ABSTRACT

ANNE E. CROOK. Uncertainty and Reasonable Assurance: Why We Need to Teach Regulators to Focus on Uncertainty in Risk Assessment and Risk Management. (Under the direction of Dr. DOUGLAS J. CRAWFORD-BROWN)

The rationality of regulatory decisions is inextricably linked to an explicit representation of the uncertainty underlying scientific predictions. The level of coverage of uncertainty in training programs on risk assessment and risk management developed by the EPA is examined in light of the above thesis. Using the EPA's Office Of Drinking Water's Workshops on Assessment and Management of Drinking Water Contamination (EPA, 1988) as an example, concepts for formalizing consideration of uncertainty are presented. A case study on the risks from radon in drinking water is developed to illustrate the recommended level of coverage of uncertainty in EPA training programs.

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CHAPTER 1

WHY UNCERTAINTY IS IMPORTANT: AN EXAMPLE

Regulators cannot be expected to make rational decisions based on risk assessment without understanding the uncertainty involved. One way to think about making a decision is to ask whether the evidence is sufficient to justify a particular action (Crawford-Brown and Pearce, 1989). A regulator is never confronted by certainties, but by an array of evidence, some of which may be contradictory and all of which will be inconclusive. For any given set of evidence, he must ask himself whether it is sufficient to justify action (which includes inaction), and if it is, how strong an action, or what type of action. Uncertainty is a fundamental part of that evidence. The decision maker must ask himself not "is this the best decision in terms of expected value?" but "is this level of certainty sufficient to justify action X?"

The EPA has recognized how important it is for the users of risk assessment to have a general understanding of risk assessment and risk management, and has developed a variety of training materials to meet this need. The

primary goal of most of these materials is to give the user an appreciation for the basis and complexities of each of these disciplines as they are performed by EPA. Users of these materials should come away from them better equipped to use and understand the results of EPA risk assessment and risk management. The materials are largely aimed at decision-making professionals in public health or environmental regulation.

Any training program for users of risk assessment that is designed to promote an understanding of the basic premises and complexities of risk assessment and risk management would be incomplete if it did not encourage participants to consider the implications of uncertainty and the degree of certainty they require to justify specific kinds of decisions or take specific actions. A selection of these training materials, evaluated for EPA's ODW (Crook, 1988), reveals a failure to address uncertainty in even a rudimentary way. Explicit coverage of uncertainty is, in fact, almost totally missing from these training materials.

This report describes why explicit coverage of uncertainty is necessary in EPA risk training materials, and makes a suggestion as to the kinds of information about uncertainty that are necessary to help regulators achieve reasonable assurance that regulations will result in an

acceptable outcome. Using the EPA's Office of Drinking Water's Workshops on Assessment and Management of Drinking Water Contamination (EPA, 1988) as an example, this report will make recommendations on how uncertainty might be treated in such training materials by providing a fully developed case study that might be included in such a workshop.

The rest of this chapter will describe the EPA's Office of Drinking Water's Workshops on Assessment and Management of Drinking Water Contamination (the Workshop) as an example of the absence of uncertainty from training materials and the need for it in them. Chapter 2 develops the need for uncertainty in more theoretical terms. Chapter 3 develops some useful concepts about uncertainty and incorporating them into existing materials. Chapter 4 provides a fully developed case study, using radon in drinking water, that could be used in training materials.

Workshops on Assessment and Management of Drinking Water Contamination

Several times a year, EPA's Office of Drinking Water conducts a three-day training course for professionals

concerned with protecting drinking water.[1] It is designed to give them an overview of risk assessment, risk management, and risk communication as they are conducted by EPA. It is not intended to make the participants experts in any of these areas, but rather to provide an appreciation of how these tasks are performed by EPA and to identify the major issues and complexities.

The Workshop consists of a series of presentations on a selection of subject areas, which are presented in Table 1-1. The presentations for risk assessment and risk management each are followed by a hands-on case study. Individuals work through the case studies during the evening, and then discuss them in small groups of about ten people, assisted by a facilitator, the following day. The Workshop spends about one day each on risk assessment, risk management, and risk communication. The section on risk communication focuses on communication of risk to the public by public officials, and is beyond the scope of this report.

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[1] The discussion of the Workshop largely refers to its general form. Specific remarks about the questions and difficulties of participants refer to the Workshop conducted in August 1988 in Valley Forge, PA.

Overview of ODW Workshop Content

The Workshop section on risk assessment is divided into three parts: principles of toxicology, toxicological approaches used in developing national drinking water standards, and the risk assessment case study.

The Workshop section on principles of toxicology generally provides excellent coverage of a complex topic. However, the only mention of uncertainty or variability in the entire presentation is the use of a graph of a cumulative probability function showing the LD50[2] of several compounds (see Figure 1-1), representing the variability of thresholds for a log-probit effects model. The Y-axis of the graph is in probit units, which are a unit of measure of standard deviation (one probit unit is the equivalent of one standard deviation). The graph is not explained. At the August 1988 Workshop, this provoked some confusion; one participant asked what the probit units on the Y-axis meant, and received a fairly unsatisfactory answer, the gist of which was "it's statistics; don't worry about it."

The section on toxicological approaches used in developing national drinking water standards is an excellent

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[2] The LD50, or lethal dose 50, is the dose required to kill half the animals in a dose-response experiment.

overview of how risk assessment is used to develop drinking water standards. The speaker does not touch upon uncertainty, except tangentially in drawing a distinction between science and policy in risk assessment. He points out that EPA's use of the linearized multistage dose-response model for cancer is a policy choice, based on a policy decision to be conservative, rather than a "scientific" choice based on some scientific proof or certainty that the model is correct. This is essentially the only mention of uncertainty in this section. This would be a good place for the Workshop to speak of reasonable assurance, since the linearized multistage model is claimed to provide strong assurance.

The risk assessment case study concerns whether vinyl chloride should be classified as a carcinogen, and explores reasons for such a decision. Participants work through the case study individually then split into groups of about ten to discuss the problem and reach a group conclusion. The information is presented clearly, and provides some necessary guidance, such as "issues to consider" to help steer, but not eliminate, the thinking process. The "issues to consider" does include some questions on how confident the participant is about the evidence presented. The case study also provides a list of alternative conclusions at the end of each section of the case study, including a

"formulate your own conclusion" option. At the August 1988 Workshop, the participants were quite willing to formulate their own hybrid conclusions from the alternatives presented and their own ideas, but they were relatively unequipped and unwilling to deal with the questions of uncertainty. They tended to make an unarticulated choice to be conservative rather than to discuss the uncertainties. This is not surprising, since the Workshop lectures do not give them a framework for thinking about and discussing uncertainty. This leaves them feeling uncertain, but without a way to articulate it.

After the case study groups reconvene, the coordinators distribute a handout that provides additional information on the case study problem and poses questions about how (and whether) this new information would change the decision reached by the group and the reasons for that decision. Incorporating new information and understanding how (or whether) more information would affect decisions is an important part of the risk assessment process; unfortunately, the coordinators do not take the opportunity to discuss this idea or the idea that reducing ignorance (by obtaining new information) can mean reducing uncertainty and increasing confidence. Particularly lacking is a discussion of the links between this increased confidence and the justification of regulatory decisions or actions.

The risk management section reveals a disappointing tendency to equate risk management with treatment technology. While treatment is undeniably an important aspect of risk management, it is not the only one. The handout for the introduction to the section on risk management states that risk management "integrates health, technology, economic, political and other considerations," (and surely dealing with uncertainty should be included in "other considerations") but this idea is not reflected in the remainder of the risk management section. The section would be strengthened by the addition of material on uncertainty (as well as economic and political considerations).

The risk management case study suffers from the omission of uncertainty in the risk management presentations. At the August 1988 Workshop, the case study participants seemed unwilling to consider the uncertainties in the problem situation when choosing an alternative. For example, the problem is based on only two samples from some contaminated wells, but participants were generally resistant to the possibility that sampling results are uncertain and that this should affect the decision. These examples illustrate how great the need is to discuss these issues explicitly.

This report will establish that it is necessary to teach risk assessment and risk management so the workshop participant grasps that focusing on uncertainty is a major component in demonstrating reasonable assurance that a regulation will accomplish the desired goals.

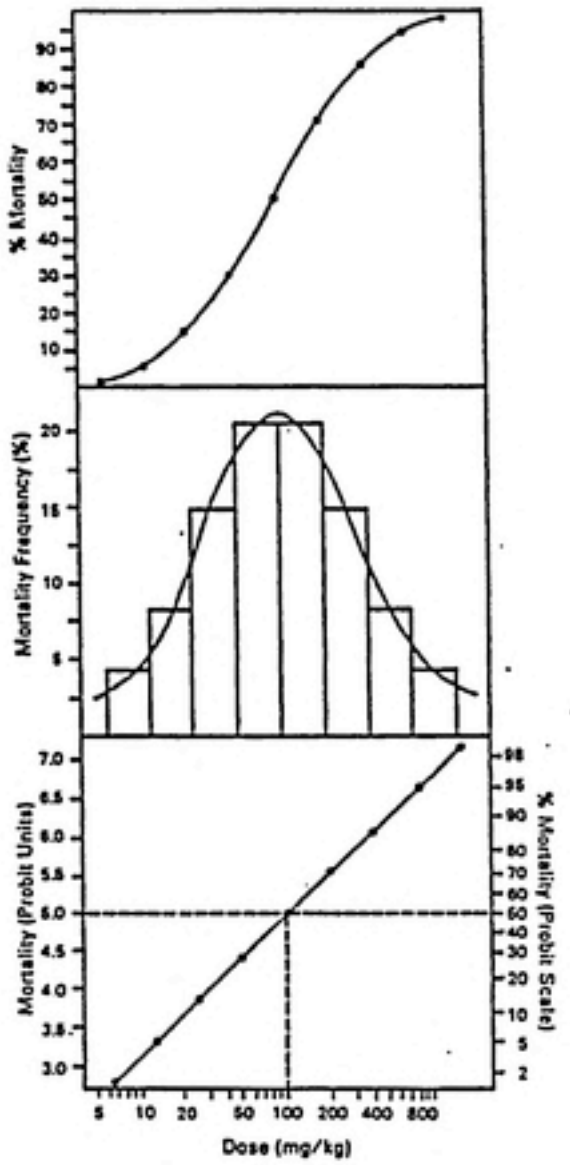
TABLE 1-1

TOPICS COVERED IN ODW WORKSHOP

- Regional/state update
- Risk Assessment:
  - Principles of Toxicology
  - Principles of Absorbtion, Distribution, Metabolism and Excretion of Chemicals
  - Toxicological Approaches Used in Developing National Drinking Water Standards
  - ODW Health Advisory Program
  - Toxicology of Inorganics, Pesticides, Solvents and Vapors
  - Principles of Carcinogenicity
  - Principles of Risk Assessment
  - Risk Assessment Case Study
- Risk Management:
  - Overview of Treatment Technology as it Applies to Risk Management
  - Inorganics and Radionuclide Treatment
  - Organics Treatment, Case Histories (granular activated carbon and aeration)
  - Risk Management Case Study
- Risk Communication:
  - Video
  - Speaker

FIGURE 1-1

LD50 FIGURE FROM ODW WORKSHOP



CHAPTER 2

WHY UNCERTAINTY IS IMPORTANT: SOME DEFINITIONS AND A THEORETICAL DISCUSSION

DEFINITIONS

The analysis of risk is a field in which no two authors seem to define their terms the same way. To avoid confusion, six words or phrases that are central to the argument made in this report are defined below. They are: risk, risk assessment, risk management, uncertainty, reasonable assurance, and confidence.

