loops, to distinguish between variability and uncertainty in exposure and toxicity variables . The first stage, often called the inner loop, involves a complete 1-D MCA simulation of variability in risk. In the second stage, often called the outer loop, parameters of the probability distributions are redefined to reflect uncertainty . These loops are repeated many times resulting in multiple risk distributions, from which confidence intervals are calculated to represent uncertainty in the population distribution of risk.
Type I Errors	False positive; the error made when the null hypothesis is rejected in favor of the alternative, when in fact the null hypothesis is true.
Type II Errors	False negative; the error made when the null hypothesis is accepted when in fact the alternative hypothesis is true.
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.

Definitions of Terms Used in PRA

Variability	True heterogeneity or diversity in characteristics among members of a population (i.e., inter-individual variability) or for one individual over time (intra-individual variability). For example, body weights of a study population at one point in time will exhibit variability, and body weight will change as an individual ages. Further study (e.g., increasing sample size, n) will not reduce variability, but it can provide greater confidence in quantitative characterizations of variability.
Variable	A quantity that can assume many values.
Variance	Measure of the spread of a distribution, equal to the square of the standard deviation (SD). Calculated as the average of the squares of the deviations of the observations from their mean . Variance is referred to as the second central moment of a distribution .
Z-score	The value of a normally distributed random variable that has been standardized to have a mean of zero and a SD of one by the transformation $Z=(X-\mu)/\sigma$. Statistical tables typically give the area to the left of the z-score value. For example, the area to the left of $z=1.645$ is 0.95. Z-scores indicate the direction (+/-) and number of standard deviations away from the mean that a particular datum lies assuming X is normally distributed. Microsoft Excel's <i>NORMSDIST</i> (z) function gives the probability p such that $p=\Pr(Z \leq z)$, while the <i>NORMSINV</i> (p) function gives the z-score z_p associated with probability p such that $p=\Pr(Z \leq z_p)$.

E.1.0 ADDITIONAL INFORMATION

Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis (Morgan and Henrion, 1990) and *Probabilistic Techniques in Exposure Assessment* (Cullen and Frey, 1999) provide excellent philosophical and practical treatises on probabilistic risk assessment. These works are highly recommended to risk assessors who wish to know more about probabilistic risk assessment. The *Summary Report for the Workshop on Monte Carlo Analysis* (U.S. EPA, 1996) and the *Summary Report for the Workshop on Selecting Input Distributions for Probabilistic Assessments* (U.S. EPA, 1999b) are other sources of information to learn more about PRA. Other additional references for reading are listed in this Appendix.

REFERENCES FOR APPENDIX E

- Cullen, A.C. and H.C. Frey. 1999. *Probabilistic Techniques in Exposure Assessment*. A Handbook for Dealing with Variability and Uncertainty in Models and Inputs. Plenum Press.
- Law, A.M. and W.D. Kelton. 1991. *Simulation Modeling and Analysis*. McGraw-Hill, Inc., NY.
- Morgan, G.M. and M. Henrion, 1990. *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*. Cambridge University Press, NY.
- National Research Council (NRC). 1983. *Risk Assessment in the Federal Government: Managing the Process*. National Academy Press. Washington, DC.
- U.S. EPA. 1989. *Risk Assessment Guidance for Superfund (RAGS): Volume I. Human Health Evaluation Manual (HHEM) (Part A, Baseline Risk Assessment)*. Interim Final. Office of Emergency and Remedial Response, Washington, DC. EPA/540/1-89/002. NTIS PB90-155581.
- U.S. EPA. 1990. National Oil and Hazardous Substances Pollution Contingency Plan. Final Rule. 40 CFR 300: 55 *Federal Register*, 8666-8865, March 8.
- U.S. EPA. 1991. *Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (HHEM), Part B, Development of Risk-Based Preliminary Remediation Goals*. Office of Emergency and Remedial Response, Washington, DC. EPA/540/R-92/003. NTIS PB92-963333.
- U.S. EPA. 1992. *Supplemental Guidance to RAGS: Calculating the Concentration Term*. Office of Solid Waste and Emergency Response, Washington, DC. OSWER Directive No. 9285.7-081.
- U.S. EPA. 1997a. *Memorandum from Deputy Administrator Fred Hansen on the Use of Probabilistic Techniques (including Monte Carlo Analysis) in Risk Assessment, and Guiding Principles for Monte Carlo Analysis*. Office of Research and Development, Washington, DC. EPA/630/R-97/001. May 15.
- U.S. EPA. 1997b. *Lognormal Distribution in Environmental Applications*. Office of Research and Development, and Office of Solid Waste and Emergency Response, Washington, DC. EPA/600/R-97/006. December.
- U.S. EPA. 1997c. *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments*. Interim Final. U.S. Environmental Protection Agency, Environmental Response Team (Edison, NJ). June 5.
- U.S. EPA. 1999a. Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites. U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response. OSWER Directive 9285.7-28 P. Stephen D. Luftig for Larry D. Reed. October 7.
- U.S. EPA. 1999b. *Summary Report for the Workshop on Selecting Input Distributions for Probabilistic Risk Assessment*. Risk Assessment Forum. EPA/630/R-98/004.

