BUREAU OF WASTE SITE CLEANUP

PROGRAM REDESIGN

CONSERVATISM & UNCERTAINTY

IN RISK ASSESSMENT

in the Context of the Massachusetts Contingency Plan

PROPOSAL & DISCUSSION DOCUMENT

MA DEP BWSC
MCP REWRITE WORKGROUP
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TABLE OF CONTENTS

EXECUTIVE SUMMARY ii

1.0 CONSERVATISM AND UNCERTAINTY 1

1.1 Common Concerns About Risk Assessment 2

1.2 Specific Issues Related to Conservatism and Uncertainty in Risk Assessment 2

1.3 Addressing Conservatism in Risk Assessment 6

2.0 EXPOSURE ASSUMPTION & TOXICITY VALUES 12

2.1 An Overview 12

2.2 Other State and Federal Programs 15

2.3 Descriptions of Exposure Factors 18

2.4 Toxicological Factors 23

2.5 Conclusion 30

3.0 REFERENCES 31

EXECUTIVE SUMMARY

The Massachusetts Department of Environmental Protection makes use of human health risk assessment as an evaluation tool in many of its regulatory functions. The potential risk of harm to human health is a consideration in state-wide decisions, such as when setting allowable levels of contaminants in drinking water, as well as in very specific decision, such as the siting of a hazardous waste facility. The Department's Bureau of Waste Site Cleanup relies upon site-specific risk assessment as one factor which may determine the need for remediation and ultimately *how clean is clean?*

The Department has undertaken the redesign of its Waste Site Cleanup program in order to streamline the process for cleaning up hazardous waste site in the Commonwealth to clean up *more sites more quickly*. As part of the program redesign, the Bureau has asked the Department's Office of Research and Standards to participate in a review all aspects of the risk assessment methodology used in the program, and recommend changes which would both streamline the site assessment and remediation process while maintaining the health-protectiveness of M.G.L. Chapter 21E.

This paper reviews some of the major comments received concerning the MCP risk assessment process, focussing on concerns expressed by DEP staff and the regulated community that it is unnecessarily over-conservative. Specific factors are briefly summarized and compared to analogous assumptions used in the federal Superfund program and the recently promulgated New Jersey cleanup requirements.

> The MCP Risk Assessment/Risk Management Workgroup recommends that the Office of Research and Standards undertake a project to review the recommended default assumptions routinely used in the WSC risk assessments and evaluate the level of conservativeness inherent in those values. The result of such a review would be an options paper which would characterize the uncertainty to the extent possible and recommend default values (or sets of such assumptions) for use in the Waste Site Cleanup program.

This paper is the second resulting from the Workgroup's discussions on risk assessment and risk management in the Massachusetts Contingency Plan. The first paper, *Risk Assessment and Risk Management Proposal and Discussion Document* (herein referred to as the *RA/RM Proposal Document*) covers broader risk assessment issues, such as the risk assessment methods used in the Massachusetts Contingency Plan, the risk management criteria, and the implications of the Bureau of Waste Site Cleanup's use of risk assessment for other MA DEP programs.

> ***A foolish consistency is the hobgoblin of little minds, adored by little statesmen and philosophers and divines.***
>
> -- Ralph Waldo Emerson, Essays: Self-Reliance

The Risk Assessment/Risk Management Workgroup of the MCP Rewrite Committee would like to acknowledge the efforts of Michael J. Murphy (formerly of the DEP's Office of Research and Standards) in laying the groundwork for this paper.

1.0 CONSERVATISM AND UNCERTAINTY

A discussion of uncertainty in risk assessment must begin with the basic understanding that a risk assessment is simply a model, not unlike other environmental models used to predict groundwater movement, leachability of chemicals from soil, or ambient air concentrations from a proposed municipal solid waste incinerator. Just like these models, the results of a risk assessment are very sensitive to the input parameters used, and the risk estimates produced can only be interpreted with an understanding of how or why these parameters are chosen. Risk assessment is, perhaps, somewhat more complex because it attempts to combine environmental fate models, toxicological models and exposure models to yield risk estimates of human health impacts. The risks associated with human exposures to environmental contamination are virtually impossible to measure directly as experience with the use of epidemiology has demonstrated. Risk assessment as a science shares all of the strengths and weaknesses of each of the disciplines from which it draws information.

Conservatism is the handmaiden of uncertainty. To generalize, uncertainty about the Department's ability to fulfill its mandate to protect the public health and the environment invariably leads to conservative positions. The more certain we are about a specific assumption, model or decision the less conservatism is needed to insure that the results will be adequately protective. This relationship must be considered in the current proposals to redesign the Waste Site Cleanup program which will transfer much of the decision making process to the private sector. The rewritten MCP and accompanying guidance must ensure that consistency and protectiveness in a program which will operate with little or no oversight. The risk assessment process is just one area of the program redesign which must where the Department must identify the correct balance of uncertainty and conservatism.

This section will review the ongoing debate, both within Massachusetts and nationally, on the risk assessment process, attempt to focus on some of the outstanding questions and provide a framework for how the Office of Research and Standards, the Bureau of Waste Site Cleanup, and ultimately the Department as a whole can begin to address these issues. The major input parameters of risk assessment are discussed individually in detail in Section 2.0 of this document.

1.1 COMMON CONCERNS ABOUT RISK ASSESSMENT

Critiques of the use of risk assessment are not limited to the Waste Site Cleanup program in Massachusetts. The comments heard here are repeated nationally concerning the federal Superfund program and other regulatory processes in which risk assessment has a role (OSHA, FDA, RCRA, to name a few). The criticism of quantitative risk assessment addresses *all* aspects of the process, but the list would include such statements as:

- The risk assessments are "*not realistic*".
- The prescribed methodology is dogmatic and its users (the DEP, for example) are inflexible.
- The exposure assumptions chosen are too conservative.
- The multiplicative effect of assumptions chosen for their protectiveness yields a condition of "*compounding conservativeness*".
- "The numbers are too low."

1.2 SPECIFIC ISSUES RELATED TO CONSERVATISM AND UNCERTAINTY IN RISK ASSESSMENT

Uncertainty is the primary source of **conservatism** in the risk assessment process, although the relationship between the two is not always direct. In the extreme and at the level of individual assumptions, it is evident that decisions should be made cautiously (or conservatively) when little or no information is available on which to base them. But are there other sources of conservatism? What is the source of conservatism in those instances where the range or variability of a factor *is* known? Is there a need to consistently choose the most protective assumptions for each factor? How conservative is conservative enough?

The controversies which surround risk assessment, and particularly the impression that it is "too conservative" and "unworkable" involve not only the choice of the specific parameters used in the assessment and the overall model, but also *how* this information is used in a regulatory framework.

This section discusses the sources of conservatism (or perceived conservatism) in the risk analysis process in order to begin to answer some of these questions.

1.2.1 Perceived Conservatism in Risk Management and the Risk Assessment Methods

Risk analysis is a process which involves both *risk assessment* and *risk management.* In order to address some of the concerns about "*conservatism in risk assessment*" we must first examine which of these issues are truly about risk *assessment*, and identify those which may actually be concerned with *risk management.*

The risk management approach mandated by M.G.L. Chapter 21E is a *risk-only* approach which requires that a permanent solution be achieved at all sites through the elimination of "significant risk". This risk management philosophy is described in Section 2.0 of the *RA/RM Proposal Document.* Some of the concerns expressed about the "inflexibility" of the risk assessment process is a direct result of the risk management approach of c.21E. It is often, in fact, the ***use*** of the risk assessment results which is questioned, and not the numbers *per se.* While mitigating factors such as cost and technical feasibility are given consideration in the MCP, they play a secondary role to the characterization of risk and the requirement to eliminate significant risk to achieve a permanent solution. As the risk management philosophy laid out in the statute is not expected to change, the perceived inflexibility of the MCP risk assessment process in this regard must be acknowledged as a consequence of the statute mandated risk-only approach.