Risk

Risk is used in this report to mean the probability of an outcome of interest for an individual or the frequency of effect in a population. It also includes a consideration of the severity of the effect. For example, the probability of getting lung cancer from radon in drinking water is a measure of the risk. A quality of the risk estimate (as opposed to the risk itself) is the confidence placed on the reliability of that estimate.

Risk Assessment and Risk Management

The Environmental Protection Agency (EPA), in the Office of Drinking Water's Workshops on Assessment and Management of Drinking Water Contamination (EPA 1988), defines "risk assessment" as follows:

> the scientific estimation of hazard which is obtained by combining the results of an exposure assessment with the results of the toxicity assessment for the subject chemical.

In the same source, EPA (1988) defines "risk management" as follows:

> the judgement and analysis that combine the scientific results of a risk assessment with economic, political, legal, and social factors to produce a decision about environmental action.

I will adopt these definitions of "risk assessment" and "risk management" with one caveat. The word "scientific" (which appears in the definition of risk assessment) is often taken (incorrectly) as connoting certainty or at least extreme epistemic strength; such a connotation should be avoided. Instead, the word "scientific" in the definition of risk assessment should be taken as connoting a systematic endeavor by a well-defined social group designed to confront and resolve uncertainties. Since uncertainty is a

fundamental part of the process of science, the uncertainty of science should be incorporated in risk assessment systematically. An awareness of the need to incorporate uncertainty in risk assessment is crucial to the professionals who use risk assessment and to those who are affected by risk management decisions.

Uncertainty

Webster's Ninth New Collegiate Dictionary defines "uncertainty" as "the quality or state of being uncertain," and "uncertain" as follows:

> 1: INDEFINITE, INDETERMINATE 2: not certain to occur: PROBLEMATICAL 3: not reliable: UNTRUSTWORTHY 4 a: not known beyond doubt: DUBIOUS b: not having certain knowledge: DOUBTFUL c: not clearly identified or defined 5: not constant: VARIABLE, FITFUL.

These definitions are all applicable to risk assessment and risk management. Anything that is projected to occur in the future is indeterminate (for example, at what time will low level radioactive waste begin to escape from a land disposal unit). Many events predicted in risk assessment are not certain to occur (for example, if a person is exposed to a small amount of radon, cancer is not certain to occur). Data frequently are not reliable (for example, a laboratory animal study may have been done poorly). Many factors in

risk assessment are not known beyond a doubt or we do not have certain knowledge of them (for example, the mechanism by which carcinogens cause cancer is not known with certainty). Factors in risk assessment may not be clearly defined (for example, "cancers" in a lab study may mean only malignant tumors or both benign and malignant tumors). Finally, many aspects of risk assessment are not constant, either over time (such as exposure) or within populations (such as threshold or sensitivity). The net result of these considerations is that all of risk assessment, from specification of analytical categories to required physical parameters, is characterized by uncertainty.

Reasonable Assurance

According to Webster's, assurance can mean "confidence of mind... : easy freedom from... uncertainty." (def. 2c) Reasonable will be used here in the sense of giving reasons: something is reasonable if reasons may be given for it. Thus reasonable assurance may be defined as giving reasons that provide confidence that predictions about risk are correct. For EPA, the kind of reasons that give confidence are scientific models and data (Crawford-Brown and Cothern, 1987).

Reasonable can also mean "not extreme or excessive" (Webster's, def. 1b). In this context, the phrase reasonable assurance also implies that it is possible to require excessive, or unreasonable, confidence.

Reasonable assurance implies that regulators are making a trade-off between increased cost and increased confidence, not increased cost and decreased risk. A wide variety of different risk levels may possibly result from a particular regulation, some of which would be acceptable and some of which would not.[3] The more stringent the regulation, the more likely it is that the actual resulting risk will prove to be acceptable. Therefore, regulatory stringency is not simply buying a reduction in risk, but also an increase in confidence that the actual (unknown) risk will be acceptable.

Confidence

It has been asserted that EPA requires the use of scientific models to have confidence. But scientific models can lead to different levels of confidence. The idea of

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3 Setting the acceptable risk level is a complex policy issue and is beyond the scope of this report. In general, the acceptable level is either a policy given, as in an inference guideline, or a publicly determined result. In neither case is it left to the analyst's choice.

science as a craft is one way of formalizing that fact. Ravetz (1971) proposes that one important measure of crafting is precision: how good the fit is between reality and the predictions of science. A science that is well-crafted will make predictions that fit well with reality, while one that is poorly-crafted will make predictions that do not fit well with reality. Ravetz also asserts that scientists learn the methods of performing science and avoiding pitfalls from other scientists, and that this craft knowledge, combined with a scientist's personal style, is fundamental to the achievement of scientific knowledge. He goes on to argue that when a scientific discipline is mature, craft knowledge allows its practitioners to chart their way around most of the pitfalls fairly easily. When a scientific discipline is young, however, the craft knowledge of pitfalls does not yet exist and must be learned by experience. Therefore, science may be well-crafted or poorly-crafted, depending on how well its predictions fit with reality and how well developed the craft knowledge of the discipline is.

It is reasonable to suppose that the more well-crafted an aspect of science is, the more confidence we will have in its results. A well-crafted discipline will have both pragmatic (or historical) evidence to support it, as well as a sound theoretical basis. Put more simply, if some aspect

of science is well-crafted, it works repeatedly (pragmatic evidence) and we understand why (theoretical evidence). Such a well-crafted discipline makes a more convincing case than a discipline that is less well-crafted. A less well-crafted discipline might be one with a theoretical basis but no pragmatic evidence, or one with some pragmatic evidence, but no theoretical basis. While it might appear on the surface that a pragmatic support would be equally compelling with or without theoretical understanding, this is not so. Pragmatic evidence is most powerful in the setting in which it was obtained. With no theoretical basis to identify the important variables in the setting, a scientist must be less certain when applying pragmatic evidence in a setting even slightly different from the one from which the evidence was derived. When, however, a scientist has theoretical evidence in addition to pragmatic evidence, it is possible to determine whether the new setting differs from the old setting in any respect that could significantly influence the precision of results. Therefore, a discipline in which the pragmatic evidence is backed up by theoretical understanding is more well-crafted than one in which the pragmatic evidence stands alone. Obviously, pragmatic or theoretical evidence alone results in a more well-crafted discipline than no evidence.

WHY UNCERTAINTY IS IMPORTANT

Two approaches to uncertainty in risk assessment and risk management are widely used, but neither of them deals explicitly or adequately with uncertainty.

The first is the use of the "best estimate" at each step of the risk assessment. Uncertainty is admitted and then resolved by comparing the relative merits of various predictions of risk. "Best" may mean different things to different people, and may be represented by a mean, median, or mode. Although this method may give the "best" single estimate of risk (e.g., the probability of getting cancer) in some sense, no single estimate is likely to be the true value when the distribution of estimates is wide. Therefore, with a "best" estimate of the risk, the regulator cannot be reasonably confident that the risk that actually results from the regulation will be as calculated and, therefore, acceptable; the true risk is very unlikely to equal the best estimate, and there is usually a fairly large probability that the risk will in fact be larger than the best estimate. If the regulation has been chosen so that the best estimate of risk coincides with the acceptable level of risk (or even a factor of ten or more lower than the acceptable risk), this approach may lead to a non-negligible probability that the regulation will fail to

bring about the desired state of the world (an acceptable level of risk).

The second approach commonly used in risk assessment is the conservative approach. Conservative values (i.e., those tending to bias the results in the direction of the upper bound of the outcome) are used for each factor in the risk assessment, typically the value that represents the 95th percentile of the data. This leads to a final risk level that is even more conservative, in most cases, than any of the inputs. As a result, a stricter regulation must be promulgated to reach an acceptable risk than if less conservative inputs were used. Stricter regulations usually result in greater compliance costs than lenient regulations. The conservative approach may result in unreasonable, or excessive, confidence.

A single estimate of the risk (e.g., the probability of getting cancer, generated by either of the above methods) may be useful in making a trade-off between cost and risk. To make a trade-off between cost and confidence the regulator must have as complete a confidence distribution of the risk for each regulatory alternative as is possible. This allows him to see his confidence that each regulatory option will result in an acceptable risk. By combining this with the cost of achieving different levels of confidence

(through different regulatory options), the regulator can make the trade-off between cost and confidence explicit, allowing him to have reasonable assurance that the actual risk will be acceptable without excessive demands for confidence.

