BUREAU OF WASTE SITE CLEANUP

PROGRAM REDESIGN

PROPOSED REVISION TO THE MASSACHUSETTS CONTINGENCY PLAN (MCP)

RISK ASSESSMENT AND RISK MANAGEMENT

PROPOSAL & DISCUSSION DOCUMENT

MCP ReWrite Workgroup

July 16, 1992

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Risk Assessment and Risk Management

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.

PROPOSED REVISION TO THE MASSACHUSETTS CONTINGENCY PLAN (MCP)

PUBLIC HEALTH RISK ASSESSMENT AND RISK MANAGEMENT PROPOSAL AND DISCUSSION DOCUMENT

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1.0 INTRODUCTION

1.1 Purpose

The Massachusetts Department of Environmental Protection (DEP) has undertaken the redesign of its waste site cleanup program in order to streamline the process for cleaning up waste sites in the Commonwealth. A major goal of DEP's new program is to focus its limited resources on the most critical sites, or those sites posing the greatest risk to public health, safety, welfare, and the environment and to remove roadblocks from private sector cleanups. Since the 1986 amendments to M.G.L. c. 21E, the waste site cleanup program has incorporated risk characterization and risk management into decision-making about sites. Given the efforts of the program redesign and the scientific and management developments since the MCP was promulgated, the Department considers it timely to reassess the risk characterization methods and criteria in the MCP.

This paper considers various risk assessment methods and risk management criteria which could be implemented. It does this by:

- reviewing the respective roles of risk assessment and risk management in the waste site cleanup program;
- outlining the legislative requirements which direct the risk management approach of the waste site cleanup program; and
- describing the risk assessment methods which are currently available and used by the DEP, the U.S. Environmental Protection Agency (US EPA) and other states.

This document identifies the strengths and limitations of the existing risk characterization methodology and makes recommendations for changes to these methods. Alternative risk management criteria associated with the risk characterization methods are also discussed. In addition, the paper identifies similar decision-making processes in other DEP programs

and discusses the similarities and differences which result from alternative approaches to regulating environmental threats to human health.

This proposal is *not* a final document, but it does lay out and make recommendations on the broad risk assessment issues and provide direction for the details which must be incorporated in many of the program redesign components. The issues discussed here are integral to the No Further Action Proposal as this paper describes the methods and criteria to be used in determining when a level of "no significant risk" of harm to human health exists or has been achieved - one part of the NFA determination. These proposals may also affect the development and use of Reportable Concentrations as part of the notification requirements. This paper is narrowly focussed on the risk of harm to human health, and it does not address the characterization of the risk of harm to safety, public welfare or the environment.

This document has been prepared by a subcommittee of the Bureau of Waste Site Cleanup's internal MCP Workgroup (the "Workgroup"). The proposals and recommendations provided are intended to promote discussions and to provide a focus for comments from reviewers. These recommendations are not necessarily the final decisions of BWSC or the Department. Comments and suggestions on any facet of this document are solicited, with particular emphasis on the questions/issues identified specifically in the text.

1.2 Background

This section of the paper will outline the basics of risk assessment and risk management to provide a background for the rest of the paper. Without an overall understanding of how risk assessment and risk management work together, information about the risk posed by sites can be misleading and misunderstood. Specifically, this section will address:

- What constitutes risk?
- How do we assess and characterize risk?
- How do we manage risk?

1.2.1 What is Risk in the Waste Site Cleanup Program?

In general, risk [within the context of the Waste Site Cleanup Program] can be described as the potential for harm to human health, safety, public welfare, or the environment.

More specifically, the legislative requirements in the existing statute and the proposed revisions to M.G.L. c.21E (currently a section of the Commonwealth's FY93 budget) introduce *risk* through the requirements that:

- the Department consider "the nature and extent of danger to public health, safety, welfare, and the environment" when adopting, amending, or repealing regulations (Section 3 (d)(2)). (Note: references are to the proposed revisions to M.G.L. c. 21E).

- "permanent solutions" are to be implemented at all sites posing "significant risk" (Section 3A (f) and (g)).

- A ***"permanent solution"*** is defined as "a measure or combination of measures that, at a minimum, shall ensure the attainment of "no significant risk" (Section 3A (g)).

- "***No significant risk***" is defined as "a level of control of each identified substance of concern at a site or in the surrounding environment such that no such substance of concern shall present a significant risk of damage to health, safety, public welfare, or the environment during any foreseeable period of time (Section 3A (g)).

