Characterization of Uncertainties in Risk Assessment with Special Reference to Probabilistic Uncertainty Analysis

BACKGROUND: The current Environmental Protection Agency (EPA) policy for risk characterization (issued by Carol Browner, EPA Administrator, in February 1995), requires that all risk assessment should have the core values of transparency, clarity, consistency, and reasonableness. To attain these core values, Agency risk assessors and risk managers are instructed to have a full and open discussion of uncertainties in the body of each risk assessment, including a prominent display of critical uncertainties. This EPA policy advocates the use of multiple risk descriptors, i.e., individual high-end, individual average or central tendency, and population, to characterize or present deterministic point estimates of risk. The characterization should include identification of uncertainties associated with the lack of knowledge as well as natural variations in the exposure parameters. Quantitative methods to assess uncertainty, such as sensitivity analysis and probabilistic analysis using Monte Carlo Simulations (MCS), have been increasingly used to identify factors that have the greatest effect on the risk estimation and to provide a frequency distribution for potential risks. This Information Brief presents an overview of the sources of uncertainty in risk assessment, how uncertainties may affect decisions, and basic concepts and the advantages/disadvantages of performing probabilistic uncertainty analysis. Because proper documentation must accompany probabilistic uncertainty analysis/MCS, which can be more costly than the deterministic-type of risk assessment, it is recommended that the analysis be used on projects where the risk estimates are at or slightly below the acceptable level of risk, and where remedial actions may require substantial resources.

STATUTES: CERCLA Section 104 (Response Authorities), Section 120 (Federal Facilities), and Section 121 (Cleanup Standards); RCRA Corrective Action Authorities, i.e., Sections 3004(u), 3004(v), 3013, 3005(c)(3), 3008(h), 6001, and 7003.

REGULATIONS: 40 CFR 300.430(d), 40 CFR 300.430(e); 40 CFR 264.101, 264 Subpart F, and 40 CFR 264 Subpart S proposed rule (55 *FR* 30798, July 27, 1990).

REFERENCES:

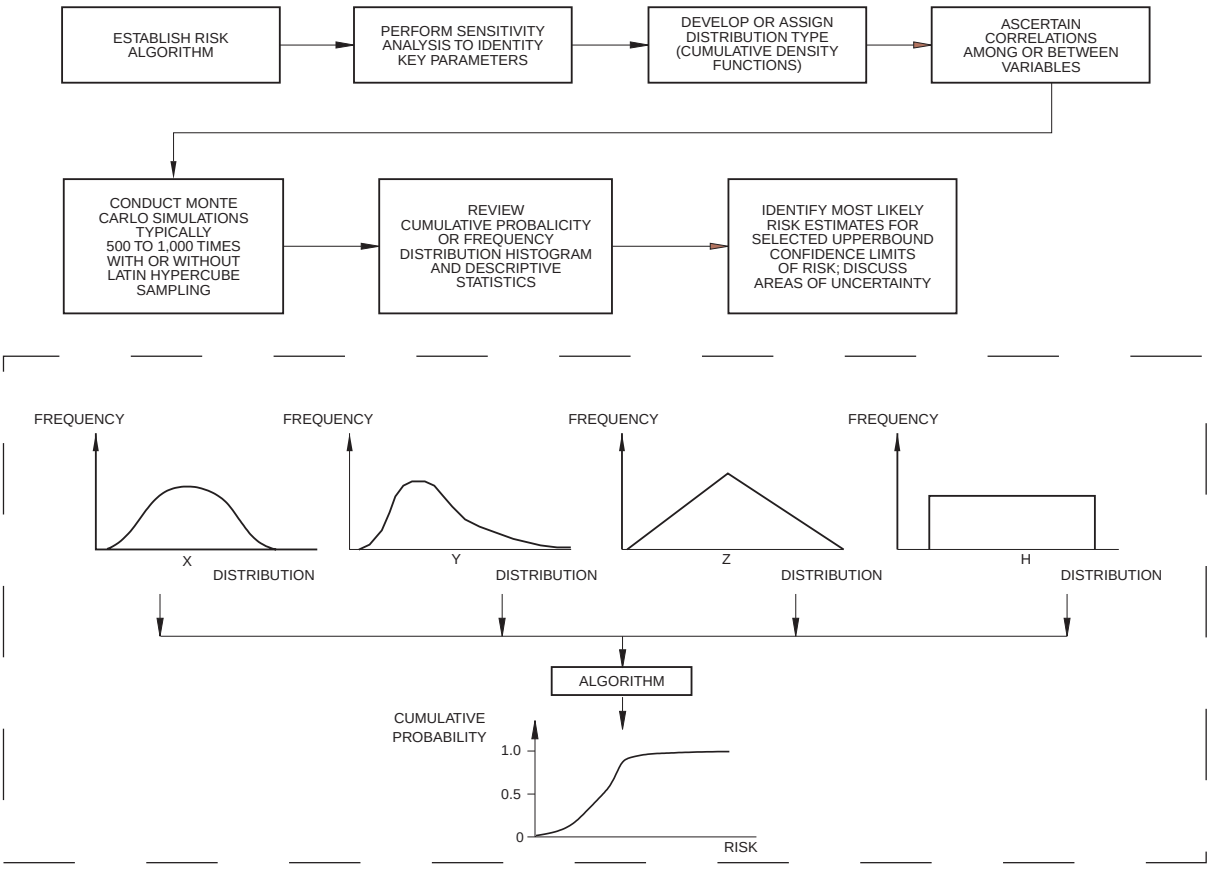
1. *Risk Assessment Guidance for Superfund, Part A, Human Health Evaluation Manual*, EPA (12/89).
2 *Guidance on Risk Characterization for Risk Managers and Risk Assessors*, H. Habicht, EPA (2/92)
3. *Guidance for Data Useability in Risk Assessment (Part A)*, EPA (4/92).
4. "Guidelines for Exposure Assessment," EPA, 57 *FR* 22888 (5/92).
5. "Guidance for Risk Characterization," C. Browner, EPA (2/95).
6. *Uncertainty - A Guide to Dealing With Uncertainty in Quantitative Risk and Policy Analysis*, Morgan and Henrion, Cambridge University Press, 1990.
7. *Science and Judgment in Risk Assessment*, CAPRA Report, NRC (94).

What are the sources of uncertainty in a risk assessment?

In quantifying risk, toxicity (hazard) and exposure information are integrated to produce a risk estimate (reference 1). Uncertainties in the hazard and exposure information may result in unrealistic risk estimates. Sources of uncertainty in a risk assessment are:

Hazard Identification. Knowledge of past site use and process knowledge, records of spills and releases, and analytical data are generally used to identify the contaminants of concern (CoCs) for the risk assessment. Incomplete knowledge, lack of records, sampling strategies that do not adequately address site conditions, use of inappropriate analytical methods, and an assumption that CoCs are present at nondetected levels are common sources of uncertainty in hazard identification (reference 3).

Toxicity Assessment. Human or animal data are generally used to assess toxicity and develop a dose-response relationship, i.e., slope factor for carcinogens and reference dose for noncarcinogens. Inadequate human or animal data, inappropriate dose-response models, and the lack of a biological basis for the adverse effects are some of the sources of uncertainty in the toxicity assessment. This uncertainty, in turn, causes the risk assessment to be conservative. For example, to compensate for the lack of data from chronic animal studies or less than ideal experimental design (e.g., when the lowest dose employed in an animal study has caused an



ASSESSMENT OF UNCERTANTY IN RISK ASSESSMENT
BY MONTE CARLO SIMULATIONS-- A PROCESS FLOW DIAGRAM

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adverse effect), EPA generally makes a substantial downward adjustment of the acceptable daily intake or dose as a matter of policy in order to establish the no adverse effect level for noncarcinogens.