The Interpretation of Reasonable Assurance

An important concern of regulators when they are pursuing reasonable assurance will be how the courts will interpret "reasonable assurance." There is not a specific precedent for the interpretation of the word "reasonable" in this exact context. However, courts have two tendencies that may be relevant to this issue.[4] The first, more general, tendency is that on some fuzzy issues of interpretation, a court may rely on the premise that "we know it when we see it." Applied to the phrase "reasonable assurance," this means the court can't define "reasonable assurance" generally, but feels it can look at any particular case and say whether or not it constitutes reasonable assurance. Therefore, the court may bring its own sense of reasonableness to the interpretation, or it may try to rely on some other concept of reasonableness (such as the "reasonable man" of common law negligence doctrine).

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4 I am indebted to Mike Berry and Milton Heath for their insightful comments on this subject, from which this discussion took its shape.

The second, more specific, tendency that courts follow in cases involving regulatory agencies is the use of the doctrine of the hard look. Under this doctrine, a court examines the rigor of the analysis performed by the agency in setting a regulation, rather than passing judgement on the quality or correctness of the resulting regulation. A court is looking at process instead of content in the doctrine of the hard look. Thus, a court using this doctrine will tend to support the agency when the agency has done a rigorous analysis, regardless of the outcome of that analysis. One reason for this approach is that courts are not experts in the fields in which agencies set regulations and are not, therefore, well-qualified to judge the content of a technical regulation (a factor presumably required for the recognition of reasonable confidence in the first approach discussed above). They are, however, quite competent to judge the quality and rigor of the process that produced the regulation, and this is what the court is doing in the doctrine of the hard look.

Under both these approaches, a court is likely to look more favorably on a regulation that is based on a full consideration of uncertainty. Under the first approach, an explicit representation of uncertainty puts the court more fully in the regulator's position and thus increases the

likelihood that the court will understand the base of confidence faced by the regulator. Under the doctrine of the hard look, an explicit treatment of uncertainty increases the rigor of the analysis and, therefore, the likelihood that the court will look favorably on it.

CHAPTER 3

SOME USEFUL CONCEPTS ABOUT UNCERTAINTY

REASONS FOR BEING UNCERTAIN

Uncertainty can arise from many different sources and be of many different types, but these all have their roots in a limited number of fundamental reasons for being uncertain. For example, a regulator may be uncertain about the correct dose-response model for carcinogens. This is a specific type of uncertainty that is part of a more general type of uncertainty: uncertainty about models and their relationship to the phenomena they model. The reason for this uncertainty is ignorance: science has not discovered completely how substances produce cancer. The type or source of uncertainty may be either general or specific, but the reasons for uncertainty are all very general.

Uncertainty may arise from any of at least three fundamental reasons for being uncertain, as follows:

- Conceptual/Perceptual Factors
- Ignorance
- Variability

Each of these reasons has different implications for risk assessment and risk management.

Conceptual/Perceptual Factors

Conceptual uncertainty exists because a regulator may not have asked an important question during the risk assessment process, or may have asked it in a vague manner. The situation he is studying may be affected by some factor that he has not considered. A common example of this is confounding in epidemiological studies. Confounding occurs in the study of the association between an exposure and a disease when a third variable is associated with the exposure and also affects the incidence of the disease independent of the exposure of interest. The presence of the confounding variable can make an association appear where none exists or mask an existing association. Failure to consider such a factor might (or might not) render the results meaningless or incorrect. What a regulator thinks he is seeing and what he is really seeing may be two different things if the problem as framed is not conceptually complete. So a regulator needs to consider whether he has asked all the relevant questions. But he can never be sure that he has, so he must be uncertain about the

results and their relationship to the overall goals of regulation.

Two major problems arise under conceptual and perceptual uncertainty. The first is the assignment of analytical categories of effects. The regulator must decide what "counts" as an effect in the risk assessment. Will he consider only cancer mortality? Cancer morbidity? Noncancer effects? The choice of these analytic categories gives rise to conceptual uncertainty. The second area that results in conceptual uncertainty is the issue of what is meant by confidence. The regulator must decide how he will measure confidence, and this choice also gives rise to uncertainty.

Uncertainty arising from conceptual and perceptual causes is not directly quantifiable. The regulator may be aware of the possibility that he has either asked the wrong question or has failed to ask a relevant question, but he cannot fully know the extent of this difficulty. He may reduce conceptual uncertainty by using procedures to elicit alternative ways to formulate the problem, but such techniques can never eliminate the uncertainty, as the regulator can never be certain that there are not additional questions he has missed.

Ignorance

Many of the uncertainties mentioned in the literature may be attributed to ignorance and insufficient information. When uncertainty is caused by ignorance, a correct answer exists, but it has not yet been found (this being different from conceptual uncertainty where humans must decide on the most important questions to be addressed). Four common types of uncertainty in risk assessment have their roots in ignorance. These are uncertainty about the following:

- Theories
- Model form
- Data choice
- Parameter estimates

The process of risk assessment is built on a framework of theories, models, data, and parameter estimation. For any particular risk situation there may be multiple theories describing the analytical categories and the physical laws relating them. For each theory there may be several different possible models formalizing the theory into mathematical equations. Finally, the regulator will be faced with competing sets of data from which parameter values (appearing in the mathematical equation) may be obtained. Since different statistical procedures may be

applied to obtain these parameter values from any specific set of data, parameter estimation is also characterized by uncertainty. The regulator is usually ignorant as to which combination of theory, model, data, and parameter estimation technique (if any) is the right one.

Theoretical uncertainty often arises from the following questions:

- Which of the available theories is correct?
- Have we thought of the correct theory at all?
- Does a theory hold outside the boundaries within which it has been tested?
- Does the theory specify all analytical categories playing a causal role in the phenomenon?

Whenever there is more than one theory, there will be some uncertainty about which is correct. For example, a variety of theories exist on the mechanisms by which chemicals cause cancer, and neither scientists nor regulators know which, if any, of them is correct. In fact, scientists may not have thought of the correct theory at all, so that none of the existing theories is correct. Finally, even if a theory is well-accepted in one realm, it may not apply in others. For example, different chemicals might cause cancer in different ways, so that one theory of carcinogenesis might hold for some chemicals but not for others. The ability of the

theory to explain the behavior of one chemical may, therefore, fail to provide confidence that it applies to another chemical. Similarly, a theory may hold for some species (such as rats) and not for others (such as humans).

Once a theory (such as a multistage theory) is specified, it must be formalized into a mathematical model for purposes of prediction. Uncertainty about models in risk assessment may arise from these questions:

- Which model is correct?
- Does the model reflect the theory accurately?
- Does the model contain the correct parameters as entailed by the theory?
- Can the model be extrapolated outside the experimental range?
- Is the model complete (i.e., does it include a representation of all analytical categories required by the theory, or at least all those adequate for reasonable precision)?

Models may not contain all of the terms specified by a theory. Some terms may be left out because they can't be measured. Some may be left out because they can't be related yet to measurements. Some may be left out because the regulator does not have time to make measurements.

Conceptual Uncertainty Arising from Ignorance

In risk assessment, the regulator is seldom able to use data that measure directly what he is interested in. Instead, he uses the data available and extrapolates it to the situation of interest. This gives rise to conceptual uncertainties about the following issues:

- How should conflicting results be reconciled?
- Is extrapolation valid?
- How should different kinds of evidence be weighted?

Conflicting results are often dealt with by using the one that results in the most conservative action. For instance, if some studies show a substance causes cancer and others do not, a regulator may treat the substance as a carcinogen to be on the safe side. This conflict in the data produces uncertainty. EPA has a weight of evidence classification scheme for carcinogens that is intended to reflect a judgement about all available data. The classifications are listed in Table 3-1.

Variability

A third basic reason for uncertainty is variability. Variability is different from the other reasons for

uncertainty in that it is a phenomenon to be described and accounted for, rather than eliminated. Many parameters and processes of interest in risk assessment are inherently variable: there is no single correct answer, but a distribution of actual (existing) answers. An example is sensitivity in a population: some subgroups may be more sensitive to the toxic effects of a chemical than other subgroups. Another example is wind and weather patterns (which are used in transport models). Variability may also be a cause of uncertainty in the measurement of a fixed parameter because the measurement process is variable.

Variability is one cause of uncertainty that can be readily quantified by probability and statistics. A regulator may artificially "reduce" variability by dealing with homogeneous subsets of the varying population, but he can't really reduce or eliminate it, nor is that really desirable. Variability is not a problem to be eliminated, but a state of the world that the regulator must describe and consider in risk assessment.

APPROACHES TO DEALING WITH UNCERTAINTY

A regulator may try to reduce uncertainty or he may describe uncertainty qualitatively or quantitatively. The

appropriateness of each of these approaches depends on the cause of the uncertainty.

Reducing Uncertainty

The regulator can reduce uncertainty due to ignorance by doing more research or getting more information. The regulator may also reduce conceptual uncertainty by asking more questions and looking for new information. These reasons for uncertainty will never be eliminated entirely, but they can be both reduced and understood. The remaining cause of uncertainty, variability, is not amenable to reduction or elimination. If a thing is inherently variable, research may reduce the regulator's ignorance about its distribution, but it will never remove its variability.

Additional research can be quite valuable, but it is often expensive and time consuming. Depending on the problem, it may or may not be worth the investment of time and money to obtain better information. One approach to deciding whether to pursue better information and for what parameters is sensitivity analysis. Sensitivity analysis considers the effect of individual components of uncertainty on the overall uncertainty. The greater effect an individual component has on the overall uncertainty, the

more worthwhile (or reasonable) the reduction of that component of uncertainty will be. An example of this will be given in the case study in Chapter 4.

Describing Uncertainty

Uncertainty can be described both qualitatively and quantitatively. This does not reduce or eliminate uncertainty, but may be quite helpful to the decision maker. Uncertainty due to ignorance might be described qualitatively by saying something like "our ignorance in this area is problematical but not crippling to the analysis" or "our ignorance in this area makes useful analysis impossible." Similarly, a regulator might know that the uncertainties are relatively large or relatively small. Unfortunately, these phrases may mean different things to different people; they are imprecise. Whether or not this limits their usefulness is a matter of debate. As a result, such qualitative approaches might still be explored in any discussion of uncertainty.