In one sense, the risk-only management approach of the MCP and the generally conservative nature of risk assessment has created a situation in which the remediation of c.21E disposal sites is driven primarily by the requirement to eliminate any significant risk of harm to *human health.* In theory, the remediation of disposal sites may be required based upon significant risk of harm to safety, public welfare and the environment, as well as to human health. As there is currently no adequate guidance on the characterization of harm to these other factors, MA DEP site managers have come to rely upon the conservative human health risk assessments as a catch-all "*safety net*". Refinement of the risk assessment process (minimization of uncertainty) will inevitably lead to situations where there is no significant risk of harm to human health, but where the site manager's professional judgement would conclude that remediation is indicated. Without a developed environmental risk *characterization process or a requirement to remediate to background levels, there* may be no legal means to such require remediations.

Section 3.0 of the *RA/RM Proposal Document* described the current MCP risk characterization methods and identified a number of disadvantages of the current MCP approach. Some of these disadvantages have been communicated to the DEP as "*risk assessment*" problems. These disadvantages include the uncertainty in the risk characterization method which is applicable to a given site and the perceived

costs associated with conducting "full-blown" risk assessments at a disposal site. Recommendations have been made to modify the risk characterization methodology required under the MCP in order to address some of the concerns raised. In addition, the Department is pursuing the development of guidance intended to streamline the risk assessment process, including the development of the *Risk Assessment ShortForms*.

Finally, the *risk management criteria* employed in the MCP have contributed to the overall conservatism of the risk assessment process. The *RA/RM Proposal Document*, Section 4.0 summarized the issues in this area and sought comments and suggestions for risk management criteria to be incorporated in a revised MCP.

1.2.2 Risk Assessment Policy

During the course of performing a risk assessment, the assessor is required to make a series of decisions related to the toxicity of the contaminants and potential exposures to the receptors of concern. Some of these decisions are relatively easy, and consist primarily of choosing among the available data for the information which most closely corresponds to the situation under study. Frequently, however, the risk assessor is attempting to model an exposure for which little or no information is available, and (s)he must rely upon professional judgement and historical precedent to complete the evaluation.

One option, of course, is to not attempt to quantify the potential human health risks when information is not complete. Certainly a decision making process can be developed for environmental programs (such as the Waste Site Cleanup program) based primarily upon qualitative information, although such a process could not avoid similar controversy about conservatism. Alternatively the risk assessor can continue with the quantitative assessment and find a means to overcome the data gaps. As with most sciences, standard protocols have developed to address such situations, and it is not necessary to reinvent the methodology on each project. Such standard protocols can be grouped under the term ***risk assessment policy.***

The National Academy of Sciences (NRC, 1983) makes a point to clearly distinguish these risk assessment policy "judgements and choices from the broader social and economic policy issues that are inherent in risk management decisions." The NAS also states that "some controversy surrounding regulatory actions has resulted from a blurring of the distinction between risk assessment policy and risk management policy." In theory, risk assessment policy is based upon scientific principles alone.

Risk assessment policy is used to make decisions about risk to human health when the evidence is not conclusive or nonexistent. Often such policies are reached

through a consensus within the scientific community and are rarely cause for dispute. An example of such risk assessment policy is the assumption that demonstration of carcinogenicity in rodents infers that a substance may be carcinogenic in humans. Such risk assessment policy statements are usually included in risk assessment guidance such as those published by the U.S. EPA (1989a, 1989b, 1991a, 1991b, 1992) or the MA DEP (1992, MA DEQE 1989). These guidelines are based on both scientific judgements and policy choices, and while these risk assessment policy decisions underlie much of the risk assessments performed under the MCP, they are commonly not listed or discussed. These policy decisions are the (often) unspoken ground rules by which risk assessments are performed.

More problematic are those risk assessment policies which provide guidance on specific numerical values to insert in the quantitative risk assessment. Such policies are developed to be protective of public health, provide consistency across risk assessments and to insure that the risk estimates are comparable for comparable situations evaluated. The quality of information on which to base these policies varies widely. One example of such a policy developed in the absence of solid data is the U.S. EPA Office of Solid Waste and Emergency Response Directive 9850.4 which specifies that risk assessors shall use a combined soil and dust ingestion rate of 200 mg/day for children ages 1 through 6. This recommendation is made given the need to evaluate a child's exposure to soil and given the relative lack of scientific data in this area. Values for other factors are often specified to provide consistency when there is good information available: the identification by the U.S. EPA of 70 kg as the adult bodyweight insures that risks to adult receptors are comparable.

The two examples mentioned above demonstrate that the default values which are often at the center of the conservatism debate can be grouped into two categories: **those assumptions made in the absence of knowledge and those made given known variability.** How we address the inherent conservativeness of risk assessment policies depends upon how much we know about each factor and how it varies. A distinction is thus made between the conservatism associated with a factor consciously chosen from a known range of potential values and that associated with a factor chosen to bound an unknown distribution.

1.3 ADDRESSING CONSERVATISM IN RISK ASSESSMENT

In order to address the question of conservatism in risk assessment, we must be more specific about the problem we are attempting to solve. As an environmental regulatory agency charged with eliminating significant risk of harm to health, safety, public welfare and the environment at c.21E disposal sites, we have established risk management criteria which tell us how protective we need be to meet our statutory goals. How certain must we be that the results achieve these goals?

1.3.1 *Defining Our Goals*

Let's begin to answer these questions by reviewing the intent of the statute and describing who/what it is that we are trying to protect. In this manner we may be able to articulate how conservative we want to be, then (and only then) we may be able to assess our key assumptions to see if we are close to our goal. The results may be that we are more or less conservative than is necessary given the objectives of the program.

1.3.1.1 Statutory/Regulatory Goals

In general, M.G.L. Chapter 21E requires that a permanent solution requires that a level of control be achieved such that no oil or hazardous material (OHM) presents a significant risk of harm to human health, safety, public welfare or the environment during any foreseeable period of time. Unfortunately each piece of this requirement (what is *significant*?, what is *foreseeable*?) is ambiguous and left to be further developed in the regulations (the MCP). It is clear from the language, however, that the intent is *not* to eliminate *all* risk, but to reduce it to a level which would not be considered significant. Thus we have a starting point: some level of risk is acceptable because it is considered to be insignificant. To take this one step further, is it reasonable to assume that a statute which does not require the elimination of all risk would require absolute certainty that the risk to any hypothetical receptor would be insignificant? Use of the term "*foreseeable*" (in this instance related to time) may also indicate that some measure of reasonableness is appropriate (a "reality check") when developing the exposure scenarios used to estimate risk.

This reasonableness concept appears in the current MCP in the discussion of exposure points and exposure point concentrations (310 CMR 40.545(3)(d)). The language "*who it is reasonable to foresee are likely to be exposed...*" certainly demonstrates that the regulations stop short of requiring the evaluation of "any exposure" or even "any likely exposure". 310 CMR

40.545(3)(g)3.b uses the term "*reasonably foreseeable exposure*" in the discussion of total site risks, again indicating that it is not the intention of the regulations to protect against any eventuality.

Thus the statute and the current regulations would indicate that a sufficient degree of conservatism should be incorporated into the exposure and risk estimates in order to be protective of public health, but that the goal of the exposure model should be the quantitative description of some reasonable (i.e., not absolute worst-case) exposure.

1.3.1.2 Current Massachusetts Risk Assessment Guidance

Chapter 21E and the MCP provide a framework for the assessment and remediation of disposal sites, but it is left up to the body of policies and guidance to provide the details of the process. The *Guidance for Disposal Site Risk Characterization and Related Phase II Activities - In Support of the Massachusetts Contingency Plan* (MA DEP, 1989) provides the guidance for conducting risk assessments under the MCP.