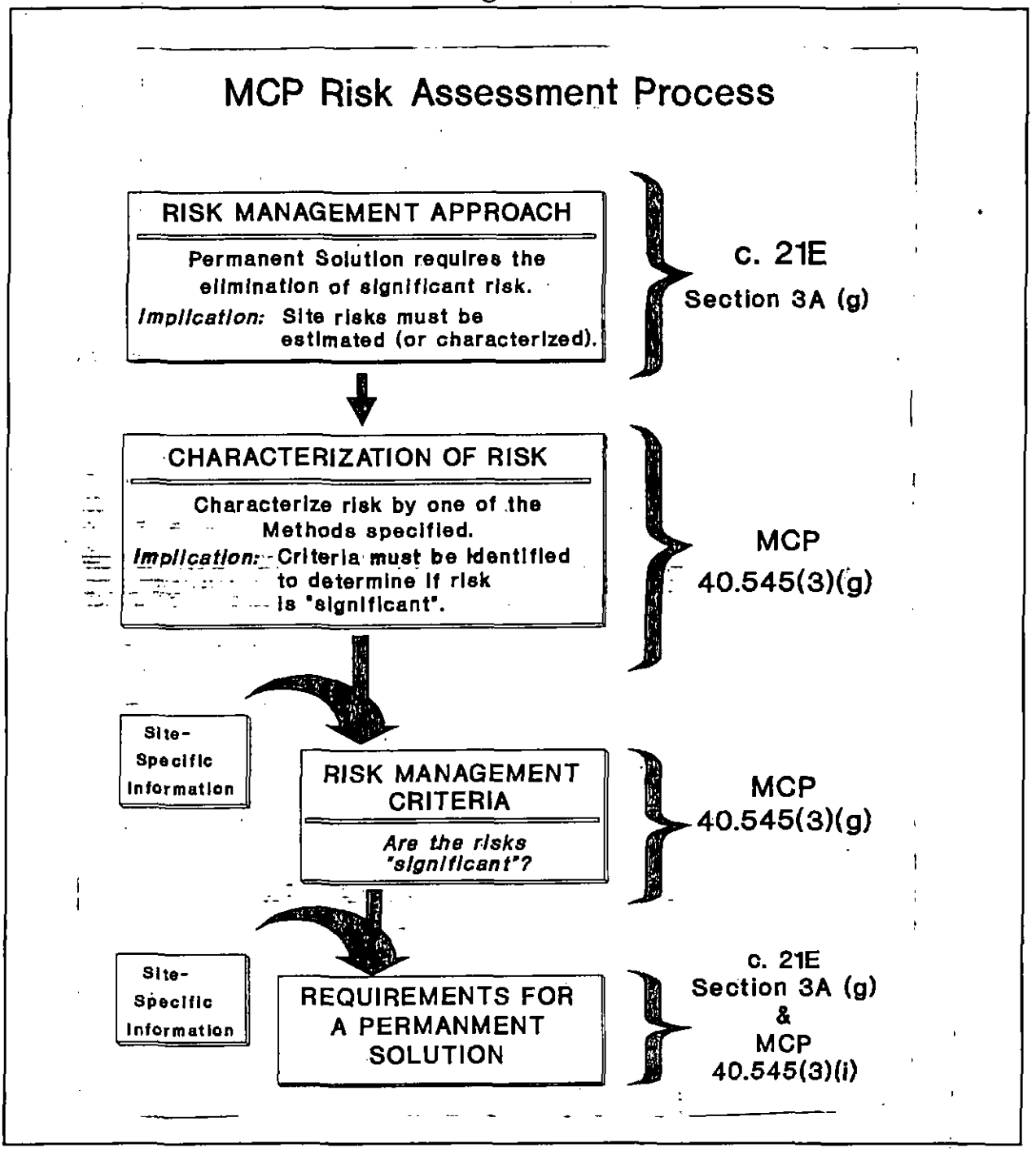
- "in determining whether a permanent solution will achieve a level of no significant risk, the Department shall consider existing public health or environmental standards where applicable or suitably analogous, and any current or reasonably foreseeable uses of the site and the surrounding environment..." (Section 3A (g)).

- Permanent solutions reduce the level of oil or hazardous material in the environment to the level that would exist in the absence of the site of concern, where feasible (Section 3A (g)). This is referred to as returning the site to "background" levels.

These legislative requirements have led to the existing MCP risk management process, as described in Figure 1-1. However, these requirements suggest several important questions. Specifically, what constitutes "significant" risk? What should be considered a permanent solution? How do we determine "background" levels of contaminants at sites? While each of these questions is being examined as part of the program redesign effort, they are integral to the science of risk assessment and the decision-making process of risk management. Each of these tools is discussed in more detail below.
the "science"), and risk management (as the "decision-making" process). Each of these tools is discussed in more detail below.

Please note that, while elimination of significant risk requires consideration of safety, public welfare, and the environment, *this* discussion document deals only with risk assessment and management related to *human health risk.*

Figure 1-1


MCP Risk Assessment Process
RISK MANAGEMENT APPROACH
Permanent Solution requires the elimination of significant risk.
Implication: Site risks must be estimated (or characterized).
c. 21E
Section 3A (g)
CHARACTERIZATION OF RISK
Characterize risk by one of the Methods specified.
Implication: Criteria must be identified to determine if risk is "significant".
MCP
40.545(3)(g)
Site-Specific Information
RISK MANAGEMENT CRITERIA
Are the risks "significant"?
MCP
40.545(3)(g)
Site-Specific Information
REQUIREMENTS FOR A PERMANMENT SOLUTION
c. 21E
Section 3A (g)
&
MCP
40.545(3)(i)