A quantitative description of uncertainty may be more useful because it can be presented more precisely, although not necessarily more clearly. There is also the risk of excessive precision; see Ravetz (1971). Probability is an important tool for describing some types of uncertainty

quantitatively. Probability may be divided into two types: long-term frequency and subjective or Bayesian. Long term frequency is the idea of probability as the limit of the frequency of an event over a large number of trials, and is primarily useful in areas where there is some past experience (or trials) available and where such trials can easily be performed. A wide variety of statistical methods are based on this kind of probability and can be used to describe uncertainty due to variability or imprecise sampling data.

Subjective probability is a measure of someone's belief; for example, a scientist's belief about whether a theory is true. Subjective probability is useful where there is little or no prior experience and trials either cannot or have not been performed (or where trails are in fact meaningless). Long-term frequency approaches are particularly weak in dealing with confidence assigned to theories. Using Bayes Rule, subjective beliefs about theories or models, called prior probabilities, may be combined with experimental observations and the probability that such observations would result from each theory or model to obtain a probability, called a posterior probability, which takes both the subjective and objective elements of evidence into account. Bayesian probabilities can be used to describe any kind of uncertainty that a

regulator has a belief about, but are most useful when no long-term frequency data are available or obtainable, such as when uncertainties are due to incomplete information (ignorance). The difficulty with Bayesian probabilities is that they represent an individual's beliefs about probabilities, which may or may not be well founded. Bayesian probabilities are a way of quantifying uncertainty that is thought of as unquantifiable within a long-term frequency approach. Whether a regulator should be willing to use such a quantification is a debatable issue; however, EPA has used such quantifications (see the case study in Chapter 4).

Regardless of the type of probability, long term frequency or Bayesian, quantified probabilities should be presented in a way that is useful to the decision maker. Two particularly useful forms, which work best when shown together, are the probability density function and the cumulative probability distribution, shown in Figure 3-1. (Another example of these is shown in Figure 1-1, from the Workshop.) The probability density function shows the probability of a particular outcome, while the cumulative probability distribution shows the probability that the outcome will fall below any particular value.

Decision making is not a trivial process even in the absence of uncertainty. Most social problems have multiple conflicting goals; making trade-offs among them can be so difficult that an enormous literature has grown up on this subject. Problems arise because risk assessment and risk management cannot be neatly separated into questions of fact and questions of values; rather, the two are intermingled at every step. Cumming (1981) calls risk assessment a "trans-science:" a discipline in which questions can be asked within a scientific framework, but are "beyond the capacity of science to answer." An example of the intertwining of fact and value in risk assessment is risk acceptability. Even as risk assessors struggle to determine what the risk in a given situation is, the person who will make use of the risk assessment must also struggle to decide how much risk is acceptable. Science cannot answer this question, nor is it clear that there is a single right answer.

Out of a desire to put as many of the questions arising in risk assessment within the "capacity of science to answer" and so simplify an already difficult decision, regulatory decision makers often ignore uncertainty and are, as a result, extremely overconfident in the results of risk assessment. Numerous studies (aptly summarized in Morgan, Henrion, and Small, 1990) have shown the overconfidence of both lay people and experts (even in their field of

expertise) when asked to make predictions. Clearly then, the consideration of uncertainty needs to be made explicit in an effort to counteract a natural tendency toward overconfidence, and because reasonable confidence implies a reasonable procedure for assigning confidence.

How should uncertainty be included in decision making? How should decision makers think about making decisions when they are uncertain? Decision theory can help to illuminate choices made under uncertainty when the uncertainty can be quantified. Uncertainty may be propagated through a decision tree to produce a range of possible outcomes and the probability (or confidence) of each. The value of each outcome is multiplied by the probability of its occurrence and the result is then summed over all outcomes for a particular decision to arrive at an expected value for that decision. Sensitivity analysis can identify the parameters that most affect the decision. Expected values, while useful, can also hide important information if improperly used. A certain outcome of five cancers and an outcome where there is a probability of 0.5 of ten cancers and a probability of 0.5 of zero cancers both have an expected value of five, but are obviously not equivalent: the second situation is less certain than the first. The use of expected values hides the uncertainty. It shields the

regulator from an explicit decision as to how uncertainty should be resolved.

Evidence that contains a lot of uncertainty does not necessarily mean that the decision maker should not act. In fact, sometimes the regulator is compelled to act regardless of the evidence because of statutory or political reasons. Also, a great deal of uncertainty may motivate the regulator to choose a very conservative regulation and to try to get more information, while a less uncertain situation might allow the regulator to set a less conservative standard (because he is more certain it will result in an acceptable outcome). The level of uncertainty may, however, affect how the regulator approaches the regulation; for example, he might regulate by way of best available technology, a standard (say for drinking water), a required treatment technology, or a labelling or disclosure requirement.

FORMALIZING CONCEPTS ABOUT UNCERTAINTY FOR INCLUSION IN RISK ASSESSMENT AND RISK MANAGEMENT TRAINING

Uncertainty is a central feature of risk assessment and risk management. Therefore, it is important for designers of risk assessment and risk management training materials to include coverage of uncertainty and reasonable assurance. All the ideas presented here are applicable to any risk assessment and risk management training materials. This

section proposes a very general process for incorporating coverage of uncertainty and reasonable assurance into existing risk assessment and risk management training programs. Chapter 4 presents a fully developed case study that incorporates many of these principles.

The first step is to assess the information on uncertainty and reasonable assurance already present in a training program. Following is a partial list of questions training designers might want to ask about what information is present:

- How is risk defined?
- How are uncertainties treated?
- Are the components of uncertainty separated?
- Are the causes of uncertainty discussed?
- Are ways for dealing with uncertainties discussed?
- Are ways for thinking about making decisions under uncertainty discussed?

For the EPA Workshop, risk assessment and risk management are well-defined, but risk is not defined at all. Uncertainties are virtually ignored (and thus components of uncertainty are not separated). The causes of uncertainty, ways for dealing with uncertainty, and ways for thinking about making decisions under uncertainty are not discussed.

Once the designers have a clear idea of the level of coverage already present in a program, they will need to think about how to add additional coverage. They might want to consider these five goals:

- Ease of understanding,
- Clarity of terms,
- Ease of demonstration,
- Completeness of conception, and
- Rigor of thought.

Ease of understanding, clarity, and ease of demonstration all have to do with how information is presented. They are important because many participants may be hesitant about tackling uncertainty. Therefore, it is crucial that the presentation be as clear and easy to understand as possible. Before the presentation can be clear, however, the designer must have a complete conception of the problem of uncertainty. This is not to say that the presentation need include all of that conception, but rather that the presenters must have that conception if they are to be clear and consistent in what they do present.

Completeness of conception as presented and rigor of thought should be tailored to fit the goals of the

particular training materials. In the Workshops discussed here, the goal was a general understanding of risk assessment and risk management. Such a goal is best served by a presentation that is not too rigorous, one that gives participants a vocabulary and framework for thinking about uncertainty without distracting them into unfruitful discussions of statistical procedures and mathematics. This is probably true in general of most of EPA's risk training materials; all of the ones reviewed in Crook (1988) had similar goals. A rigorous treatment of uncertainty analysis and statistical methods for dealing with some uncertainties would be far beyond the scope of any Workshop; even if they were not, such topics would not be beneficial until the student has grasped the more conceptual tools discussed here.

In the next chapter, a case study is presented that illustrates the concepts developed in this chapter.

TABLE 3-1

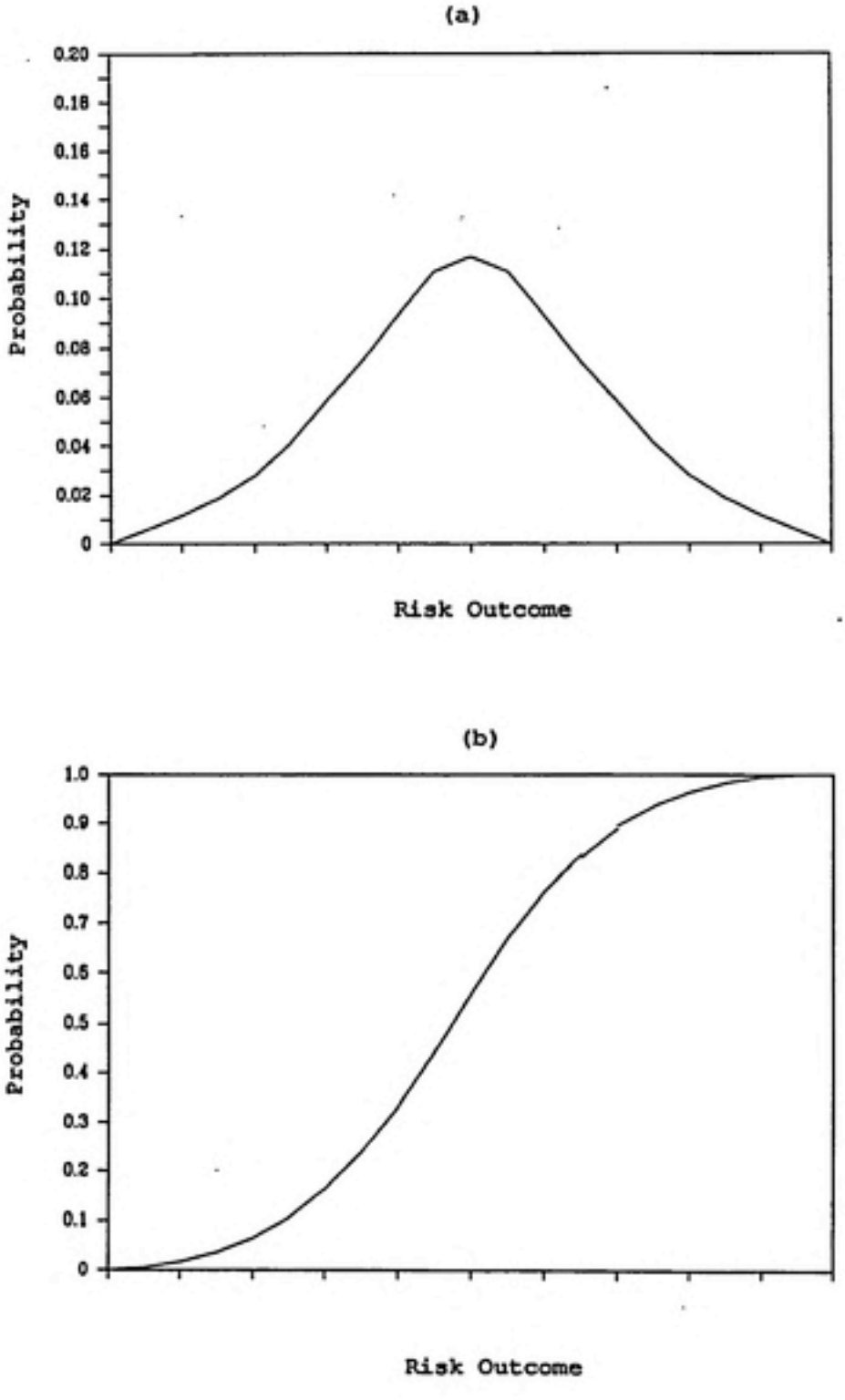
EPA CARCINOGEN CLASSIFICATIONS

A	Human Carcinogen
B	Probable Human Carcinogen
	B1 - Limited human data, sufficient animal data B2 - Sufficient animal data
C	Possible Human Carcinogen - limited animal data
D	Not Classified - inadequate or no data
E	No Evidence for Carcinogenicity in Humans - data in animals indicates the chemical is not carcinogenic