REFERENCES FOR FURTHER READING

- Baird, B.F. 1989. *Managerial Decisions Under Uncertainty*. John Wiley & Sons, Inc., NY.
- Bevington, P.R. 1969. *Data Reduction and Error Analysis for the Physical Sciences*. McGraw-Hill, NY.
- Bratley, P., B.L. Fox, and L.E. Schrage. 1987. *A Guide to Simulation*. Springer-Verlag, NY.
- Burmaster, D.E. and P.D. Anderson. 1994. Principles of Good Practice for the Use of Monte Carlo Techniques in Human Health and Ecological Risk Assessment. *Risk Anal.* 14(4):477–481.
- Clemen, R. 1990. *Making Hard Decisions*. Duxbury Press.
- Conover, W.I. 1971. *Practical Nonparametric Statistics*. John Wiley & Sons, NY.
- Cox, D.C. and P. Baybutt. 1981. *Methods for Uncertainty Analysis: A Comparative Survey*. *Risk Anal* 1(4):251–258.
- Cullen, A.C. and H.C. Frey. 1999. *Probabilistic Techniques in Exposure Assessment*. Plenum Press, NY.
- D’Agostino, R. and M.A. Stephens, eds. 1986. *Goodness-of-Fit Techniques*. Marcel Dekker, Inc., NY.
- Devroye, L. 1986. *Non-Uniform Random Deviate Generation*. Springer-Verlag, NY.
- Evans, M., N. Hastings, and B. Peacock. 1993. *Statistical Distributions*. John Wiley & Sons, NY.
- Finkel, A.M. 1990. *Confronting Uncertainty in Risk Management: A Guide for Decision-Makers*. Resources for the Future, Washington, DC.
- Gilbert, R.O. 1987. *Statistical Methods for Environmental Pollution Monitoring*. Van Nostrand Reinhold, NY.
- Hamby, D.M. 1994. A review of Techniques for Parameter Sensitivity Analysis of Environmental Models. *Environ. Monit. and Assess.* 32:135–154.
- Hammersley, J.M. and D.C. Handscomb. 1964. *Monte Carlo Methods*. John Wiley & Sons, NY.
- Hertz, D.B. and H. Thomas. 1983. *Risk Analysis and Its Applications*. John Wiley & Sons, NY.
- Hertz, D.B. and H. Thomas. 1984. *Practical Risk Analysis - An Approach Through Case Studies*. John Wiley & Sons, NY.
- Hoffman, F.O. and J.S. Hammonds. 1992. *An Introductory Guide to Uncertainty Analysis in Environmental and Health Risk Assessment*. ES/ER/TM-35, Martin Marietta.
- Hoffman, F.O. and J.S. Hammonds. 1994. *Propagation of Uncertainty in Risk Assessments: The Need to Distinguish Between Uncertainty Due to Lack of Knowledge and Uncertainty Due to Variability*. *Risk Anal* 14(5):707–712.