Exposure Assessment. Uncertainties associated with assessing exposure can generally be categorized as : (1) lack of precise knowledge of the potential exposure scenario (i.e., activity patterns or behaviors leading to exposure to CoCs), and (2) distributional uncertainty, which deals with the variation of exposure factor or parameter values for a defined exposure scenario or setting (i.e., for each parameter, there is a range of values that could be used to represent the parameter). For example, variations in body weights, exposure frequency and duration, soil ingestion rates, etc., illustrate this type of uncertainty. Professional judgment exercised by risk assessors may reduce uncertainty in the exposure assessment.

Risk Characterization. Potential sources of uncertainty in risk characterization affect the manner in which the risk or hazard is calculated and presented for a risk management decision. They include (but are not limited to) a bias toward high-end deterministic point estimation of risk and hazard for a hypothetical individual, ignoring the average or central tendency and population risks, assuming that any exposure can cause an incremental risk in cancer occurrence (non-threshold dose-effect model), and adding risk or hazard from individual contaminants to produce an aggregate risk or hazard without examining the biological basis for doing so.

How do standard default exposure factors or scenario assumptions affect uncertainty?

Standard default exposure factors (input values for exposure parameters) and exposure scenario

assumptions have been used by the regulatory agencies to screen or identify sites for further evaluation or propose regulatory standards (reference 7). To quantify or estimate exposure to current or hypothetical receptors at a contaminated site, EPA headquarters, regional offices, and state agencies may recommend their own preferred standard default exposure assumptions and factors. Use of these default exposure assumptions and exposure factors in a site-specific risk assessment is likely to produce a highly conservative or unrealistic risk, and can represent the major source of uncertainty in a risk assessment.

For many states and EPA regions, the standard default assumption for an exposure setting may be residential land use. Unsubstantiated land use assumptions will contribute to a high degree of uncertainty in the exposure assessment. For example, if an industrial site is located in an area in which re-development is regulated or controlled, it would be inappropriate to assume that the future use is residential and that exposure pathways commonly associated with residential receptors are complete. Similarly, it is not appropriate to assume that a current ground water source which has low yield, high natural salinity, existing contamination from upgradient sources, or is otherwise not approved for use by public health agencies, will be used as drinking water by future residents or workers.

In the above examples, the assumptions of a residential setting and a drinking water aquifer will require the assessment of highly unlikely exposure pathways such as incidental ingestion of and dermal contact with contaminated soil by children, and household use and consumption of ground water. Since the standard default exposure factors for such pathways are generally high-end or highly conservative, they would result in high exposed doses or daily intakes of CoCs and would likely result in unacceptable risks or uncertain risk estimates.

Why is uncertainty analysis an important component of risk assessment?

Uncertainty analysis provides a yardstick to measure how "conservative" the risk estimate(s) is. In the uncertainty analysis, the potential sources of error (data gaps, assumptions and bases of judgment) are identified for each step in the risk assessment and their overall impact on the site risk estimate(s) is evaluated qualitatively and/or quantitatively. Understanding the uncertainty in a risk assessment will help risk managers to make more informed and reasoned risk-based decisions. Unrealistic or highly conservative risk assessment could lead to costly cleanup decisions.

What approaches are used to characterize uncertainty or to make risk assessment more understandable?

The policy guidance for risk characterization (references 2 and 5) recommends the use of multiple descriptors to characterize risk, in addition to qualitatively identifying the sources of uncertainty in the risk assessment. The objective is to provide a full range of risk estimates, not only the high-end risk estimate, to the risk managers, decision-makers and stakeholders so that they can make informed decisions based on the degree and probability of actual site risk.