Source: ODW Workshops (EPA, 1988)

FIGURE 3-1

SAMPLE PROBABILITY DENSITY FUNCTION AND
CUMULATIVE PROBABILITY FUNCTION



CHAPTER 4

RECOMMENDATIONS AND CASE STUDY FOR INCLUDING IDEAS ABOUT UNCERTAINTY IN ODW WORKSHOPS

RECOMMENDATIONS FOR INCORPORATING GENERAL CONCEPTS

The Workshop as a whole should include a discussion or presentation on why uncertainty is not merely important to risk assessment and risk management, but central to them. The concept of reasonable assurance, developed earlier, should also be introduced. This material is critical in motivating the participant to make the effort to face the problems resulting from uncertainty. Without this motivation, all that follows on uncertainty in the workshop will be wasted.

The section on risk assessment needs a more explicit discussion of the reasons for uncertainty. At a minimum, the presentation should cover ignorance and variability. Conceptual/perceptual reasons for uncertainty would also be useful. The level of coverage on these ideas need only be a brief description of what is meant by each cause, some examples of types of uncertainties that spring from each of the causes, and how these are related to confidence.

The risk assessment section also needs a discussion of ways the regulator might think about or describe uncertainty. This should not be a rigorous, statistical presentation on uncertainty analysis, but rather a discussion of basic ideas of probability and an explanation of probability density function and cumulative probability function graphs. The participants in the case study groups reviewed earlier had a lot of trouble deciding how they should express the uncertainty in the problem; they badly needed a vocabulary (including some graphical devices) for talking about uncertainty.

Finally, the risk assessment section would benefit from a discussion of the idea of sufficient evidence for justifying decisions to act, discussed earlier. This is a very powerful way of thinking about making decisions under uncertainty. The coordinators need to raise questions such as "how much certainty is necessary to take different kinds of action?" and "does the evidence justify action X?" There are no easy answers to these questions, nor should the Workshop attempt to provide answers. But the Workshop must raise these questions so that they may be discussed. The participants in the case study groups struggled with how to incorporate the uncertainty in the evidence into the decision making process; the concept of sufficient evidence

would provide them with a framework for articulating this difficulty.

In risk assessment, the concern with uncertainty is focused on how to express it; in risk management, the concern should be on how to make decisions under uncertainty. Dealing with uncertainty is central to risk management, but it was almost entirely missing from the Workshop presentation.

The section on risk management needs a presentation of reasonable assurance. The concept of reasonable assurance should be the foundation of any regulatory decision making process involving risk and uncertainty. Participants should be introduced to the idea of reasonable assurance and encouraged to work from that base. The presentation should include an analysis of why best estimates and conservatism do not satisfy the requirements of reasonable assurance, as discussed earlier. Participants should be encouraged to use the idea of reasonable assurance in the risk management case study.

The section on risk management also needs a basic discussion of the ideas of decision theory. The presentation need not be highly theoretical or in-depth; instead, the goal is to give participants a structure for

thinking about the implications of uncertainty in the decision making process. They need to be made aware that trade-offs must be made and how uncertainty might affect those trade-offs. Participants in the risk management case study groups had no feeling for the importance of uncertainty to the decision making process. They ignored all kinds of uncertainty built into the problem in their rush for the most conservative decision. It is not surprising that the participants behaved this way; by ignoring uncertainty, the presentations did nothing to validate the idea that uncertainty was worth considering. More important, it caused participants to resolve uncertainty through implicit, rather than explicit, means.

Finally, the discussion of sufficient evidence recommended for the risk assessment section is equally applicable here. The risk management section might include another discussion of that subject as it applies to risk management.

CASE STUDY: RADON IN DRINKING WATER

Introduction

To illustrate the ideas about uncertainty and reasonable assurance presented in this report, this section

provides a worked example using the risks from radon in drinking water. The example is designed so that it could be used directly by EPA in a training program with little alteration.

Reasonable has been defined previously as "the giving of reasons." Using that definition, reasonable assurance was defined as the giving of reasons that provide some confidence that predictions about risk are correct. For EPA, prediction from a scientific model is what provides confidence (Crawford-Brown and Cothern, 1987; Crawford-Brown and Pearce, 1989). Therefore, to achieve reasonable assurance, EPA's regulations must be based on predictions of risk from scientific models. Risk has been defined as the probability of an outcome for an individual (e.g., health effects). This case study uses scientific models to predict the health effects from radon in drinking water and the uncertainty about those effects. (The effect considered is lifetime incidence of cancer mortality.)

Sources of Uncertainty

The EPA has proposed a standard for radon in drinking water of 300 pCi/l (Crawford-Brown and Cothern, 1987). The standard-setting approach to regulating health hazards raises two major questions or sources of uncertainty.

First, will it be possible to attain the standard? Second, if the standard is attained, will it result in the desired level of health effects?

How confident can EPA be that radon can be removed from drinking water to a level of 300 pCi/l? There is solid pragmatic evidence that radon can be removed to levels well below 300 pCi/l. Granular activated carbon (GAC) and aeration have both been used reliably at full scale to remove radon from drinking water with removal efficiencies of 90 percent and greater (Reid, et al., 1985). Over 99 percent of the homes in the U.S. have radon levels of 1,000 pCi/l or less (Crawford-Brown and Cothern, 1987); 90 percent removal in those homes would result in levels at or below 100 pCi/l. In light of such well-crafted pragmatic evidence, there is virtually no uncertainty that a standard of 300 pCi/l can be achieved. This case study will therefore assume that the 300 pCi/l standard is met or exceeded in all homes.

How confident can EPA be that once the 300 pCi/l standard is achieved, it will result in an acceptable level of health effects? The main health effect of concern with radon is lung cancer. There is crafting in the predictions of lung cancer risk at high doses of radon, such as are experienced by uranium miners (Crawford-Brown and Cothern,

1987). The evidence of this crafting is the ability of the dose-response equations to fit the data with a large value of R^2 (the correlation coefficient, or measure of the degree of empirical support for the dose-response equation). This does not, however, necessarily provide confidence at low levels. The bulk of the uncertainty associated with predicting health effects from exposure to radon in drinking water arises from questions about the reliability of predictions of lung cancer cases at low doses. This case study will use a scientific model to predict the health effects of radon in drinking water and to analyze the uncertainty about that prediction.

Risk Model

Individuals may be exposed to radon from drinking water by two pathways: inhalation of radon volatilized to air and ingestion of contaminated water. The EPA standard for radon in drinking water is based only on the air pathway, for which an uncertainty analysis has been done (Crawford-Brown and Cothern, 1987). EPA concluded that the water pathway was not significant, but this decision was not based on a scientific model and therefore does not satisfy EPA's requirements for reasonable confidence (Cothern, pers. comm.). It has since been estimated that the risks associated with the water pathway are roughly comparable

with those of the air pathway, but no uncertainty analysis has been done for the water pathway (Crawford-Brown, 1989). Because the 300 pCi/l standard is based only on air exposures, this case study will focus on that pathway.

The risk from radon in drinking water by way of the air pathway can be predicted as the product of several parameters.[5] To express the uncertainty associated with the resulting estimates, it is necessary to make two assumptions.

First, each parameter is assumed to be log-normally distributed. The literature suggests that many parameters relevant to environmental risk assessment are log-normally distributed (Crawford-Brown and Cothern, 1987). The log-normal assumption also results in an uncertainty analysis that is relatively straightforward, both conceptually and computationally. An important property of a log-normal distribution is that 68 percent of the values fall within one geometric standard deviation (GSD) of the median (or 50th percentile). The GSD is applied by multiplying or dividing the median; thus the range of "within one GSD" is from the median divided by the GSD to the median times the GSD. This is conceptually easy to understand, since

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5 The risk model and all median and geometric standard deviation (GSD) values used in this case study are from Crawford-Brown and Cothern (1987).

statements of confidence are formulated as "accurate to within a factor of 2." Using the median and the GSD of a log-normal distribution, the 16th and 84th percentiles can be calculated (16th = median/GSD, 84th = median*GSD). With those points and the median, a cumulative confidence curve can easily be plotted on log-probability paper as a straight line.

The second assumption is that confidence is a measure of the subjective state of an individual (such as the regulator). The GSD for each parameter is a measure of the uncertainty associated with it. The GSDs used in this case study reflect the expert judgement of Crawford-Brown and Cothern (1987). For each parameter, the paper provides two GSDs: one that reflects uncertainty about the average value of the parameter and one that reflects the variability of the parameter. The first expresses the uncertainty of predicting an average value for the U.S. population, while the second expresses the uncertainty about predicting a value for a particular individual or home.

Calculating Risk

The unit individual risk (or probability of contracting lung cancer) per pCi/l of radon in drinking water by the air

pathway is estimated by the following model:

$$UIR = Ca/Cw * F * CF1 * CF2 * T * RF \qquad \text{(Eqn. 4-1)}$$

where:

UIR = unit individual risk in probability/person/pCi/l.