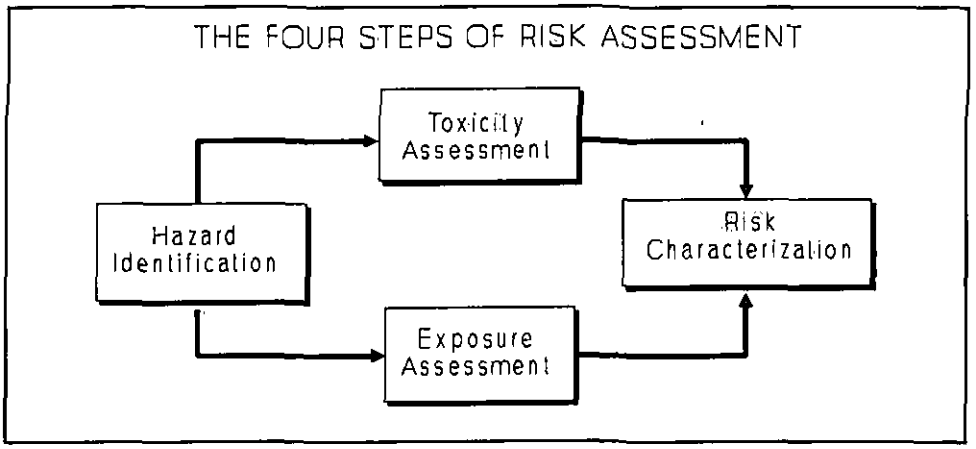
1.2.2 Risk Assessment

***Human health risk assessment** is the process for evaluating the potential human health effects of human exposures to environmental hazards.*

Risk assessment uses both laboratory and field work to evaluate the potential for adverse health effects related to exposure of individuals or populations to hazardous substances located at a site. It is an analytic tool that is used by regulatory agencies to assess a wide variety of environmental problems. Risk assessment is used in both setting environmental standards and in the evaluation of environmental "situations".

There are four basic steps to risk assessment, as outlined by the National Research Council (NRC, 1983) and as implemented in Massachusetts. These steps are shown in Figure 1-2 and described briefly below:

Figure 1-2
The Four Steps of Risk Assessment



Step 1: Hazard Identification

Do the substance(s) found at the site cause adverse health effects?

This first step of risk assessment involves gathering data about a site and evaluating the adverse effects to health that might be posed by the chemicals found at the site. This may include characterizing the impact of the chemical(s) on the human body related to different exposure pathways.

Step 2: Dose-Response Evaluation (Toxicity Assessment)

What is the effect of the substance(s) on human health?

This step involves calculating and describing the relationship between the amount of exposure to a substance and the expected extent of injury or disease to human health.

Step 3: Exposure Assessment

What is the human exposure to the substance(s) now, in the past, in the future?

The nature and the size of the population and the duration of the exposure to particular hazards identified in the above two steps is quantified in this step. This may include current, past and/or future exposures. Exposure is based on pathways to human populations through air, soil and water, via inhalation, ingestion, or dermal contact. The exposures that may be included in this step may be linked to the "foreseeable uses" of the site in question. The specifics of how selection of exposure pathways relate to current and foreseeable uses of a site were presented to the Waste Site Cleanup Advisory Committee in the May 8, 1992 document "Draft Proposal for Considering Current and Foreseeable Uses of Contaminated Property".

One result of an exposure assessment could be the documentation that certain exposure pathways are <u>not</u> significant, and can be eliminated from further evaluation in the risk assessment.

Step 4: Risk Characterization

What is the likelihood that humans will experience any of the various forms of adverse human health effects associated with the substance based on the analysis performed in the first three steps?

<u>Risk characterization</u>, the last step in the risk assessment process, describes the potential for harm to human health related to human exposure to substances at a site. It includes consideration of both the scientific confidence and uncertainty underlying the analysis conducted in the first three steps of risk assessment, and presents the effects of reasonable alternative assumptions on the risk estimates.

Risk characterization is considered the "starting point for risk management considerations and the foundation for regulatory decision-making" (US EPA, 1992). Risk characterization can be broken down into four basic steps:

A. Integrate and summarize the first three steps of risk assessment: hazard identification, dose-response assessment, and exposure assessment.

B. Develop public health risk estimates based on the integration of risk assessment steps 1 through 3 (Step A above).

C. Develop a framework to define the significance of risk to human health.

D. Present and integrate into the risk characterization assumptions, uncertainties, and scientific judgements. (US EPA, 1991a)

Risk assessment has been separated from risk management to delineate the *science* underlying risk analysis from the *decision-making* processes that must consider risks in the context of broader social and economic factors surrounding environmental decisions. However, risk assessment, by necessity, also depends on certain types of policy decisions. This issue is described in the *Residential Shortform* documentation (MA DEP, 1992):

> "While ideally risk assessment is an objective analytic process based solely on scientific considerations, subjective decisions are often made when available evidence is not conclusive or assumptions need to be made. These judgements draw on both scientific and policy decisions."

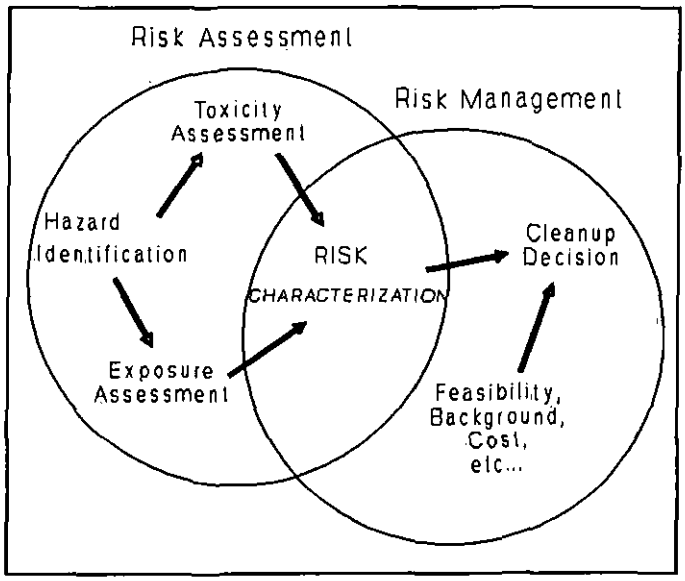
The workgroup would like to emphasize that the subjective policy decisions that are made as part of the risk assessment process (for example, how many years to use for lifetime exposure), should be viewed as separate from the policy decisions that are made as part of the risk management process. Risk management decisions are made on the basis of broader social and economic factors that do not relate to the assumptions and decisions made in the risk assessment process. In blurring this distinction, risk assessment has often become the target of criticisms that should, more appropriately, be addressed in the risk management arena. The specifics of risk management will be outlined in the next section.