The Guidelines for Exposure Assessment (reference 4) indicate sensitivity analysis and probabilistic risk assessment are also acceptable ways to characterize uncertainty in exposure and risk. The approaches to characterize uncertainty, based on current EPA policy, are summarized below:

Individual Risk or Hazard: Either a deterministic or a probabilistic approach may be used to estimate individual risk or hazard. EPA policy encourages presenting the high-end and central tendency point estimate of risk, or the entire risk distribution as a way to characterize uncertainty in individual risk.

Population Risk or Hazard: Estimation of risk for an actual or future group of people who reside or work at a contaminated site is based on the fraction of a population which could be exposed to an unacceptable average daily intake of a noncarcinogen, or the potential number of cases of cancer for an exposed population from long-term exposure to a carcinogen. Population statistics and the central tendency individual risk are used to estimate cancer incidence within a population.

What is Monte Carlo Simulation (MCS)?

Probabilistic analyses represent one means of characterizing uncertainties in risk assessment. MCS is one tool used to generate probabilistic risk estimates and is a computer-assisted propagation of risk based on various combinations of exposure

parameters (or toxicity values) to simulate the entire spectrum or distribution of risk and hazard for a potentially exposed individual. Using MCS techniques, it is possible to represent the uncertainty in the risk characterization model by generating sample values (in the form of frequency distributions) for the model input and running the model repetitively. Instead of obtaining a single risk estimate to represent the model output as in a deterministic risk assessment, a set of sample results are obtained that can present the output as a frequency distribution or a cumulative density function (reference 6). These results can then be summarized using typical statistics such as mean and variance. When applied to risk assessments, the output can be used to identify central tendencies (expected risks) and associated high-end exposure with probability of occurrence

There are several commercially available MCS software packages which can be used in conjunction with standard spreadsheet software to perform probabilistic risk computations. Most commercial MCS software packages include Latin Hypercube (LHC) sampling capability as a means to reduce the number of computer runs by selectively sampling more at the tails (i.e., upper and lower ends) of the distribution. The basic steps in performing MCS are presented in Figure 1.

What are the advantages and disadvantages of performing MCS?

The advantages and disadvantages of performing MCS are:

Advantages:

- More complete characterization of uncertainty in a form that is less likely to include a bias.
- The probability distribution enables the risk manager to associate the high-end (e.g., Reasonable Maximum Exposure [RME]) risk with the likelihood or probability of occurrence.
- Distribution data already exist for a number of exposure parameters.
- When combined with sensitivity analyses, MCS allows a more informative and quick "what-if" assessment of the impact on the risk estimate of a change in an individual parameter or a group of parameters, thus providing a cost-effective tool for making risk management decisions.
- The probabilistic analysis permits more constructive comparisons of remedial alternatives when diverse attributes must be compared to systematically reduce the baseline risk. This includes comparing alternatives or intervening measures that could also cause remediation risks.

Disadvantages:

- MCS requires time and effort to set up the database and document the rationale for the cumulative density function (distribution of possible values) for individual parameters in the risk algorithm.
- The distribution patterns for some parameters are not definitively known, requiring the use of credible professional judgment or costly site-specific studies or data collection efforts. (Despite the cognizance of a risk assessor of parameters which could be dependent variables, the impact of such interdependencies between or among variables may be difficult to quantify if their co-relations are not well known.)
- MCS is resource intensive. Additional costs could be higher than that of a standard site-specific deterministic risk assessment

In view of the above discussion, MCS appears to be most appropriate for sites where the risk is at or slightly below the acceptable level of risk or hazard, and where the remediation cost is potentially high. The DOE's Residual Radioactivity (RESRAD) model and RESRAD-Chem model contain tools for probabilistic analyses of risks associated with radionuclides and chemicals, respectively.

Questions of policy or questions regarding policy decisions are not addressed in EH-413 Information Briefs unless that policy has already been established through appropriate documentation. Please refer any questions concerning the subject material covered in this Information Brief John Bascietto, RCRA/CERCLA Division, EH-413 (202) 586-7917.

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