Ca/Cw = transfer factor from water to air in pCi/l air per pCi/l water.

F = equilibrium factor (unitless).

CF1 = conversion factor, 1 WL/100 pCi/l air (WL = Working Level, a measure of radioactive activity).

CF2 = Conversion factor from years to working months (170 hours), adjusted for unattached fraction and lung model, in WM/year.

T = length of exposure in years.

RF = risk factor, adjusted for latency period, in probability/person/WLM (WLM = Working Level Month, a measure of radiation dose).

Table 4-1 shows the median, uncertainty GSD, and variability GSD for each of these parameters. Some parameters have more than one GSD, because the uncertainty about them stems from more than one separable source. Each parameter and the sources of its uncertainty are discussed briefly in the following paragraphs.

The transfer factor from water to air, Ca/Cw, depends on a variety of factors such as dwelling ventilation rate, building size, water use, and water temperature (Crawford-Brown and Cothern, 1987). Crawford-Brown and Cothern suggest a median value of $1x10^{-4}$; thus, for each pCi/l in

water, there will be $1x10^{-4}$ pCi/l in air. The range of values in the literature for Ca/Cw suggest that this parameter is accurate only to a factor of 2 to 3. Therefore, Crawford-Brown and Cothern estimate the uncertainty GSD to be 2. Because ventilation rates, building size, water use, and water temperature vary among homes, the GSD is greater when variability is included. Crawford-Brown and Cothern set the variability GSD at 4.

The concentration of radon in air is not directly of concern in predicting health effects. Rather, the concentration of radon progeny (the radioactive decay products of radon) is what is of concern. The equilibrium factor, F, is used to predict the equilibrium concentration of radon progeny in air based on the radon concentration. It is a fraction of the radon concentration and so must fall between 0 and 1. The equilibrium factor depends on ventilation rate, building volume, and aerosol characteristics. As shown in Table 4-1, Crawford-Brown and Cothern suggest a median value of 0.5, with an uncertainty GSD of 1.2 and a variability GSD of 1.4. The variability GSD is slightly higher, due to variability in building characteristics.

The conversion factor, CF1, from pCi/l to WL is equal to 0.01 by definition and is neither uncertain nor variable.

The second conversion factor, CF2, from years to working (or occupational) months encompasses uncertainty from two sources and is adjusted for a third. One occupational month is 170 hours, so there are 51.5 occupational months in a year. However, Crawford-Brown and Cothern adjust this to 18 to account for the fact that people spend only a fraction of their time at home. This conversion factor includes uncertainty from two sources: unattached fraction and breathing rate. The unattached fraction is a measure of the fraction of radon progeny not attached to particles. Radon progeny deposit differently in the lung when they are attached to particles than when they are not. Crawford-Brown and Cothern estimate the uncertainty GSD from unattached fraction to be 1.2 and the variability GSD to be 1.4. The typical individual has a lower breathing rate than a uranium miners (on whom most of the data on effective dose are based). The breathing rate affects a person's exposure and therefore, the effective dose. Crawford-Brown and Cothern suggest an uncertainty GSD of 2 and a variability GSD of 3 for breathing rate. These values are summarized in Table 4-1.

The length of exposure in years, T, is taken to be 70, the average lifespan of a person in the U.S. It is not considered to be uncertain for the purposes of this case study.

The risk factor, RF, relates dose to risk, (meaning probability in this context), of contracting cancer. The risk factor is based on data from uranium miners exposed to high doses of radon. It is adjusted for latency period, and encompasses uncertainty from that adjustment as well as two other distinct sources (available data and extrapolation to low dose). Crawford-Brown and Cothern find an median unadjusted value of $1x10^{-5}$ per person/WLM/year. (Note that these are not the same units as the adjusted risk factor used in the unit risk equation.) Based on the range of available data, Crawford-Brown and Cothern suggest an uncertainty GSD of 2 for the unadjusted value. Because it is not known how risk factors vary among individuals, the variability GSD is taken to be the same as the uncertainty GSD as a lower bound. The risk factor is also uncertainty as a result of extrapolation from the high doses experienced by uranium miners to the low dose experienced by a typical individual. Crawford-Brown and Cothern suggest an uncertainty GSD of 3 and a variability GSD of 5 for the extrapolation form high to low dose. Finally, the risk factor is adjusted to account for the absence of risk during the latency period (the time between exposure and manifestation of the effects). Crawford-Brown and Cothern give a median adjusted value of $3x10^{-4}$ per person/WLM. Note that this changes the risk factor from an annual risk factor

to a lifetime risk factor. The uncertainty GSD associated with the latency adjustment is 2 and the variability GSD is 3. These values are summarized in Table 4-1.

Using the median values in Table 4-1 and the unit risk equation given at the beginning of this section, the median value of unit individual risk is 1.9×10^{-7} per person/pCi/l. The lifetime individual risk can then be calculated from this equation:

$$LIR = UIR * Cw \qquad \text{(Eqn. 4-2)}$$

where:

LIR = lifetime individual risk in probability/person.

UIR = unit individual risk in probability/person/pCi/l.

Cw = concentration of radon in drinking water in pCi/l.

Using this equation and a value of 300 pCi/l, the lifetime individual risk is 5.7×10^{-5}.

Calculating the Overall GSD

For a multiplicative function of log-normally distributed parameters, the overall GSD can be calculated

from the individual GSDs by the following equation:

$$GSD = \exp\left[\sum_{i=1}^{N} \ln^2(GSD_i)\right]^{1/2} \qquad \text{(Eqn. 4-3)}$$

where:

GSD = overall GSD

GSD_i = GSD of parameter i

The overall GSD is calculated separately for uncertainty and variability. Using this equation and the GSD values in Table 4-1, the overall uncertainty GSD is 6 and the overall variability GSD is 16. A GSD of 6 corresponds to a 95 percent confidence interval spanning 3 orders of magnitude (the 95 percent confidence interval ranges from the median divided by the GSD squared to the median times the GSD squared). A GSD of 16 corresponds to a 95 percent confidence interval of 4 orders of magnitude.

Constructing a Cumulative Confidence Distribution

Crawford-Brown and Cothern calculated median risk and the overall GSD as discussed above, but they did not develop a cumulative confidence distribution (CCD) from that information. With a cumulative confidence distribution, a regulator can determine the confidence that the risk will be less than or equal to some specific, acceptable risk level. For the purposes of this case study, an acceptable risk is 10^{-4} (EPA, 1986).

The cumulative confidence distribution is constructed by plotting the median, 16th percentile (median/GSD), and 84th percentile (median * GSD) on log-probability paper. The scale on the y-axis of log-probability paper is called a probability scale, and is designed to allow the plotting of a CCD as a straight line.

Figure 4-1 shows the CCDs for uncertainty and variability. The x-axis shows lifetime individual risk from 300 pCi/l on a log scale. The y-axis is cumulative confidence. Both CCDs have the same median, but the variability CCD is less steep, indicating greater uncertainty. The cumulative confidence of an acceptable risk of 10^{-4} as a national average (i.e., accounting only for uncertainty) is 62 percent. The cumulative confidence of 10^{-4} risk for any particular individual (i.e., accounting for both uncertainty and variability) is only 58 percent.

The CCDs in Figure 4-1 are both based on the proposed 300 pCi/l standard. CCDs may also be plotted for different possible standards to compare the confidence that an acceptable risk will result from different alternative standards. Table 4-2 shows the median value of lifetime individual risk for a range of radon concentrations (Cw) from 100 to 800 pCi/l, calculated from Equation 4-2. The

GSD is the same for all values of Cw, since all of the uncertainty and variability are in the unit individual risk. Figure 4-2 shows the CCDs based on uncertainty for the different values of Cw. The higher the standard, the less confidence that a particular risk (here, 10^{-4}) will be achieved. Table 4-2 also shows the confidence associated with a risk of 10^{-4} for each concentration. As the standard drops from 800 to 100 pCi/l, the confidence increases from 41 percent to 83 percent.

Calculating Cost

Each different standard implies not only a different level of confidence, as seen in Figure 4-2, but a different cost. Cost can be calculated as follows:

$$TAC = UAC * HSHLDS \qquad \text{(Eqn. 4-4)}$$

where:

TAC = Total annual cost in $/year

UAC = Unit annual cost in $/year/household

HSHLDS = Number of households affected

The unit annual cost is a function of the method used to remove radon (granulated activated carbon (GAC) or aeration). In this range of target concentrations, it is not a function of the desired concentration. Reid (1985, citing Lowry, 1981) presents the capital and operating costs

per household of removing radon by GAC and aeration. Table 4-3 summarizes those costs. Unit annual cost can be calculated from these values by the following equation:

$$UAC = (CAP + 70 * OPER)/70 \qquad \text{(Eqn. 4-5)}$$

where:

CAP = Capital cost in $

OPER = Operating cost in $/year

70 = Lifetime in years

Table 4-3 also presents the unit annual cost for each option. For GAC, the annual cost is $27/household; for aeration, it is $73/household.

The number of households affected is a function of the standard. A household is affected if it has a radon concentration above the standard. The lower the standard, the greater the number of households affected, and therefore, the greater the cost. Crawford-Brown and Cothern (1987) present graphically the cumulative incidence of population for a range of radon concentrations. These represent the fraction of population with radon concentrations at or above any particular concentration. Table 4-4 presents the fraction of population exceeding each of the concentrations in the 100 to 800 pCi/l range. Table 4-4 also shows the total population exceeding each concentration, based on a total U.S. population of 250 million people. The last column in Table 4-4 shows the

number of households exceeding each concentration, assuming an average of 3 people per household. As the standard drops from 800 to 100 pCi/l, the number of households affected increases from 830,000 to 25,000,000.

Table 4-5 presents the total annual cost for each possible standard for GAC and aeration. The cumulative confidence of achieving a risk of 10^{-4} is also reproduced from Table 4-2. Plotting these against each other produces a cost versus confidence graph, shown in Figure 4-3, with confidence on the x-axis and total annual cost on the y-axis. Using this graph, a regulator can easily compare the costs of different levels of confidence. The costs for both treatments, but especially aeration, increase sharply after about 60 percent confidence, with costs exceeding one billion dollars for confidence over 70 percent for aeration. The proposed 300 pCi/l standard falls right at the 60 percent point, before costs begin to increase sharply.