1.2.3 Risk Management

Risk management is a decision-making process in which alternative regulatory actions are reviewed and actions are selected.

As shown in Figure 1-3, risk management is the decision-making process which utilizes the results of the risk assessment. While risk assessment provides us with an evaluation of the potential human health risks posed by a site, risk management is the process for determining *what to do about the risks*. Risk management may combine risk assessment (characterization) with judgements about engineering data and social and economic factors to reach a decision about the need to take action. The risk management process employed in the Waste Site Cleanup program must ensure that all sites are appropriately addressed.

Figure 1-3
Risk Assessment & Risk Management



There are two components to consider in evaluating the risk management process used in waste site cleanup: risk management *approaches* and risk management *criteria*. A risk management approach describes how risk information will be used in making decisions, what other factors, if any, should be considered, and the point in the decision-making process at which the various factors should be considered.

Risk management *criteria* are distinct from the risk management approach in that they impose specific constraints on risk management decision-making. For example, EPA has established risk management criteria as an "allowable" range for cancer-risk at Superfund sites of between 1×10^{-4} and 1×10^{-6}, or between 1 in 10,000 and 1 in 1,000,000 additional cases of cancer. Superfund sites must, therefore, be remediated to a cancer-risk level within this range.

Risk management, by its nature, requires that value judgements are made about what constitutes an acceptable level of risk, a reasonable cost of cleanup, or what is truly a "feasible" cleanup alternative. These types of decisions are affected by many factors such as social, political, and economic considerations that can vary across communities and change from year to year. Each of these factors affect the risk management decisions made by the Department and directly affect our ability to define: what is "significant" risk, what constitutes a "permanent" solution, and what is "feasible"?

1.3 Environmental Risk

As indicated earlier, the risk assessment and risk management tools discussed in this paper and used in evaluating hazardous waste sites in the Commonwealth deal with *human health risks* only. That is not to say, of course, that environmental risk is not an important element to consider when evaluating sites. The Bureau has included elements of environmental assessment as part of its site scoring process (see "Subpart C and D: Tier Classification", January 27, 1992, for a detailed discussion of the site scoring mechanism). The process of environmental risk assessment is also being reviewed by the MCP Rewrite workgroup as part of the revisions being made to the Phase II process.

1.4 Structure of the Paper

The remaining sections of this paper will address in greater detail each of the topics outlined briefly above. These include:

- *Approaches to risk management*: What approach is described in M.G.L. c. 21E. What other approaches are available?
- *Risk assessment methods*: What methods are available for characterizing risk? Which best supports the goals of program redesign?
- *Risk management criteria*: What are they? What are they based on? What criteria are currently used by DEP, by other programs?
- *Risk management processes*: What are the risk management and risk assessment approaches across different programs within DEP.

3.3.3 Proposed Method 2

3.3.3.1 Framework for Total Site Risk

The MCP would contain a description of this risk characterization method, which would be essentially unchanged from the current Method 3b. This method uses a comparison of exposure point concentrations to applicable or suitably analogous public health standards and a calculation of total site risks. Total site risks should be calculated for each current or likely receptor group considering all relevant current and future exposure pathways and exposure point concentrations. The *Risk Assessment ShortForms* may be used to conduct this analysis in situations when applicable.

3.3.3.2. Use of Total Site Risk

This method can be used at the discretion of the PRP (or DEP in the case of a publicly funded site) for the evaluation of the significance of the risk of harm to human health posed by the site. This is in contrast the restrictions imposed on the use of the current Method 3b, which is applicable only at multi-media type sites.

An exceedence of either an applicable public health standard or the total site risk limits would indicate the existence of a significant risk to public health. As with the proposed Method 1, additional evaluation of risks to safety, public welfare and the environment would also be required.

The proposed Method 2 requires the same level of site characterization as the proposed Method 1 in order to ensure that exposure point concentrations are representative, and that all applicable and foreseeable exposure pathways are considered.

For the evaluation of proposed remedial alternatives and the development of target cleanup levels, the proposed Method 2 offers unlimited flexibility at the cost of increased complexity (compared to the simplicity of Method 1). All applicable or suitably analogous public health standards become minimum cleanup requirements, which restricts the flexibility of the method to some degree, but the requirement could also serve as a starting point in the development of target cleanup levels. The identification of such target remedial goals could be accomplished by apportioning risk equally among the chemicals and/or exposure media at the site, *or* remedial goals could be developed considering factors specific to that remedial alternative. The latter approach can take into account exposure reduction alternatives by modifying the exposure pathways analysis. In addition, this approach can accommodate some trade-offs in the cleanup of specific substances as long as total site risk requirements are met.