- Iman, R.L. and W.J. Conover. 1982. A Distribution-Free Approach to Inducing Rank Correlation Among Input Variables. *Commun. Stat*, Part B 11:311–331.
- Iman, R.L. and J.C. Helton. 1988. An Investigation of Uncertainty and Sensitivity Analysis Techniques for Computer Models. *Risk Anal.* 8(1):71–90.
- Iman, R.L., J.M. Davenport, and D.K. Zeigler. 1980. *Latin Hypercube Sampling (A Program Users Guide)*. Technical Report SAND 79:1473, Sandia Laboratories, Albuquerque.
- Johnson, M.E. 1987. *Multivariate Statistical Simulation*. John Wiley & Sons, NY.
- Johnson, N.L. and S. Kotz. 1970. *Continuous Univariate Distributions*. Vols. 1 & 2. John Wiley & Sons, NY.
- Johnson, N.L., S. Kotz, and A.W. Kemp. 1992. *Univariate Discrete Distributions*. John Wiley & Sons, NY.
- Kendall, M. and A. Stuart. 1979. *Advanced Theory of Statistics, Volume I - Distribution Theory, Volume II - Inference and Relationship*. MacMillan, Inc., NY.
- Kennedy, W.J. and E. Gentle. 1980. *Statistical Computing*. Marcel Dekker, Inc., NY.
- LePage, R. and L. Billard. 1992. *Exploring the Limits of Bootstrap*. John Wiley & Sons, NY.
- Lipton, J., W.D. Shaw, J. Holmes, and A. Patterson. 1995. Short Communication: Selecting Input Distributions for use in Monte Carlo Analysis. *Regul. Toxicol. Pharmacol.* 21:192–198.
- McKone, T.E. and K.T. Bogen. 1992. Uncertainties in Health Risk Assessment: An Integrated Case Based on Tetrachloroethylene in California Groundwater. *Regul. Toxicol. Pharmacol.* 15:86–103.
- Megill, R.E., ed. 1985. *Evaluating and Managing Risk*. Penn Well Books, Tulsa, OK.
- Morgan, G.M. and M. Henrion. 1990. *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*. Cambridge University Press, NY.
- NCRP. 1996. Commentary No. 14. *A Guide for Uncertainty Analysis in Dose and Risk Assessments Related to Environmental Contamination*. National Committee on Radiation Programs, Scientific Committee 64-17. Washington, DC.
- Palisade Corporation. 1994. *Risk Analysis and Simulation Add-In for Microsoft Excel or Lotus 1-2-3*. Windows Version Release 3.0 User's Guide, Palisade Corporation, Newfield, NY.
- Press, W.H., B.P. Flannery, S.A. Teulolsky, and W.T. Vetterling. 1989. *Numerical Recipes in Pascal: the Art of Scientific Computing*. Cambridge University Press, NY.
- Press, W.H., S.A. Teulolsky, W.T. Vetterling, and B.P. Flannery. 1992. *Numerical Recipes in FORTRAN: the Art of Scientific Computing*. Cambridge University Press, NY.

- Press, W.H., S.A. Teulolsky, W.T. Vetterling, and B.P. Flannery. 1992. *Numerical Recipes in C: The Art of Scientific Computing*. Cambridge University Press, NY.
- Read, T. and N. Cressie. 1988. *Goodness-of-Fit Statistics for Discrete Multivariate Data*. Springer-Verlag, NY.
- Rohatgi, V.K. 1984. *Statistical Inference*. John Wiley & Sons, NY.
- Rubenstein, R.Y. 1981. *Simulation and the Monte Carlo Method*. John Wiley & Sons, NY.
- Sachs, L. 1984. *Applied Statistics - A Handbook of Techniques*. Springer-Verlag, NY.
- Saltelli, A and J. Marivort. 1990. Non-Parametric Statistics in Sensitivity Analysis for Model Output: A Comparison of Selected Techniques. *Reliab. Eng. Syst. Saf.* 28:299–253.
- Schneider, H. 1986. *Truncated and Censored Distributions from Normal Populations*. Marcel Dekker, Inc., NY.
- Seiler, F.A. 1987. Error Propagation for Large Errors. *Risk Anal.* 7(4):509–518.
- Seiler, F.A. and J.L. Alvarez. 1996. On the Selection of Distributions for Stochastic Variables. *Risk Anal.* 16(1):5–18.
- Slob, W. 1994. Uncertainty Analysis in Multiplicative Models. *Risk Anal.* 14(4):571–576.
- Smith, A.E., P.B. Ryan, and J.S. Evans. 1992. The Effect of Neglecting Correlations when Propagating Uncertainty and Estimating the Population Distribution of Risk. *Risk Anal.* 12(4):467-474.
- Smith, R.L. 1994. Uses of Monte Carlo Simulation for Human Exposure Assessment at a Superfund Site. *Risk Anal* 14(4):433–439.
- Sokal, R. and R. Rohlf. 1981. *Biometry: The Principles and Practice of Statistics in Biological Research*. Second Edition. W.H. Freeman & Co., NY.
- U.S. EPA. 1978. *Source Assessment: Analysis of Uncertainty - Principles and Applications*. EPA/600/2-79-004.
- U.S. EPA. 1992a. *Guidelines for Exposure Assessment*. *Federal Register*. 57(104):22888-22938. May 29.
- U.S. EPA. 1992b. *Guidelines for Carcinogenic Risk Assessment*. *Federal Register*. 57(185):33992-34003. May 29.
- U.S. EPA. 1996. *Summary Report for the Workshop on Monte Carlo Analysis*. Office of Research and Development, Washington, DC. EPA/630/R-96/010.
- U.S. EPA. 1999. *Guidelines for Carcinogenic Risk Assessment*. Review Draft. Risk Assessment Forum. Washington, DC. NCEA-F-0644.