Discussion

Reducing Uncertainty

The cumulative confidence of achieving 10^{-4} risk with a standard of 300 pCi/l is not very high, even considering only uncertainty (and not variability). EPA typically uses

a confidence level of 95 percent, whereas the confidence for 300 pCi/l is only 62 percent. One way to increase confidence is to lower the standard; however, as seen in Figure 4-3, this may be quite expensive. It is clearly not feasible to reduce the standard to a point where 95 percent confidence is achieved.

There is another way to increase confidence, and that is by reducing uncertainty about the parameters in the risk model. Uncertainty can be reduced by two kinds of research, depending on the nature of the parameter and the uncertainty about it. The first group of parameters requires more knowledge or fundamental research to reduce uncertainty. Such parameters include the lung deposition model, latency, and high to low dose extrapolation. The other group of parameters requires more accurate measurements to decrease uncertainty. These parameters include the water to air transfer factor, equilibrium factor, unattached fraction, and lung deposition.

The CCD can be used to identify the relative sensitivity of confidence to the uncertainty of each parameter by eliminating the parameter's GSD from the overall GSD and plotting a new CCD. Table 4-6 shows the uncertainty GSD of each parameter and the overall GSD if the uncertainty from that parameter were eliminated. The larger

the parameter GSD, the greater the effect eliminating it has on the overall GSD. Figure 4-4 shows CCDs for 300 pCi/l with a range of GSDs. The GSD doesn't affect the median, so the median is the same for each CCD. Instead, the GSD affects the slope of the CCD, with flatter curves providing less confidence of a particular risk being achieved.

Table 4-7 shows the cumulative confidence of achieving 10^{-4} risk for each of the CCDs shown in Figure 4-4. Even with the overall GSD reduced to 2 (which would require the elimination of uncertainty from extrapolation, with a GSD of 3, and any one of the parameters with a GSD of 2, such as latency) the confidence of achieving 10^{-4} is only 80 percent. The difficulty achieving high levels of confidence stems from the closeness of the median risk (5.7×10^{-5}) to the acceptable risk (10^{-4}). With a lower standard (and hence lower median risk) the effects of reducing uncertainty would be more striking. An analysis like this could be useful in targeting research where it has the most potential to reduce uncertainty and increase confidence.

Targeting Susceptible Populations

One reason regulating radon in drinking water is so costly is the large number of households with radon concentrations over the standard. An alternative approach

would be to try to target particularly susceptible households for radon removal. Suppose the risk model parameter median values are taken as given (i.e., no uncertainty about the "average" value). Some of the parameters still exhibit considerable variability, so that all homes with a radon concentration over 300 pCi/l may still result in a wide range of different risks. What if EPA could target houses with a tendency toward high water-to-air transfer factors, equilibrium factors, or unattached fractions? Or identify individuals who deposit radon preferentially in their lungs or have higher breathing rates? It is not feasible to identify the second set of individual characteristics (breathing rate, etc.), and it may not even be feasible to identify the first set of household characteristics, but such an approach might be feasible in other regulatory settings. EPA might also attempt to control building characteristics (such as ventilation rates) that contribute to extreme parameter values that increase risk above the median.

TABLE 4-1

RISK MODEL PARAMETERS

Parameter		Median	Units	GSD Unc.	GSD Var.	Source
Ca/Cw	Air/Water Transfer Factor	$1x10^{-4}$	pCi/l per pCi/l	2	4	
F	Equilibrium Factor	0.5	unitless	1.2	1.4	
CF1	Conversion Factor 1	0.01	WL/pCi/l	--	--	
CF2	Conversion Factor 2	18	WM/year	1.2	1.4	Unattached Fraction
				2	3	Lung Model
T	Exposure Duration	70	years	--	--	
RF	Risk Factor	$3x10^{-4}$	1/WLM/ person	2	2	Available Data
				3	5	Extrapolation
				2	3	Latency

Source: Crawford-Brown and Cothern (1987)

FIGURE 4-1

CUMULATIVE CONFIDENCE DISTRIBUTIONS FOR
UNCERTAINTY AND VARIABILITY
FOR Cw = 300 pCi/l

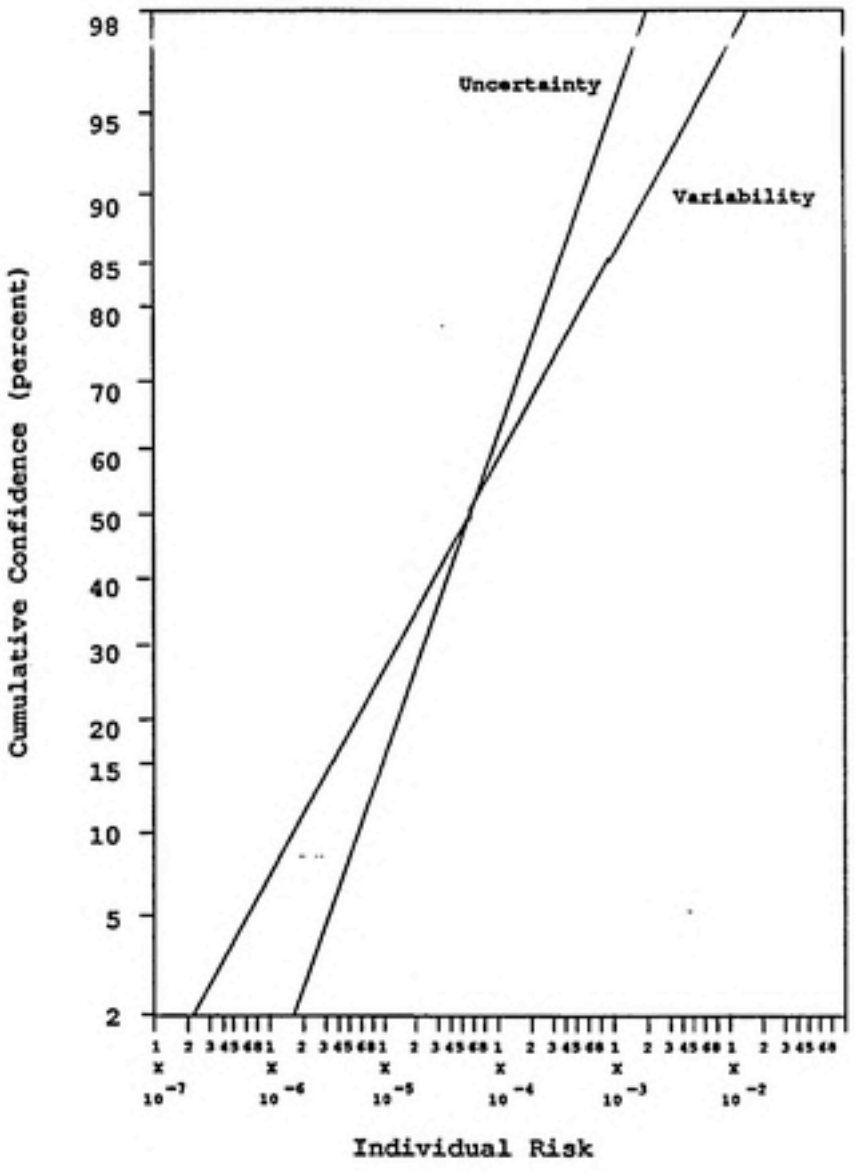

TABLE 4-2

MEDIAN RISK AND CUMULATIVE CONFIDENCE OF 10^{-4} RISK
FOR Cw = 100 to 800 pCi/l

Cw (pCi/l)	Median Lifetime Individual Risk (risk/person)	Cumulative Confidence (percent)
100	1.9×10^{-5}	83
200	3.8×10^{-5}	70
300	5.7×10^{-5}	62
500	9.5×10^{-5}	51
800	1.5×10^{-4}	41