2.0 RISK MANAGEMENT APPROACH

2.1 Introduction

As described in the previous section, risk management is generally considered to be the process by which decisions are made utilizing risk characterization information. In some cases, additional information beyond that provided in the risk characterization is used in such decisions. Typical factors also considered are cost and technical feasibility, among others. The purpose of this section of the issue paper is to describe the risk management approach contained in M.G.L. c. 21E, and the approaches used by others.

2.2 MCP Risk Management Approach

The risk management philosophy utilized in the waste site cleanup process is described in M.G.L. c. 21E (and the current amendments) and is amplified in the MCP. This approach requires a decision as to whether or not significant risk exists at a site. The criterion used to determine whether cleanup is required is the presence or absence of significant risk to health, safety, public welfare or the environment. In selecting a remedy, the elimination of significant risk is a requirement. Flexibility exists in the definition of what constitutes significant risk. Considerations of feasibility, including cost and implementability, are examined as part of the evaluation of remedial alternatives that eliminate significant risk. This risk management approach is expressed in the statute primarily in the requirement that a permanent solution ultimately be implemented at all sites. If a feasible permanent remedial alternative is not available, the statute requires that a plan be developed for identifying, developing and implementing a permanent solution.

While the above risk management approach comes directly from c.21E, the statute does not define "significant risk" (or a level of "no significant risk"), nor does it describe how risk should be assessed. Thus, the Department has some flexibility in defining what risks are to be considered significant in the MCP. (The risk assessment methods and risk management criteria will be discussed in Sections 3.0 and 4.0, respectively.) The consideration of feasibility in the development of remedial alternatives allows additional flexibility in response actions.

A permanent solution must meet one of the specific health risk reduction requirements (as well as an elimination of significant risk to safety, public welfare and the environment) for any foreseeable period of time. The one exception to this requirement in the MCP is when "background" prevents the achievement of the risk reduction requirements. In this situation, the Department can determine that the achievement of "background" conditions meets the requirements of a permanent solution. Cost and implementability issues cannot be used to justify calling a remedial alternative a permanent solution if significant risk has not been eliminated.

2.3 Other Risk Management Approaches

Many regulatory agencies utilize a risk management philosophy similar to that described above, in that there is an implicit or explicit level of risk which will always require action, and which is minimally acceptable. There are theoretically alternative risk management approaches that are also used by regulatory agencies. Two common approaches are "risk balancing" and "technology based". Combinations of two or more of these approaches may be used in a regulatory program. These two theoretical approaches and the EPA Superfund risk management approach, as outlined in the National Contingency Plan, are described below. This discussion focuses on the general approach and not the specific risk management criteria.

2.3.1 Pure Risk Balancing Approach

In this approach, the need for remediation is considered in the broad context of a no further action alternative in comparison to other alternatives considering costs, effectiveness and feasibility. The "allowable" residual risk level would be determined on a site-by-site basis using some objective criteria for balancing the benefits of risk reduction against a variety of considerations (including, for example, the cost to remediate and the capabilities of available technologies). The "allowable" level of residual risk would be a function of the benefits of the degree of risk reduction, costs and feasibility. In general, the risks remaining after remedial response actions (or after a No Further Action determination) would be higher at sites where the type of contaminant or specific site conditions make risk reduction more costly or make commonly available remedial technologies technically infeasible. While theoretically this approach does not specify levels of risk that require action, the implementation of this approach has resulted in an implicit level of risk that will always require remediation and that is minimally acceptable. In this sense, it is similar to the 21E risk management approach described above.

When the risk reduction requirements are implicit and in the form of minimum requirements, the development of detailed and objective criteria for balancing risk reduction and the non-health related factors on a site-by-site basis is required. These criteria would be used to assess and balance the nature and degree of risk reduction (perhaps even population risk or numbers of people potentially affected), remedial costs, the public welfare costs of remediation, the public welfare benefits of remediation, the actual capabilities of various remedial technologies, public perception and other consequences of remediation or "no action" decisions. The development of such criteria

is often controversial as the population asked to live with the elevated risk levels is usually *not* the population which would bear the cost of further risk reduction.

- In addition, this approach requires a fairly complicated analysis at all sites in order to consistently determine the degree of remediation required. While it is relatively easy to describe the factors to be considered in such balancing, it is extremely difficult to determine and adequately describe allowable or appropriate trade-offs, resulting in inconsistent risk balancing decisions.

2.3.2 Technology-based Risk Management Approach

The "technology based" approach does not incorporate distinct decisions as to whether or not significant risk exists or whether "controls" are required. It generally stipulates some level of control that will be required, for example, "best available control technology" (BACT). In other words, the technology-based approach to risk management does not specifically identify a level of acceptable risk, but specifies a level of *technology* that must be implemented.

This approach has generally been utilized in permitting specific sources where available technologies are well-defined, and where there is an *a priori* decision that controls are required. This approach has not been implemented at sites, probably due to the significance of site-specific issues in identifying the "best technology".

2.3.3 EPA Superfund Risk Management Approach

The EPA Superfund process for assessment and remediation of sites is described in the newly revised National Contingency Plan (NCP). This process is, in general, similar to the 21E risk management approach described above. The approach has clear criteria for determining *if* remediation is necessary. In addition, it has "risk balancing" activities for selecting from remedial alternatives which meet the ARARs (Applicable, Relevant and Appropriate Requirements) and broad health risk criteria. The process for selecting remedies in the Superfund program, as described in the NCP, is much more detailed than that described in the MCP.