U.S. EPA. 2001. *Guidelines for Carcinogenic Risk Assessment. Federal Register.* 66(230):59593-59594.
November 29.

Wilks, D.S. 1995. *Statistical Methods in the Atmospheric Sciences, An Introduction.* Academic Press, San
Diego.

APPENDIX F

WORKPLAN AND CHECKLIST FOR PRA

F.0 INTRODUCTION

This appendix provides guidance on developing a workplan prior to the initiation of a probabilistic risk assessment (PRA), and using a checklist when reviewing a PRA. Like the quality assurance project plan (QAPP), the workplan for PRA generally should document the combined decisions or positions of the remedial project manager (RPM), risk assessor, and stakeholders involved in the risk assessment. Often there are many stakeholders in a risk assessment, and it is important to involve and engage all stakeholders early in the decision-making process. These are important steps that should save time and effort.

F.1.0 WORKPLAN

In general, PRAs may be developed by Environmental Protection Agency (EPA), EPA contractors, or a potentially responsible party (PRP) with appropriate EPA oversight. In each case, it is important to develop a workplan early in the risk assessment process. PRAs to be submitted by a contractor or PRP should generally be submitted for EPA review before commencing the analysis. The workplan should describe the software to be used, the exposure routes and models, and input probability distributions and their basis (e.g., relevance to the site-specific contamination and pathways), including appropriate literature references. Examples of the elements of a workplan are given in Exhibit F-1, as well as Exhibit 4-8 in Chapter 4 (Example Elements of a Workplan for Ecological PRA). It is important that the risk assessor and risk manager discuss the scope of the probabilistic analysis and the potential impact on the Remedial Investigation/Feasibility Study (RI/FS).

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

EXHIBIT F-1

EXAMPLES OF ELEMENTS OF THE WORKPLAN FOR PRA

1. Statement of the ecological assessment endpoints and/or human risk
2. Summary of the point estimate risk assessment
3. Potential value added for risk management by conducting a PRA and proceeding to the subsequent tiers (quantify variability, uncertainty, or both)
4. Discussion of adequacy of environmental sampling for PRA (e.g., data quality issues)
5. Description of the methods and models to be used (e.g., model and parameter selection criteria)
6. Proposal and basis for probability distributions and point estimates
7. Methods for deriving the concentration term
8. Proposal for probabilistic sensitivity analysis
9. Method for dealing with correlations
10. Bibliography of relevant literature
11. Software (i.e., date and version of product, random number generator)
12. Simulation approach (e.g., iterations, Monte Carlo or Latin Hypercube sampling, time step)
13. Proposed schedule and expertise needed

The EPA generally will not accept probabilistic analysis where a workplan for the analysis has not been initially submitted to the Agency and approved by the Regional risk assessor and RPM. Exceptions to this process may be considered on a case-by-case basis.