The Guidance Document does not explicitly describe the level of conservativeness which should be the goal of the exposure assessment, although there are several indications that a worst-case assessment is not required. First, Appendix B (Exposure Assumptions) lists suggested default exposure assumptions to be used "*in the absence of site-specific, or otherwise justifiable exposure information*". It is noted that these default assumptions are intended "*to provide realistic yet adequately conservative dose calculations*". Second, in Section IV.D. (Identification of Exposure Point Concentrations (EPC)), the guidance steers away from using worst-case concentrations and suggests methodologies which would provide a mean, or average EPC.

In the development of MA DEP risk assessment guidance, informal discussions have described the exposure assessment as being tailored to "*the average exposure to the maximally exposed receptor*". This has been interpreted to mean that the factors related to the number of exposure pathways and the duration and frequency of exposure would be upper-bound estimates, while those factors which describe the exposure point concentration and the hypothetical receptor (body weight, ingestion rates, etc.) would be assigned mid-range values.

A more recent document, the *DRAFT Background Documentation for the DRAFT Residential ShortForm* (MA DEP, 1992) attempts to better characterize the exposure assessment. The stated goal of the *ShortForm*

assessment is to "*produce realistic risk estimates which are health protective (they are not underestimates of the likely 'true risk')*". To this end, the *ShortForm* risk assessment uses a combination of mid-range or mean values (exposure point concentrations, body weights, some intake rates) and "upper bound" values (toxicity information, some exposure parameters). Comments received to date from the regulated community on this work indicates that the resulting assessment continues to be perceived as overly conservative.

As we have thus seen, the statute, regulations and guidance governing the Waste Site Cleanup program indicate that the aim of the risk assessment should be a combination of parameters which yield a realistic, upper-bound risk estimate which could be considered protective of the public health, but *not* taken to the extreme of a so-called "*worst-case*" analysis. This goal has rarely been explicitly stated, however, and it is clear from the experiences of implementing the MCP that more detailed guidance is needed in this area. Not so coincidentally, the same issues have arisen on the national level, and the U.S. EPA has already taken steps to address them in recent guidance. The following subsection reviews this information.

1.3.1.3 The Federal Superfund Program

Recent U.S. EPA guidance on risk assessment has focused on estimating the "*reasonable maximum exposure*", or RME. The goal of the RME is "*to combine upper-bound and mid-range exposure factors ...so that the result represents an exposure scenario that is both protective and reasonable; not the worst possible case*" (US EPA, 1991). The RME assessment is designed to replace the EPA practice of calculating two risk estimates (an "average" case and a "maximum" case) with an estimate which is a hybrid of the two.

The RME is defined (US EPA, 1989a) as "*the highest exposure that is reasonably expected to occur at a site*", and the guidance indicates that the choice exposure assumptions to achieve the RME may also depend upon the number of exposure pathways present at the site. This indicates that the EPA is sensitive to the issue of "*compounding conservativeness*" in the risk assessment process. As the number and type of exposures experienced by a receptor increase, the individual assumptions must be examined to insure that the cumulative (overall) effect is not unreasonable. This is a basis for recommending different exposure assumptions for chemical- and medium-specific exposures vs. a multi-media, mixture exposure.

The reality of implementing a program is often different from the guidance, however. The EPA is still struggling to define *which* parameters should be upper-bound and which should be mid-range values, and how to choose these

values. Region I continues to follow its own risk assessment guidance (US EPA, 1989b) which calls for an "average case" and a "reasonable worst case" exposure scenario. Both scenarios are based upon "reasonably conservative exposure assumptions", with the difference that average concentrations are used in the former scenario and maximum concentrations in the latter. [Note that the MA DEP generally uses the EPA's "*average case*" risk estimates to evaluate MCP requirements at federal Superfund sites.]

In general guidance (agency-wide, not specific to the Superfund program) the U.S. EPA has outlined a more detailed approach for describing risk assessment results in EPA reports, presentations and decision packages (US EPA, 1992). Essentially the guidance attempts to move away from the single point-estimate of risk to present EPA decision makers with more complete information about the range of potential risks accompanied by sufficient documentation to place the risk estimates in context. Within the Superfund program this guidance would indicate a trend towards better description of the exposure scenario and fuller documentation of the uncertainties and conservatism inherent in the risk estimates.

In summary, the U.S. EPA has taken some steps to focus on a reasonable maximum exposure within its Superfund program, and to better describe the exposure scenarios used in all EPA risk assessments. The description of the RME is similar to what has been discussed as the goal of the MCP risk assessment process, and some of the available EPA guidance adapted for use by the Department. Comments received on the *Residential ShortForm* have also stated this.

1.3.1.4 Options for Addressing Conservatism in Risk Assessment

At the present time there are three basic options which the Department is considering:

i. Adopt the U.S. EPA standard assumptions and update them as further guidance is developed by the federal government.

   This option is attractive in that the MA DEP resources required are minimal, and the issues which currently confront the DEP are similar to those faced by the U.S. EPA. There are problems with this option, however. First, as the risk management requirements and the risk characterization methods of the two programs differ, it is likely that the acceptable level of conservatism would also be different. Second, there are currently differences *within* the EPA on risk assessment

methodology, particularly Region-to-Region and Headquarters-to-Region, which the DEP would have to reconcile in the process of adopting EPA default values (resulting in time and resource commitments). Third, the U.S. EPA maintains strict oversight of all Superfund risk assessment activities, and allows more flexibility (ambiguity) in risk management than is possible under the proposed state program, under which the investigation and remediation of most sites will proceed with no oversight.

ii. Review and evaluate the MA DEP default assumptions and recommend values which would be protective of public health yet not overly conservative in nature.

This option would provide guidance which is tailored to the requirements of the Waste Site Cleanup program. In addition, information learned in the process could be applied throughout the Department as considered appropriate. The level of effort required for such a review would depend upon the scope of the project: it could be limited to review of the existing literature or it could be broadened to include original research funded by the Department.

iii. Maintain the current level assumptions and level of conservatism.

This option minimizes the immediate level of effort required, although controversy over the appropriateness of the default assumptions would continue to require DEP staff response in each of the program redesign projects which involve risk assessment.

1.3.1.5 Recommendation

The workgroup recommends that the Bureau of Waste Site Cleanup and the Office of Research and Standards undertake a project to review the standard exposure assumptions and other risk assessment factors used in the MCP risk assessment process. This project would define the appropriate level of conservatism and recommend values for each of the factors considered. The project should make use of information on uncertainty and conservatism available in the literature and through the U.S. EPA.

The workgroup seeks comments on this recommendation and on the issues raised in this section.

1.3.2 Approaches to the Conservatism Project

The above discussion has led to the conclusion that the first step in addressing conservatism in the risk assessment process is to define "*How conservative is conservative enough*?". Within the context of the Waste Site Cleanup program, that question must be answered in recognition of the mandate of c.21E and the requirements of the Massachusetts Contingency Plan and the goals of the redesigned program. An approach must be identified which is compatible with the decision making process contained in the MCP and the program's reliance upon point estimates of risk, either in the form of a chemical-specific standard or a risk limit.

A further constraint on the available options derives from the nature of the risk estimate. We noted earlier that risk assessment combines a number of different models: environmental fate & transport, toxicological, and exposure assessment. Each section introduces different types of uncertainty and conservatism into the final risk estimates, and the ability of risk assessors to modify or manipulate these models vary. One is best able to target a specific level of conservatism in those parameters which may vary on a site-by-site basis, such as the choice of receptor or the calculation of exposure point concentrations. The toxicological factors (described in Section 2.0) developed by the U.S. EPA and adopted by the MA DEP incorporate a number of conservative assumptions which can not be manipulated by the risk assessor.