FIGURE 4-2

CUMULATIVE CONFIDENCE DISTRIBUTIONS
FOR UNCERTAINTY ONLY
Cw = 100 to 800 pCi/l

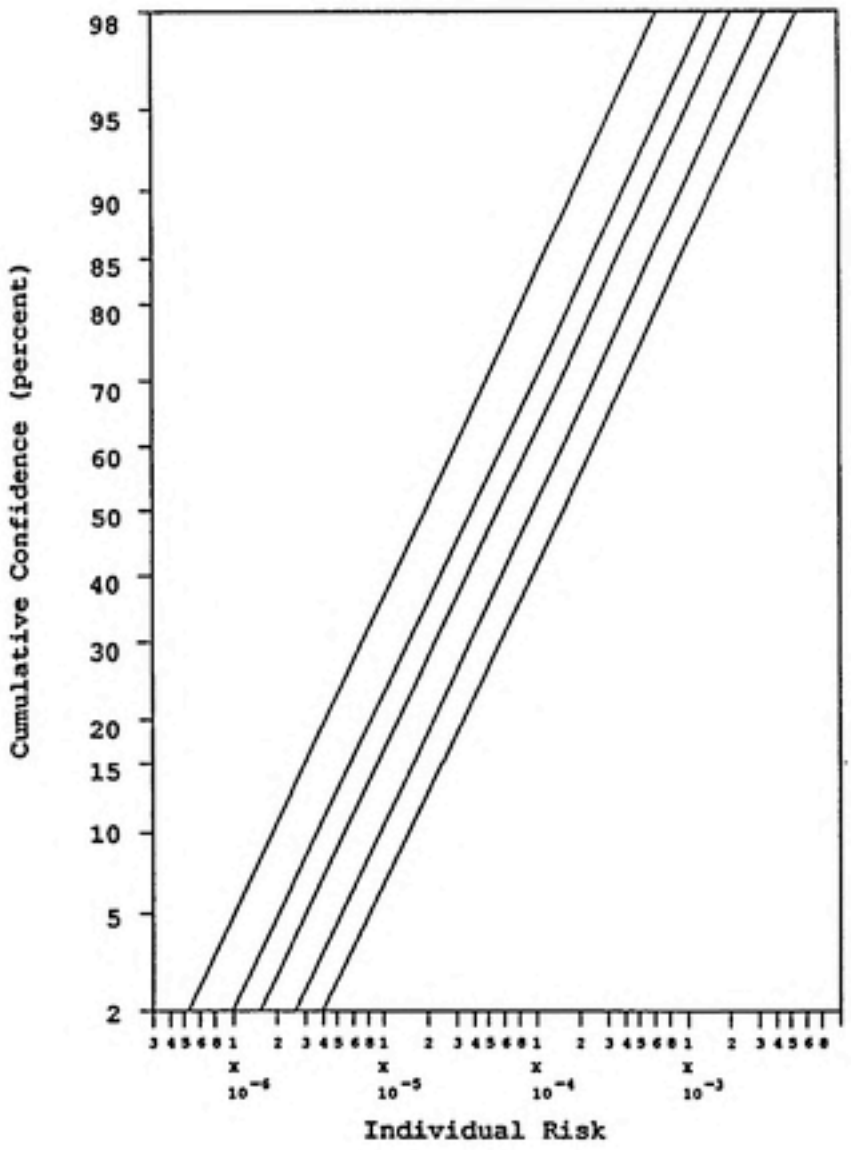

TABLE 4-3

CAPITAL AND OPERATING COST PER HOUSEHOLD
OF RADON REMOVAL

Treatment Option	Capital Cost ($/hshld)	Annual Operating Cost ($/yr/hshld)	Total Annual Cost* ($/yr/hshld)
GAC	500	20	27
Aeration	900	60	73

* Assumes lifespan of 70 years

Source: Reid (1985) citing Lowry (1981)

TABLE 4-4

AFFECTED HOUSEHOLDS FOR
Cw = 100 to 800 pCi/l

Cw (pCi/l)	Population Exceeding Cw (fraction)	Population Exceeding Cw (millions)	Households Exceeding Cw (millions)
100	0.30	75	25
200	0.15	38	13
300	0.07	18	5.8
500	0.04	10	3.3
800	0.01	2.5	0.83

Source: Crawford-Brown and Cothern (1987)

TABLE 4-5

ANNUAL COST AND CUMULATIVE CONFIDENCE OF 10^{-4} RISK
FOR Cw = 100 to 800 pCi/l

Cw (pCi/l)	Annual Cost		Cumulative Confidence (percent)
	GAC (million $)	Aeration (million $)	
100	680	1,800	83
200	340	910	70
300	160	430	62
500	90	240	51
800	23	61	41

FIGURE 4-3

ANNUAL COST VS. CUMULATIVE CONFIDENCE
OF 10^{-4} RISK

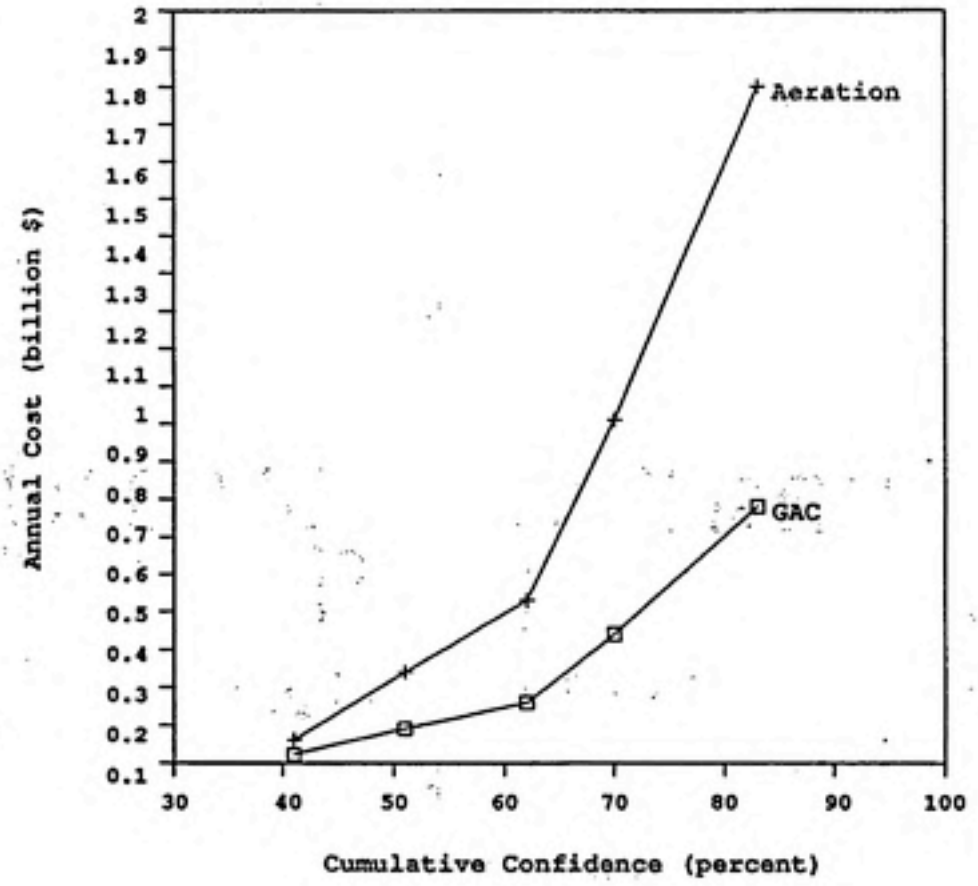

TABLE 4-6

EFFECT ON OVERALL GSD OF ELIMINATING
INDIVIDUAL UNCERTAINTY SOURCES

Parameter		Source	Parameter Unc. GSD	Overall GSD if omitted
Base Case (no parameter GSDs omitted)				6
Ca/Cw	Air/Water Transfer Factor		2	5
F	Equilibrium Factor		1.2	6
CF2	Conversion Factor 2	Unattached Fraction	1.2	6
		Lung Model	2	5
RF	Risk Factor	Available Data	2	5
		Extrapolation	3	4
		Latency	2	5

FIGURE 4-4

CUMULATIVE CONFIDENCE DISTRIBUTIONS FOR
A RANGE OF GSD VALUES
Cw = 300 pCi/l

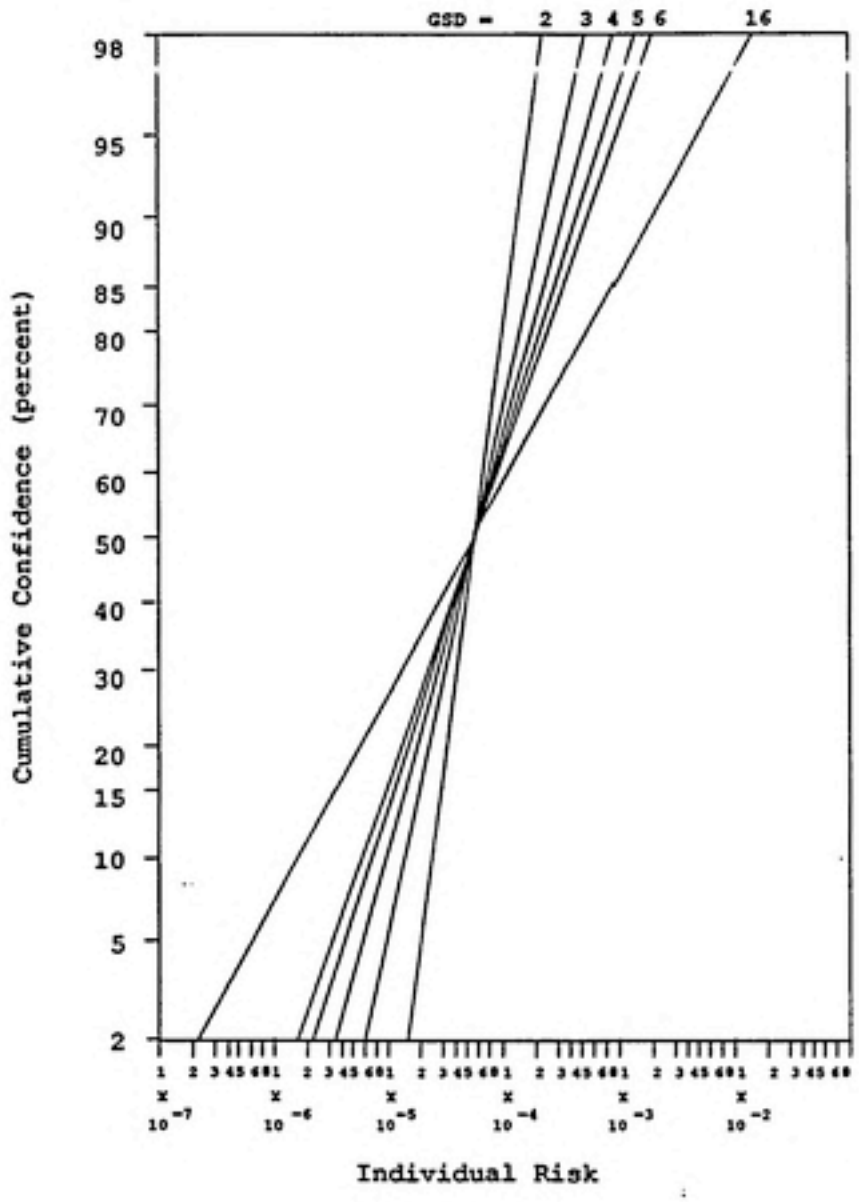

TABLE 4-7

CUMULATIVE CONFIDENCE OF 10^{-4} RISK
FOR A RANGE OF GSD VALUES
Cw = 300 pCi/l

GSD	Cumulative Confidence (percent)	Source of Uncertainty Omitted*
16	58	None (from Variability)
6	62	None Omit Equilibrium Factor Omit Unattached Fraction (CF2)
5	64	Omit Lung Model (CF2) Omit Air/Water Transfer Omit Available Data (RF) Omit Latency (RF)
4	66	Omit Extrapolation (RF)
3	69	
2	80	Omit Extrapolation (RF) and any source with GSD = 2

* From overall uncertainty GSD, except for GSD = 16, which represents overall variability GSD.

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