Conducting a PRA is an iterative process. In general, as new information becomes available, it should be used to evaluate the need to move to a higher tier. The decision to move an assessment to a higher tier of complexity should result in a revised workplan and consultation with the Agency. The previous PRA, and its sensitivity analysis, should be included in the revised workplan, along with a point estimate risk assessment based on any data collected as part of a lower tier. The assessment will often be restricted to the chemicals and pathways of concern that contribute the greatest risk.

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

F.2.0 FOCAL POINTS FOR PRA REVIEW

In reviewing a PRA, it is recommended that a systematic approach be adopted to ensure that all key technical elements of the PRA are evaluated and potential weaknesses are identified. A review check list can facilitate this process and promote consistency in the reviews of PRAs. Such a list can be developed from EPA's guiding principles (U.S. EPA, 1997) and other reviews on the subject of PRA quality review (e.g., Burmaster and Anderson, 1994).

In general, the review of a PRA can be organized into four focal points listed in Exhibit F-2. PRAs can vary in complexity, from relatively simple to very complicated; thus, the review strategy may need to be customized for specific sites.

EXHIBIT F-2

KEY FOCAL POINTS FOR PRA REVIEW

1. Clarity of and conformation to objectives.
2. Scientific basis and documentation of input distributions and assumptions.
3. Model structure and computational mechanics.
4. Results, including, limitations, reasonableness, and clarity of documentation.

F.3.0 CHECKLIST FOR REVIEWERS

The exposure pathways and chemicals considered in a PRA should be clearly stated and related to the assessment endpoint. Often, the simplest way of doing this is to use the site conceptual model.

Table F-1 provides a list of major points that may be used to evaluate the quality of a probabilistic assessment. This is not an exhaustive list. The ultimate judgment of the acceptability of a PRA is the responsibility of the regional EPA personnel.

The issues that a reviewer should focus on may be different for each assessment. The workplan and the assessment should address each of the items on the checklist, but the workplan may include

additional items. The reviewer is responsible for ensuring that the workplan and the assessment are complete and of sufficient quality to help support a risk management decision under the National Contingency Plan (NCP).

The report should include a discussion of the results of assessment and how they relate to the point estimate of risk and hazard. A clear and concise description of what the results mean is an important part of each report.

F.4.0 INTERNAL AND EXTERNAL REVIEW

There are two levels of review that may be appropriate for a PRA. If an EPA reviewer feels the need for help with a review, other EPA personnel may be contacted formally or informally to provide additional review capabilities. The EPA personnel should also review the draft workplan for PRA to evaluate the appropriateness and consistency with Agency guidance. If EPA personnel are contacted early in the risk assessment process, the review can occur in a more productive and timely manner.

When the issues at a particular site are complex or contentious, EPA reviewers may also wish to obtain the services of outside experts for peer review (U.S. EPA, 2000). According to EPA's Peer-Review Policy Statement dated June 7, 1994 (U.S. EPA, 1994), "Major scientifically and technically based work products related to Agency decisions normally should be peer-reviewed." External peer review should be considered when allocating resources for a PRA. The EPA reviewers generally should select external peer reviewers who possess no bias or agenda regarding the process or methods of PRA.

Table F-1. Example of a Generic Checklist for Reviewers [2 pages]