The EPA Superfund approach can be described briefly by the following steps:

1. Identify Applicable or Relevant and Appropriate Requirements (ARARs)
2. Conduct baseline risk assessment
3. Identify preliminary remedial goals
4. Develop remedial alternatives
5. Screen alternatives for effectiveness, implementability and cost
6. Evaluate the alternatives remaining after the initial screening

7. Select remedy or remedies.

The detailed evaluation conducted in step 6 uses the following nine criteria:

THRESHOLD CRITERIA

A. Overall protection of human health and the environment;
B. Compliance with ARARs;

PRIMARY BALANCING CRITERIA

C. Long term effectiveness and permanence;
D. Reduction of toxicity, mobility, or volume through treatment;
E. Short-term effectiveness (adverse implementation impacts);
F. Implementability;
G. Cost;

MODIFYING CRITERIA

H. State acceptance; and
I Community acceptance.

Criteria A and B are considered Threshold Criteria. They must be met in order for an alternative to be considered for selection, unless a specific ARAR is waived. Exposure levels are considered acceptable if they are less than toxicity values (reference doses), and if they represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using information on the relationship between dose and response. The 10^{-6} risk level is used as the point of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or multiple pathways of exposure. These risk management criteria are the primary difference between the EPA approach and the 21E approach, as described in Section, 4.0.

Criteria 6.C through 6.G (the Primary Balancing Criteria) are used to evaluate and compare the alternatives which comply with ARARs and meet the risk criteria above. These balancing criteria are used to select from among the protective alternatives Although these criteria may result in the selection of a "more protective" or "less protective" alternative, the selected alternative would always fall within the protective range as specified in the NCP. EPA's goal is to select the more protective alternative whenever feasible. These criteria are not used to redefine the protective range on a site-by-site basis, as occurs in a pure risk balancing approach.

The EPA Superfund risk management approach theoretically provides some flexibility in considering site specific conditions, while maintaining some consistency in levels of acceptable risk. However, when significant risk is expressed as a range, it is difficult to justify the selection of a higher cost alternative, even if it provides greater benefits in terms of risk reduction, if both alternatives fall within the acceptable risk range. Thus, the less protective end of the range can become the default requirement.

2.4 DISCUSSION

Table 2-1 provides a summary comparison of the risk management approaches described above. The technology-based approach is not shown since it does not appear to be applicable to site risk management decisions. A consideration of these other risk management approaches has shown that, in practice, they are similar to that used by 21E. The primary difference exists in how and whether significant risk is defined.

Those who suggest that the 21E risk management approach should be changed maintain that permanent solutions are currently impossible or extremely difficult and costly to attain as a result of the risk management approach. In addition, it is argued that less expensive alternatives are available that could be implemented with only minor impacts on risk reduction.

Many of the perceived problems with DEP's existing risk management approach for waste site cleanup can be addressed by appropriate application of risk characterization methods, and by an expanded exploration of potential remedial alternatives, including more emphasis on migration prevention, exposure point elimination and concentration reduction at potential exposure points.

In addition, a realistic application of applicable or suitably analogous standards, particularly groundwater standards, would go a long way toward identification of feasible alternatives. The Department has established a Workgroup with representatives from the Bureau of Waste Site Cleanup and the Bureau of Resource Protection to address the applicability of groundwater standards, and that work has begun. (See Section 5.3.1.4 for a discussion of this work.)

Thus, there are other issues that affect the utility of current MCP risk management practices aside from the approach itself.

TABLE 2-1

COMPARISON OF RISK MANAGEMENT APPROACHES

MANAGEMENT APPROACH	ADVANTAGES	DISADVANTAGES
21E Approach	* Consistent level of health protection * Predictable results * Requires cleanup below acceptable risk levels if feasible (background requirement)	* Significant risk defined generically rather than on a site specific basis * Permanent solution at all sites may not be perceived as cost effective
Risk Balancing	* Cost and feasibility of remediation can be considered in defining acceptable risk on a site specific basis	* Level of health protection inconsistent * Considerable work effort required to develop criteria needed for implementation * Detailed analysis required at all sites to determine level of remediation required
EPA Superfund	* Consistent level of health protection (within a range) * Predictable results * Theoretically allows greater level of health protection when cost effective (risk range)	* Use of a risk range can result in the less protective end of the risk range becoming the default requirement * Approach requires considerable site-specific effort to select the "best alternative"

3.0 RISK CHARACTERIZATION METHODS

3.1 Introduction

The requirement for risk characterization in the MCP stems from the statute's (M.G.L. c. 21E Sec. 3A(g)) reference to the need for the implementation of a permanent solution at all disposal sites, as discussed in the previous section. A permanent solution ensures that the disposal site will not pose a significant or otherwise unacceptable risk of damage to health, safety, public welfare, or the environment during any foreseeable period of time. The MCP currently requires a characterization of such risks posed by the disposal site in Phase II, following the comprehensive site investigation. In that way the identified risks can be addressed in Phases III and IV in order to achieve a level of no significant risk and a permanent solution once remediation is complete.

The Study Committee for Waste Site Cleanup Program Improvements and Long Term Funding did not specifically identify in the Interim Report changes that should be made to the risk characterization methods as part of the program redesign. They did, however, identify that a significant failing of the existing program was the "lack of clear standards and guidelines defining which sites need to be cleaned up and which do not". Since the remediation decision is based on a Phase II risk characterization, this failing indicates that the existing risk characterization methods should be clarified or reconsidered.