Thus this project should develop a process by which fate & transport model assumptions and exposure assumptions are identified which will, in combination with the adopted EPA toxicity factors, yield a risk estimate protective of public health with an adequate margin of safety (conservatism). The answer to the question "*How conservative is conservative enough?*" defines the adequate margin of safety. The individual factors which must be considered are discussed in Section 2.0 of this document.

2.0 EXPOSURE ASSUMPTIONS & TOXICOLOGICAL FACTORS

The MCP Rewrite Workgroup recommends that the Department review its default risk assessment assumptions and recommended values to minimize unnecessary conservatism while maintaining a level of public health protection consistent with the requirements of the Massachusetts Contingency Plan and the risk management philosophy of M.G.L. Chapter 21E. This section will briefly discuss the factors which would be included in such a review and provide some perspective on the scope of the proposed project. One fact which should be come clear is that, while methods for the quantitative modelling of variability have recently become available (e.g., Monte Carlo analysis), the data needed for such analyses is currently available for a small number of factors. The goal of this project will be to incorporate as much of these new approaches as is warranted given the existing data and to continue monitoring the literature as this science reaches maturity.

2.1 AN OVERVIEW

Quantification of the potential risk of harm to human health brings together all the pieces of the risk assessment: hazard identification, dose-response assessment and the exposure assessment. These factors are merged arithmetically to yield the risk estimate. Risk varies directly as a function of the concentration of the OHM, the exposure experienced by the receptor and the toxic qualities of the OHM:

RISK α CONCENTRATION, EXPOSURE, DOSE-RESPONSE VALUE

Obviously, uncertainty and/or variability inherent in the analytical data, the exposure assessment or the dose-response value will contribute to uncertainty or variability in the final risk estimate. The following two sections briefly examine the issues which arise concerning each of these factors.

2.1.1 Analytical Data

The analytical data collected at a c.21E disposal site are used to generate the Exposure Point Concentrations (EPCs). EPCs are calculated to be representative of the actual or potential exposures to the receptor, and thus may incorporate a subset of all the samples taken. (Environmental samples are taken for many purposes, such as defining the extent of contamination, evaluating human health risks or establishing background conditions.) There are many potential sources of variability and uncertainty in analytical data generated at disposal sites, including real variability of

environmental concentrations, the heterogeneity of the sample, the introduction of bias (either intentionally or unintentionally) through the choice of sampling location, the choice of analytical method, chemical or matrix interferences and generic technical problems. Some of these can be controlled to some extent, but overall the uncertainty of the analytical results must be acknowledged and considered in discussions of the conservative nature of risk assessments. This is particularly true as the number of samples taken is often held to the bare minimum as a cost control measure: the surest way to reduce uncertainty in this area is to take an adequate number of samples.

2.1.2 Exposure Assumptions

The exposure assessment concerns itself with identification of receptors, exposure *pathways, exposure points, exposure routes, and the frequency, duration and* magnitude of exposures. It is often claimed that the strength of risk assessment is the ability to consider site-specific information in the decision-making process. The reality is that the use of site-specific information is limited by the ability/desire to collect such information at every c.21E site and the (unknown) future exposures which must be addressed. The use of default exposure assumptions in risk assessment has been identified by the regulated community as a shortcoming of the process.

The scope of the exposure assessment is *primarily* determined by the type of site, the activities which take place there and the presence of oil or hazardous material in an environmental medium. Such factors are **site-specific**, identified as part of the Phase II investigation. For example, the presence of OHM in an aquifer used as a source of drinking water would indicate that the potential exposure through the use of that aquifer must be evaluated. Conversely, if the Phase II investigation reveals no contamination in that aquifer, then that site-specific information can be used to conclude that the drinking water should not be evaluated. Occasionally risk assessment or risk management policy will provide guidance on how to address these factors (e.g., the *Foreseeable Future Use Policy*).

The assumptions which quantify the frequency, duration and magnitude of exposure are nominally site-specific, although standard default assumptions are commonly used in the risk calculations. The drinking water example demonstrates why the use of default assumptions is so common: If one family were using the contaminated aquifer discovered at a disposal site, it would be theoretically possible to monitor each individual's use of the water over a period of time to establish their actual exposure, subject to some experimental uncertainty. Such monitoring is less practical if ten families were to use the aquifer as their source of drinking water, and it is impossible if the groundwater were used by a public water supply system of a reasonable size.

In addition, the monitoring of the potential *future use* of that drinking water is impossible. Thus the use of standard drinking water intakes is the norm rather than the exception at c.21E disposal sites.

Table 2-1 briefly lists some of the more common factors which are considered in an exposure assessment and describes how these factors are related and gives an indication of how "site-specific" the factor may be.

Section 2.3 will discuss these factors and others in more detail.

Table 2-1

EXPOSURE PARAMETERS	
PARAMETER	**DESCRIPTION**
Use of Site & Surrounding Area	Site-specific, assisted by policy.
Potential Receptor	Site-specific, dependent on use.
Exposure Pathway(s)	Site-specific, dependent on contaminated media, receptors, & use.
Frequency of Exposure	Site-specific, dependent on use of site & receptor.
Duration of Exposure	Site-specific, dependent on use of site & receptor.
Exposure Point Concentration	Site-specific.
Soil Ingestion Rate	Default assumption dependent on receptor.
Drinking Water Intake Rate	Default assumption, dependent on receptor.
Inhalation Rate	Default assumption, dependent on receptor.
Body Weight	Default assumption, dependent on receptor.

2.1.3 Toxicological Factors and Assumptions

Dose-response values also contribute to uncertainty in the risk estimates. The Massachusetts DEP generally adopts the toxicological values derived and published by the U.S. Environmental Protection Agency. Only under certain limited

circumstances (usually when no EPA value is available, and the alternative is to *not evaluate* that chemical) does the Office of Research and Standards develop its own dose-response values. [In the *Residential ShortForm*, 22% (42/187) of the toxicity values used were developed by the DEP ORS.] In the cases where the DEP derives a dose-response value, the methodology used is generally consistent with the published EPA guidance.

The standardization of the dose-response value development does not, however, eliminate the uncertainty inherent in the actual value. Many assumptions are incorporated in the methodology, and these are often not described in the c.21E risk assessment work. The uncertainty derives from the extrapolation of the results from high-dose animal studies to low-dose human environmental exposures, the adoption of a particular model of carcinogenicity (the "one-hit" model), as well as the limited experimental data available to the toxicologists developing these values. While standardization does not reduce uncertainty, it does increase consistency from assessment to assessment, which is one of the Department's goals.

Section 2.6 will discuss each of the dose-response values in more detail.

2.2 OTHER STATE AND FEDERAL PROGRAMS

Other programs, such as the U.S. EPA Superfund program and other states, use an identical array of factors to estimate risk, although the recommended numerical values may differ depending upon the specific goals of the program and the professional judgement of the program's risk assessors.

Tables 2-2, 2-3,2-4 and 2-5 present a simple comparison of point estimates used in the MA DEP's *Residential ShortForm* (an optional tool for use in the Waste Site Cleanup program) to the equivalent factors recommended in the federal guidance for risk assessment (US EPA, 1989) and those used in the development of the New Jersey cleanup concentrations. Note that the *Residential ShortForm* by nature ***must*** specify values for each of these factors, while the EPA or New Jersey may not address some factors specifically.

The comparisons are presented to provide a general knowledge of the relative level of conservatism which is currently incorporated in one DEP project. The assumptions contained in these tables should not be assumed to be the *only* acceptable values for these factors.