Focal Point	✓	Evaluation Criterion
<i>Objectives and Purpose</i>		
Assessment Endpoints	✓	Are the human health and/or ecological assessment endpoints clearly stated and consistent with the workplan?
Benefits	✓	Are the rationales for, and benefits of, performing the PRA clearly stated and consistent with the workplan?
Site Conceptual Model	✓	Is there a description or graphic representation of the receptors and pathways considered in the assessment? Has the PRA addressed each of the pathways for completeness (e.g., sources, release mechanisms, transport media, route of entry, receptor)?
Separation of Variability and Uncertainty	✓	What is the modeling strategy for separating variability and uncertainty in the PRA? Is this strategy consistent with the assessment endpoints?
<i>Model Structure and Computational Mechanics</i>		
Flow Chart	✓	Is a diagram of the computational sequence provided so that the pathways of inputs and outputs and data capture can be understood and easily communicated?
1-D MCA / 2-D MCA	✓	Is a 1-D MCA or 2-D MCA being implemented in the PRA? What is represented by either or both dimensions?
Algorithms	✓	Are all algorithms used in the model documented in adequate detail to recreate the analysis?
Integration	✓	Are the algorithms used in numerical integration identified and documented?
Dimensional Analysis	✓	Has a unit analysis been conducted to ensure that all equations balance dimensionally?
Random Number Generation	✓	What random number generator is used in model computations? Is it robust enough? What reseeding approach is used to minimize repeated sequences?
<i>Input Distributions and Assumptions</i>		
Variability and Uncertainty	✓	Is there a clear distinction and segregation of distributions intended to represent variability from distributions intended to represent uncertainty?
Data sources	✓	Are the data or analysis sources used in developing or selecting the input distributions documented and appropriate for the site?
Distribution Forms	✓	Are the analyses used in selecting the form of the distribution adequately documented (i.e., understandable and repeatable by a third party?)
Distribution Parameters	✓	Are the analyses used to estimate the distribution parameters adequately documented?
Distribution Tails	✓	Do the estimation methods precisely depict the tails of the input distributions; how was this evaluated? Is there sufficient information to depict tails for empirical distributions? Are these estimated as exponential tails with bounding values?
Truncations	✓	Are any input distributions truncated? Do these truncations make sense? Should truncations be applied to any of the distributions?
Concentration Term	✓	Is the derivation of a point estimate or distribution for the concentration term adequately documented? Is sufficient information provided to enable the reviewer to recreate the concentration term?
Variable Correlations	✓	Have variable independence and correlations been addressed? Has the methodology for representing variable correlations in the model been documented and is it reasonable in terms of the variables, the site, and the statistical approach?

Focal Point	✓	Evaluation Criterion
Time Step	✓	Has the basis for the time step used in the model been documented? Is a single time step used, or do variables have different time steps? Are the time steps conceptually reasonable for the variables; for the site? Has the time step been evaluated in the sensitivity analysis?
Sensitivity Analysis	✓	Has a sensitivity analysis been conducted? Are the methods used in the analysis statistically valid? What did the analysis reveal about uncertainties in the assessment and the relative contributions of input variables to uncertainty?
<i>Results of Modeling</i>		
Completeness	✓	Are all the exposure routes identified in the site conceptual model and workplan addressed in the model results? Has the PRA fulfilled the objectives and satisfied the purpose stated in the workplan?
Point Estimate Calculation	✓	Has a point estimate calculation, using mean or median values of the input distributions, been performed? How do these results compare with the central tendencies calculated with the probabilistic model? How do the reasonable maximum exposure (RME) estimates compare? Have the similarities or differences between risk estimates from the point estimate and probabilistic approaches been adequately addressed?
Stability of Output Tails	✓	Has the stability of the high-end tail of the risk distribution been adequately evaluated? How stable are the estimated tails (in quantitative terms?) Is this level of stability adequate to support the risk management decisions that the model is intended to support?
Significant Figures	✓	Is the number of significant figures used in the output reasonable and consistent with model uncertainty?
Limitations	✓	Are the strengths and weaknesses of the PRA methodology and limitations of the results for decision making clearly presented?
Clarity	✓	Are the results and conclusions clearly presented and consistent with model output (e.g., central tendency exposure (CTE) and RME identified in the Executive Summary along with discussion of uncertainty)?
Graphics	✓	Are there graphics included that show both the risk distribution and PRA results (e.g., CTE and RME risk)?

REFERENCES FOR APPENDIX F

- Burmaster, D.E. and P.D. Anderson. 1994. Principles of Good Practice for the Use of Monte Carlo Techniques in Human Health and Ecological Risk Assessment. *Risk Anal.* 14(4):477-481.
- U.S. EPA. 1994. Memorandum from Deputy Administrator Carol Browner on *Peer Review and Peer Involvement at the U.S. Environmental Protection Agency*. June 7.
- U.S. EPA. 1997. Memorandum from Deputy Administrator Fred Hansen on the *Use of Probabilistic Techniques (including Monte Carlo Analysis) in Risk Assessment, and Guiding Principles for Monte Carlo Analysis*. Office of Research and Development, Washington, DC. EPA/630/R-97/001. May 15.
- U.S. EPA. 2000. *Peer Review Handbook: 2nd Edition*. Science Policy Council. Washington, DC. EPA/100/B-00/001. December.