The purpose of this section of the issue paper is to provide recommendations for changes to the existing MCP risk characterization methods. It is the intent that these methods be may be used at any point in the site assessment/remediation process when the significance of risk of harm to human health posed by the site is considered. This may occur as part of an NFA determination, for example. In order to provide appropriate background for these recommendations, this section describes the risk characterization methods for public health currently set forth in the MCP in Phase II (310 CMR 40.545(3)(g)). Problems or concerns with those methods are also discussed based on issues that have been identified through their use and through current discussions regarding the site remediation program redesign. In addition, recommendations are provided that address some of the issues identified.

3.1.1 Current MCP Risk Characterization Methods

There are four methods for characterizing **human health risks** as described in Phase II of the MCP. These methods have been labelled Methods 1, 2, 3.a, and 3.b and are summarized in Table 3-1. (Note: These methods do not address risks to safety, public welfare or the environment.) The four separate methods for characterizing health risks and identifying clean-up requirements have been criticized as cumbersome, confusing and perhaps inconsistent.

Table 3-1

CURRENT MCP RISK CHARACTERIZATION METHODS

Method	Applicability	Risk Characterization Approach	Example
1.	When there is a promulgated standard that is applicable or suitably analogous standard for each OHM at each current and reasonably foreseeable exposure point	Comparison of exposure point concentrations to applicable or suitably analogous public health standards	Comparison of drinking water exposure point concentrations to MCLs
2.	When there is a promulgated set of cleanup levels which are applicable for the site pursuant to 310 CMR 40.800. (No such sets of cleanup levels have been promulgated)	Comparison of exposure point concentrations to applicable set of cleanup levels.	Has not been implemented
3.a	When neither Method 1 nor Method 2 applies and if OHM are likely to be transported to exposure points through only one medium (single medium sites)	Comparison of exposure point concentrations to (in order of precedence): (1) Applicable or suitably analogous public health standards; (2) Public health or risk-based guidelines or policies approved by the Department; or (3) Public health or risk-based guidelines proposed by the PRP	Drinking water is the only route of exposure; comparison of drinking water exposure point concentrations to MCLs, ORS risk-based guidelines, and PRP risk-based guidelines
3.b	When neither Method 1 nor 3.a applies and the PRP chooses not to use Method 2. Intended for sites where OHM are transported to exposure points through more than one medium (multi-media sites)	Comparison of exposure point concentrations to applicable or suitably analogous public health standards and calculation of total site cancer and non-cancer risks for all OHM	Exposures to drinking water and soils may occur; calculation of total exposure and risk for drinking water and soil routes, for a hypothetical receptor

The four risk characterization methods and associated risk management criteria were developed during 1987 and 1988. The U.S. EPA was developing and using some approaches that addressed the additivity of risks from multiple chemicals and multimedia exposures in risk assessments for Superfund sites. At the time, it seemed that the total site risk concept should be incorporated into the Ch. 21E sites program in order to be consistent with the direction that the federal Superfund program was

taking and the state of the art of risk characterization in 1988. In addition, it made sense to assess disposal sites as a whole, rather than as a collection of discrete units or contaminated media. Ultimately the Department was concerned about the cumulative impact the site was having on the health of potentially exposed individuals. However concerns were raised about the consistency of using a total site risk approach for Ch. 21E while other DEP regulatory programs utilized chemical-specific regulations. As a result of these concerns, the following approach was developed (Table 3-1).

1. In all circumstances where promulgated standards existed for all the OHM at all exposure points, those standards would serve as the basis for decisions to remediate. Quantitative risk assessment and total site risk limits would not take precedence over those standards. This was developed as Method 1.

2. Since quantitative risk assessment was relatively new, expensive, and an "unknown", it was thought that it would be beneficial for DEP to develop "sets of cleanup levels" using these techniques for commonly encountered Ch. 21E site types (PCBs, petroleum, coal gasification sites). This was developed as Method 2.

3. At Ch. 21E sites involving contamination in a single media which would normally be addressed by a single DEP Division (Water Supply, Air Quality or Water Pollution Control), the waste site cleanup program would evaluate risks and require remediation per the standards, guidelines and policies of that DEP Division. This was developed as Method 3.a.

4. At Ch. 21E sites involving contamination in multiple media which would not normally be addressed by a single DEP Division, the waste site cleanup program would evaluate risks and require remediation per the chemical-specific standards (not guidelines or policies) of the DEP Divisions and via the use of quantitative risk assessment and upper limits on allowable total site risk. This was developed as Method 3.b.

3.1.2 Issues Relative to Current Risk Characterization Methods

The primary criticisms of the four risk characterization methods raised over the last five years include:

1. The current risk characterization methods are too complicated and determining the need for (or the adequacy of) remediation is too time-consuming and expensive;

2. The applicability of the four methods is unclear. In particular, it is unclear when Method 3.a vs. 3.b applies;

3. Method 1 has rarely been implemented because situations where a promulgated standard exists for all hazardous materials found at a site are uncommon; Method 2 has not been implemented because specific sets of cleanup levels have not been developed.

4. Even though guidance exists for the use of the current risk characterization methods, the results of risk characterizations are neither predictable nor consistent.