Table 2-2

SOIL INGESTION EXPOSURE FACTORS

Factor	MA DEP ShortForm	EPA Washington Superfund	NJ DEPE Cleanup Standards
Intake Rate (Child) On Day Exposed	100 mg/day	200 mg/day	200 mg/day
Intake Rate (Adult) On Day Exposed	50 mg/day	100 mg/day	100 mg/day
Exposure Frequency Outdoor & Indoor Soils	153 days/year	350 days/year	365 days/year
Exposure Frequency Indoor Soil/dust (Child)	212 days/year	Not Considered	Not Considered

Table 2-3

RESIDENTIAL EXPOSURES

Factor	MA DEP[1] ShortForm	EPA Washington Superfund	NJ DEPE Cleanup Standards
Bodyweight:			
Infant (1-2 yr)	10.8 kg	Not generally evaluated	Not evaluated
Child (1-6 yr)	16.8 kg	15 kg	16 kg
Adult	62 kg	70 kg	70 kg
Exposure Duration	75 years	30 years	30 years

[1] MA DEP Bodyweight is for a female receptor, the other programs do not specify sex.

Table 2-4

INDOOR AIR EXPOSURES

Factor	MA DEP ShortForm	EPA Washington Superfund	NJ DEPE Cleanup Standards
Time Exposed (per day)			
Subchronic Exposure:	24 hr/day	Not Specifically Stated	Not Addressed
Chronic Exposure:	16 hr/day	Not Specifically Stated	Not Addressed
Lifetime Exposure:	16 hr/day	Not Specifically Stated	Not Addressed
Frequency of Exposure:	365 days/yr	350 days/year	Not Addressed
Inhalation Rate:	Not Used (Based on Reference Concentrations & Unit Risk)	20 m^3/day (total) 15 m^3/day (indoors)	Not Addressed

Table 2-5

DRINKING WATER EXPOSURES

Factor	MA DEP ShortForm	EPA Washington Superfund	NJ DEPE Cleanup Standards
Drinking Water Intake			
Infant:	1 Liters/day	Age-specific, no standard value	Not Evaluated
Child:	1 Liters/day	Age-specific, no standard value	Not Evaluated
Adult:	2 Liters/day	2 Liters/day	2 Liters/day
Inhalation of Volatilized Vapors:	Equivalent to Ingestion Exposure	No Model Recommended, Not Generally Evaluated	Not Addressed
Dermal Exposure:	Equivalent to Ingestion Exposure	No Model Recommended, Not Generally Evaluated	

2.3 DESCRIPTIONS OF EXPOSURE FACTORS

2.3.1 EXPOSURE FACTORS LENDING THEMSELVES TO QUANTITATIVE DESCRIPTIONS OF VARIABILITY

There are certain exposure factors for which it is possible to describe the distribution of potential values with some confidence. As uncertainty is one of the driving forces of conservativeness, the more one knows about the variability of a factor (and the possible values the factor could take) the less one feels compelled to add additional conservative elements. Table 2-6 lists some of the factors for which a great deal of information exists. In the context of the proposed project, these factors would be analyzed to determine which point values should be recommended to provide an appropriate level of conservatism. Note that a common element of this group is the ease by which these factors are (or, in the case of Exposure Point Concentrations, *can be)* measured.

Table 2-6

FACTORS WITH WELL DESCRIBED DISTRIBUTIONS
Body Weight
Inhalation Rate
Drinking Water Intake
Skin Surface Area
Life Expectancy
Residency Duration
Respirable Particulate Concentration
Exposure Point Concentration

Two of these factors may be used in a simplified demonstration of one method of analyzing the conservative nature of a risk assessment: Monte Carlo analysis. Figures 2-1 and 2-2 present distributions of adult body weight and drinking water intakes. As these are known distributions, any body weight or intake rate point value chosen for a risk assessment can be described statistically. For instance, the MA DEP *ShortForm* utilizes the mean female adult bodyweight of 64 kg and a drinking water intake of 2 L/day. Based on the distributions in Figures 2-1 and 2-2, these represent

the 40th and 96th percentiles for the general population. That is to say that 40 percent of the adult population (male and female) weigh less than 64 kg (141 lbs) and that 96 percent of the adult population will consume less than 2 liters of water per day. What we don't know from the information presented is the combined effect of using these factors in the risk characterization. This is where a Monte Carlo analysis can provide information.

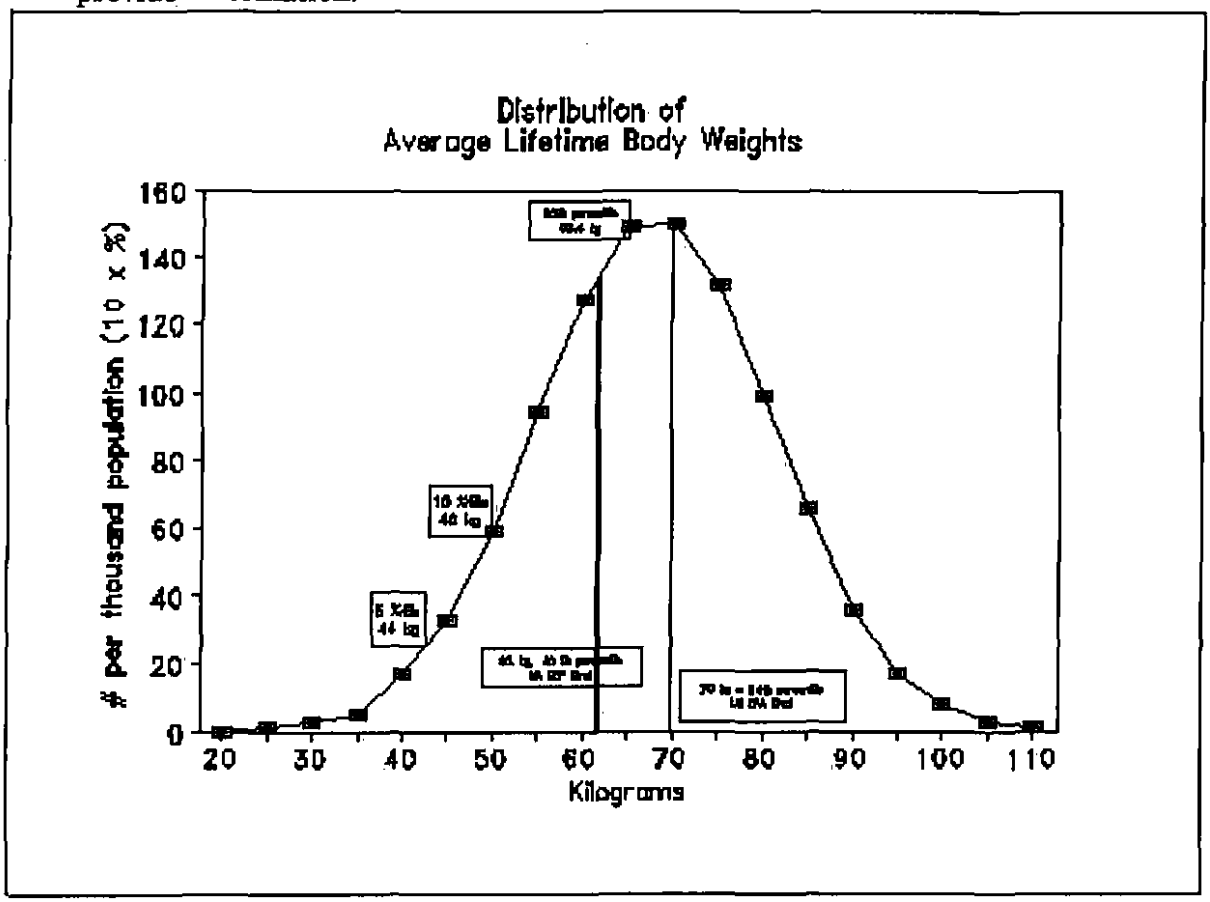

Figure 2-1

In simple terms, a Monte Carlo analysis randomly selects values from the distributions for use in the calculations, rather than relying on a single point value. If a large number of such calculations are performed, the results themselves will vary and may be represented as a statistical distribution. Computer software is now available which makes such calculations extremely simple ***if the distributions of the input parameters are known.***

Figure 2-3 graphs the distribution of results of the ratio of the drinking water intake divided by the body weight (Intake/Body Weight, *or* I/BW). This is just one piece of

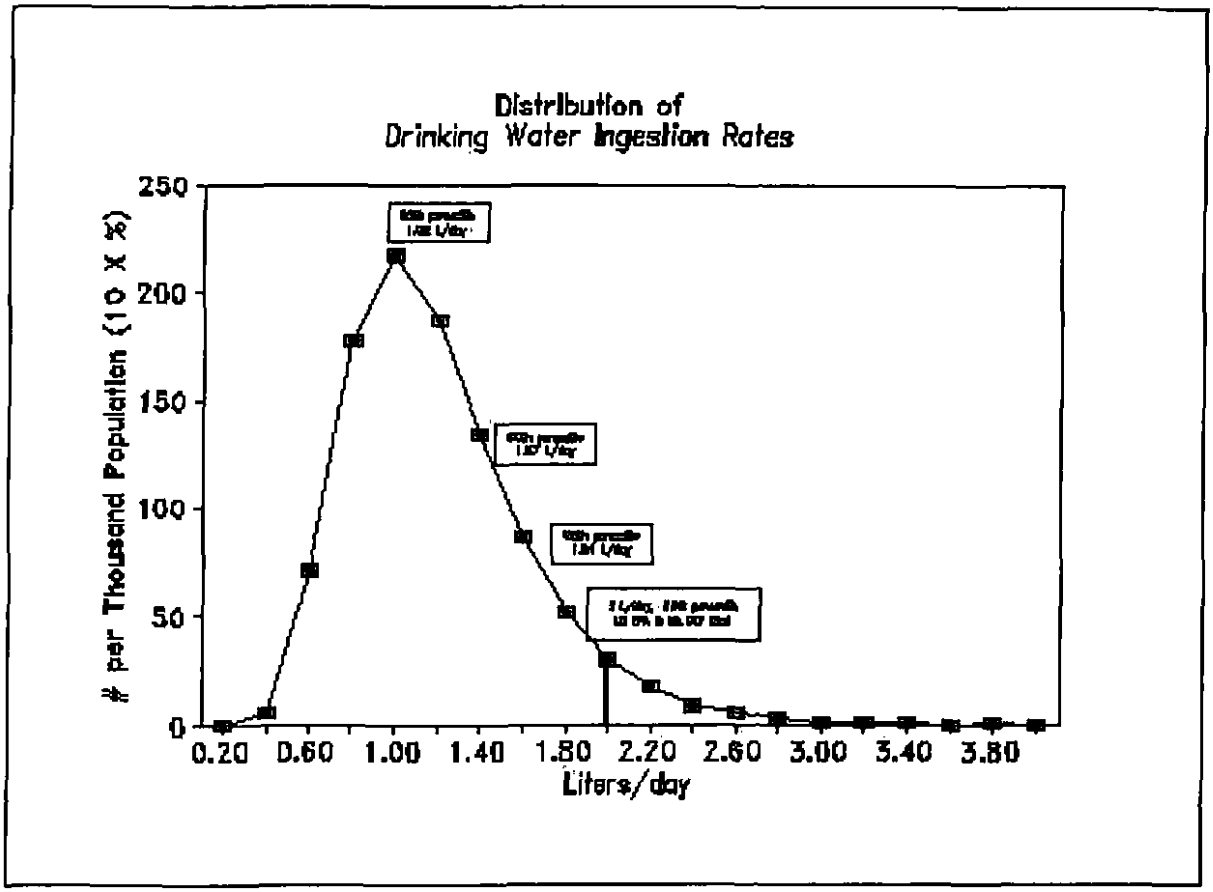

Figure 2-2

a complex equation used to estimate the risk associated with drinking contaminated water. Note that the ratio of the 96th percentile drinking water intake and the 40th percentile body weight represents the 95th percentile of the quotient distribution. The same figure effectively demonstrates the issue of *compounding conservatism*: use of the health-protective 95th percentile values for both input parameters yields a result which represents the 99th percentile of the results.

The simple example above demonstrates the potential use of Monte Carlo analyses to describe conservativeness in risk assessment. Substantial work has been recently published on this topic (Burmaster, 1991; Shylakhter, 1992; Harris, 1992; Israeli, 1992; Thompson, 1992; Iman, 1991, etc...).

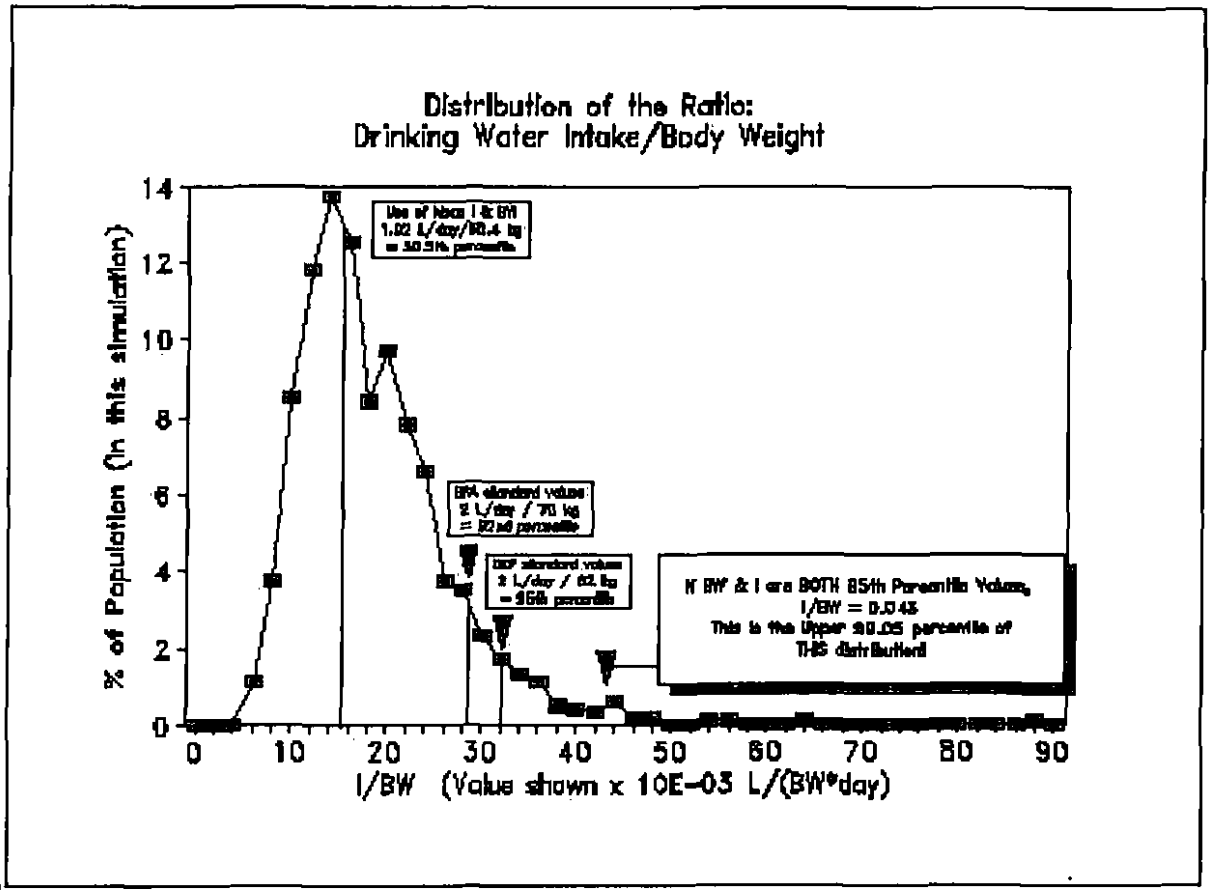

Figure 2-3

2.3.2 EXPOSURE FACTORS WITH DISTRIBUTIONS WHICH ARE LESS WELL DESCRIBED

Other factors are more difficult to measure, and the current level of information is inadequate to fully describe the range of potential values. This may be due to analytical limitations, such as for soil ingestion rates, or due to the complexity of the factor, as in the case of the intake of homegrown fruits and vegetables. The default assumptions used for these values can be greatly refined as new information becomes available. Table 2-7 lists some of the factors which would fall into this category.

Table 2-7

FACTORS WITH LESS INFORMATION AVAILABLE
Soil Ingestion Rate
Mass of Soil In Contact with the Skin (Dermal Absorption)
Fish Intake Rate
Homegrown Food Intake Rates
Plant Uptake Factors

2.3.3 SITE AND USE SPECIFIC FACTORS

There are many other factors which are incorporated into the risk assessment and contribute to uncertainty. Not all of them appear in the equations, yet they influence the choice of point values, and, more importantly, they influence the types of exposures which are evaluated for a given site. Another part of the conservatism question is the broader question of what receptor is assumed to be exposed and by what pathways? Other factors which are more directly site-related can be generalized, but it would be difficult to quantify the level of conservatism on a generic basis: what may be overly conservative for one site may *underestimate* exposure at another. Table 2-8 lists some of these factors. One goal of the proposed project would be to better define the selection of these factors which would result in a health protective assessment which is appropriately conservative.

Table 2-8

SITE SPECIFIC FACTORS
Current & Foreseeable Use
Identification of Receptors
Identification of Exposure Pathways
Duration of Exposure
Frequency of Exposure

2.4 TOXICOLOGICAL FACTORS

The descriptions of the toxicological factors which follow have been taken directly from the background documentation for the U.S. EPA's *Integrated Risk Information System* (IRIS), an on-line computer database. The Department is not proposing the development of alternative toxicity information if such factors have already been developed by the U.S. EPA. It is important, however, that the uncertainty inherent in these factors and the conservative assumptions used in their development be considered when evaluating the uncertainty of the final risk estimates.

2.4.1 Reference Dose (RfD)

Systemic [non-cancer health] effects have traditionally been evaluated using such terms as "acceptable daily intake (ADI)," "safety factor (SF)," and "margin of safety (MOS)," concepts that are associated with certain limitations. The US EPA has coined less value-laden terminology -- "reference dose (RfD)," "uncertainty factor (*UF*)"; "margin of exposure (*MOE*)"; and "regulatory dose (*RgD*)" -- to clarify and distinguish between aspects of risk assessment and risk management.

The U.S. EPA's approach to assessing the risks associated with systemic toxicity is different from its approach to assessing the risks associated with carcinogenicity, because of the different mechanisms of action thought to be involved in the two cases. In the case of carcinogens, the Agency assumes that a small number of molecular events can evoke changes in a single cell that can lead to uncontrolled cellular proliferation. This mechanism for carcinogenesis is referred to as "nonthreshold," since there is theoretically no level of exposure for such a chemical that does not pose a small, but finite, probability of generating a carcinogenic response. In the case of systemic toxicity, however, organic homeostatic, compensating, and adaptive mechanisms exist that must be overcome before a toxic endpoint is manifested. For example, there could be a large number of cells performing the same or similar function whose population must be significantly depleted before the effect is seen.

The threshold concept is important in the regulatory context. The individual threshold hypothesis holds that a range of exposures from zero to some finite value can be tolerated by the organism with essentially no chance of expression of the toxic effect. Further, it is often prudent to focus on the most sensitive members of the population; therefore, regulatory efforts are generally made to keep exposures below the population threshold, which is defined as the lowest of the thresholds of the individuals within a population.

In many cases, risk decisions on systemic toxicity have been made by the Agency using the concept of the "acceptable daily intake (ADI)" derived from an experimentally determined "no-observed-adverse-effect level (NOAEL)." The ADI is commonly defined as the amount of a chemical to which a person can be exposed on a daily basis over an extended period of time (usually a lifetime) without suffering a deleterious effect. The ADI concept has often been used as a tool in reaching risk management decisions (e.g., establishing allowable levels of contaminants in foodstuffs and water.)

A NOAEL is an experimentally determined dose at which there was no statistically or biologically significant indication of the toxic effect of concern. In an experiment with several NOAELs, the regulatory focus is normally on the highest one, leading to the common usage of the term NOAEL as the highest experimentally determined dose without a statistically or biologically significant adverse effect. The NOAEL for the critical toxic effect is sometimes referred to simply as the NOEL. This usage, however, invites ambiguity in that there may be observable effects that are not of toxicological significance (i.e., they are not "adverse"). For the sake of precision, this document uses the term NOAEL to mean the highest NOAEL in an experiment. In cases in which a NOAEL has not been demonstrated experimentally, the term "lowest-observed-adverse-effect level (LOAEL)" is used.

Once the critical study demonstrating the toxic effect of concern has been identified, the selection of the NOAEL results from an objective examination of the data available on the chemical in question. The ADI is then derived by dividing the appropriate NOAEL by a safety factor (SF), as follows:

$$\text{ADI (human dose)} = \text{NOAEL (experimental dose)}/\text{SF}. \qquad \text{(Equation 1)}$$

Generally, the SF consists of multiples of 10, each factor representing a specific area of uncertainty inherent in the available data. For example, a factor of 10 may be introduced to account for the possible differences in responsiveness between humans and animals in prolonged exposure studies. A second factor of 10 may be used to account for variation in susceptibility among individuals in the human population. The resultant SF of 100 has been judged to be appropriate for many chemicals. For other chemicals, with data bases that are less complete (for example, those for which only the results of subchronic studies are available), an additional factor of 10 (leading to a SF of 1000) might be judged to be more appropriate. For certain other chemicals, based on well-characterized responses in sensitive humans (as in the effect of fluoride on human teeth), an SF as small as 1 might be selected.

While the original selection of SFs appears to have been rather arbitrary (Lehman and Fitzhugh, 1954), subsequent analysis of data (Dourson and Stara, 1983) lends theoretical (and in some instances experimental) support for their selection. Further, some scientists, but not all, within the EPA interpret the absence of widespread effects in the exposed human populations as evidence of the adequacy of the SFs traditionally employed.

The term "safety factor" suggests, perhaps inadvertently, the notion of absolute safety (i.e., absence of risk). While there is a conceptual basis for believing in the existence of a threshold and "absolute safety" associated with certain chemicals, in the majority of cases a firm experimental basis for this notion does not exist.

In practice, the ADI is viewed by many (including risk managers) as an "acceptable" level of exposure, and, by inference, any exposure greater than the ADI is seen as "unacceptable." This strict demarcation between what is "acceptable" and what is "unacceptable" is contrary to the views of most toxicologists, who typically interpret the ADI as a relatively crude estimate of a level of chronic exposure which is not likely to result in adverse effects to humans. The ADI is generally viewed by risk assessors as a "soft" estimate, whose bounds of uncertainty can span an order of magnitude. That is, within reasonable limits, while exposures somewhat higher than the ADI are associated with increased probability of adverse effects, that probability is not a certainty. [In other words, an exposure greater than the ADI does not guarentee that an adverse health impact will occur: the risk of experiencing such an impact increases as the exposure increases above the ADI. At some point above the ADI, however, the likelihood of an adverse health impact would be a virtual certainty.] Similarly, while the ADI is seen as a level at which the probability of adverse effects is low, the absence of all risk to all people cannot be assured at this level.

In addition to occasionally selecting different critical toxic effects, [U.S. Environmental Protection] Agency scientists have reflected their best scientific judgments in the final ADI by adopting factors different from the standard factors listed in Table 2-9. For example, if the toxic endpoint for a chemical in experimental animals is the same as that which has been established for a related chemical in humans at similar doses, one could argue for an SF of less than the traditional 100. On the other hand, if the total toxicologic data base is incomplete, one could argue that an additional SF should be included, both as a matter of prudent public policy and as an incentive to others to generate the appropriate data.

Such practices, as employed by a number of scientists in different programs/agencies, exercising their best scientific judgment, have in some

cases resulted in different ADIs for the same chemical. The fact that different ADIs were generated (for example, by adopting different SFs) can be a source of considerable confusion when the ADIs are used exclusively in risk management decisionmaking (see Section 1.2.2.2.3). The existence of different ADIs need not imply that any of them is more "wrong"--or "right"--than the rest. It is more nearly a reflection of the honest difference in scientific judgment.

However, on occasion, these differences in judgment of the scientific data, can be interpreted as differences in the management of the risk. As a result, scientists may be inappropriately impugned, and/or perfectly justifiable risk management decisions may be tainted by charges of "tampering with the science." This unfortunate state of affairs arises, at least in part, from treating the ADI as an absolute measure of safety.

TABLE 2-9

Guidelines for the Use of Uncertainty Factors
in Deriving Reference Doses and Modifying Factors

Standard Uncertainty Factors (UFs):

Use a 10-fold factor when extrapolating from valid experimental results in studies using prolonged exposure to average healthy humans. This factor is intended to account for the variation in sensitivity among the members of the human population and is referenced as "10H".

Use an additional 10-fold factor when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. This factor is intended to account for the uncertainty involved in extrapolating from animal data to humans and is referenced as "10A".

Use an additional 10-fold factor when extrapolating from less than chronic results on experimental animals when there are no useful long-term human data. This factor is intended to account for the uncertainty involved in extrapolating from less than chronic NOAELs to chronic NOAELs and is referenced as "10S".

Use an additional 10-fold factor when deriving an RfD from a LOAEL, instead of a NOAEL. This factor is intended to account for the uncertainty involved in extrapolating from LOAELs to NOAELs and is referenced as "10L".

Modifying Factor (MF):

Use professional judgment to determine the MF, which is an additional uncertainty factor that is greater than zero and less than or equal to 10. The magnitude of the MF depends upon the professional assessment of scientific uncertainties of the study and data base not explicitly treated above; e.g., the completeness of the overall data base and the number of species tested. The default value for the MF is 1.

*Source: Adapted from Dourson and Stara, 1983

2.4.2 Carcinogenic Potency

Dose-response assessment usually entails an extrapolation from the generally high doses administered to experimental animals or exposures noted in epidemiologic studies to the exposure levels expected from human contact with the agent in the environment. It also includes considerations of the validity of these extrapolations. Extrapolation is ordinarily carried out first by fitting a mathematical model to the observed data and then by extending the model (or a bound on the risks it predicts) from the observed range down toward risks expected at low exposure.

Dose-response assessment includes (1) selection of the appropriate data sets to use; (2) derivation of estimates at low doses from experimental data at high doses, using an extrapolation model; and (3) choice of an equivalent human dose when animal dat sets are used.

In addition to data quality, the choice of data sets to use for quantification included the following considerations:

(1) Human data are preferable to animal data;

(2) In the absence of appropriate human data, information from an animal species whose biological responses are most like those of humans (e.g., similar metabolism) is preferable;

(3) In the absence of the ability to identify such a species or to select such data, data from the most sensitive animal species/strain/sex combination are given the greatest emphasis;

(4) The route of administration which most resembles the route of human exposure is used. Where this is not possible, the differences in route are noted as a source of uncertainty;

(5) When the incidence of tumors is significantly elevated at more than one anatomical site by the agent, estimates of overall risk are made by determining the number of animals with tumors at one or more of these sites;

(5) Benign tumors are generally combined with malignant tumors, unless the benign tumors are not considered to have potential to progress to the associated malignancies of the same histogenic origin [see McConnell et al. (1986) for guidance].

Since risk at low exposure levels cannot be measured directly either by animal experiments or by epidemiologic studies, a number of mathematical models and procedures have been developed for use in extrapolating from high to low doses. Different extrapolation models or procedures, while they may reasonably fit the observed data, may lead to large differences in the projected risk at low doses. The choice of a low-dose extrapolation method in EPA assessments is dependent upon chemically specific information bearing on the mechanism of carcinogenesis and other relevant biological information, and not solely on goodness-of-fit to the observed tumor data. When data are limited, however, and when uncertainty exists regarding the mechanisms of carcinogenic action, models or procedures which incorporate low-dose linearity are preferred when compatible with the information available. EPA usually employs the linearized multistage procedure in the absence of adequate information to the contrary.

The first step of the linearized multistage procedure calls for the fitting of a multistage model to the data. Multistage models are exponential models approaching 100% risk at high doses, with a shape at low doses described by a polynomial function. When the polynomial is of first degree, the model is equivalent to a one-hit model, which produces an approximately linear relationship between dose and cancer risk at low doses.

In the second step of the linearized multistage procedure, an upper bound for the risk is estimated by incorporating an appropriate linear term into the statistical bound for the polynomial. At sufficiently small exposures, any higher-order terms in the polynomial will contribute negligibly, and the graph of the upper bound will appear to be a straight line. The slope of this line (formerly called the potency) is called the slope factor in the IRIS chemical files. Its units are (proportion of individuals with tumors)/mg/kg/day. Since the slope at higher exposures may differ from that at lower exposures, IRIS chemical files identify exposures associated with a risk greater than or equal to 1 in 100, as above the range where the slope factor in the file can be applied.

Other models that may be used for dose-response assessment include the Weibull, probit, logit, one-hit, and gamma multi-hit models. These models are defined in the Glossary of Terms. Except for the one-hit model, they all tend to give characteristic S-shape dose-response curves of many biological experiments, with varying curvature and tail lengths. Their upper bounds tend to parallel the curvature of the models themselves, unless a procedure has been devised to provide otherwise, as is the case with the linearized multistage procedure. The slope factor designated in the IRIS chemical files

for these models is the slope of the straight line from the upper bound risk at zero dose to the dose producing an upper bound risk of 1%.

When animal data are used as a basis for extrapolation, the human dose that is equivalent to the dose in the animal study is calculated using the assumption that different species are equally sensitive to the effects of a toxin if they absorb the same dose per unit of body surface area. This assumption is made only in the absence of specific information about equivalent doses for the chemical in question. Since surface area is approximately proportional to the 2/3 power of body weight, the equivalent dose is expressed in milligrams per (body weight raised to the 2/3 power) per day. In the calculation of human equivalent doses, the actual animal weight in the bioassay is used whenever that information is available; otherwise, standard species weights are used. It follows that if the animal dose is expressed in units of mg/kg/day, the equivalent human dose (assuming a body weight of 70 kg), in the same units, is smaller than the animal dose by a factor of 13 for mice (weight of 30 grams) and 5.8 for rats (weight of 350 grams).

In using animal inhalation experiments to estimate lifetime human risks for partially-soluble vapors or gases, the air concentration (ppm) is generally considered to be the equivalent dose between species based on equivalent exposure times (e.g., a lifetime exposure to a 1 ppm). With regard to the inhalation of particulates or completely-absorbed gases, the amount absorbed per unit of body surface area is considered to be the equivalent dose between species.

2.5 CONCLUSION

The workgroup seeks comments on:

* Means to evaluate uncertainty in risk assessment,
* Sources of information to better describe the distribution of possible values of the exposure factors used in risk assessment,
* Description and justification of a level of conservatism at which the MA DEP should regulate exposures to material at c.21E sites.

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