As a result of the criticisms raised about the existing risk characterization methods, the following objectives were developed in order to guide the development of alternatives:

1. Simplify the characterization of health risk in determining the need for remediation, achieving greater consistency and predictability and perhaps reducing cost and time requirements;

2. Simplify the identification of remedial concentrations which would meet the no significant health risk requirements of the MCP, also achieving greater consistency and predictability and perhaps reducing cost and time requirements;

3. Clarify the applicability of the risk characterization methods proposed;

4. Retain some flexibility provided by the focus on cumulative (total) risk in achieving the no significant health risk requirement of the MCP; and

5. Assure that risk characterization methods maintain the protection of public health.

3.2 Alternative Risk Characterization Methods for Sites

3.2.1 Conceptual Alternatives

Section 1.0 describes the basic components of risk characterization. In general, a measured or hypothetical exposure is used in combination with a representation of toxicity in order to provide a characterization of risk or hazard. This evaluation can be done on several different levels. These increasingly complex levels of evaluation are described below and in Figure 3-1:

1. *Chemical-specific Evaluation*

At the simplest level, risks can be characterized by looking at each chemical and each exposure pathway separately. For example, exposures to lead in groundwater would be evaluated independently of other chemicals present in the groundwater and independently of other exposure pathways (e.g. soil pathways) that may involve lead. Using this approach, the risk characterization is conducted by comparing measured or modelled environmental concentrations with some type of media specific clean-up levels or by using the concentrations to estimate exposure and risk or hazard estimates and comparing those to a risk management standard appropriate for single chemicals and single pathways(See next section). The exceedance of either a cleanup level or a risk management standard can trigger the need for remediation to that level, further investigation, or a more detailed risk characterization.

2. *Pathway-specific Evaluation*

Risks can also be characterized by assuming cumulative (additive) effects for chemicals within a pathway and considering each pathway independently. For example, exposure to groundwater would be considered by evaluating the additive effects of all chemicals found in that medium, regardless of other exposure pathways that may be relevant. Using this approach, the risk characterization is conducted by using measured or modelled environmental concentrations to develop exposure and risk or hazard estimates for a pathway. These estimates are then compared to a pathway specific risk management standard in order to evaluate the need for or adequacy of remediation.

3. *Multi-media Evaluation*

In its most complex form, risks can be evaluated by considering all of the pathways through which a person (receptor) may reasonably be exposed to contamination from a site. For example, if a person could be exposed to soil and groundwater, the exposures and risks or hazards are considered by evaluating the additive effects of all chemicals in each medium, and the additive effects of the two media (soil and groundwater). Using this approach, the risk characterization is conducted by using the measured or modelled environmental concentrations to develop exposure and risk or hazard estimates for a pathway. These estimates are then summed to represent total exposure and risk to a hypothetical individual (receptor). The total risk estimates are then compared to a total risk management standard in order to evaluate the need for or adequacy of remediation.

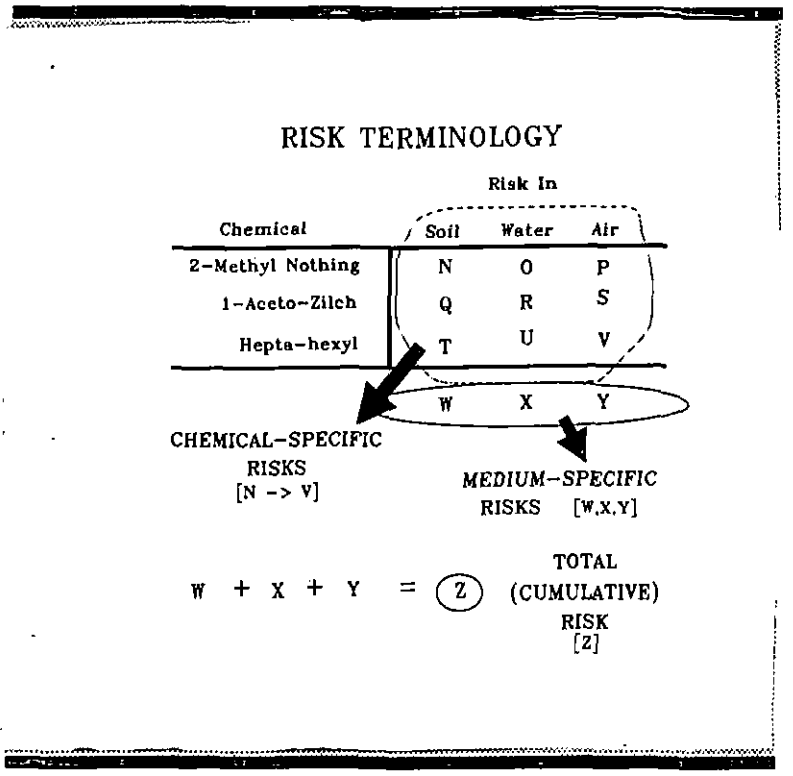


Figure 3-1

3.2.2 Risk Characterization Methods Used by Others

3.2.2.1 Other State Superfund Programs

Other states use a variety of combinations of the above conceptual methods. Most states have a chemical-specific component, and some also have a multi-media approach that comes into play either in more detailed phases of an investigation, or at more complex sites.

For example, **California** has three levels of risk characterization. Upon exceedance of risk management criteria, a higher level (more detailed) risk characterization is performed, leading ultimately to remediation of the site. The first level of risk characterization involves a comparison of levels of contamination to chemical-specific screening levels. Screening levels have been developed for drinking water supplies, ambient water for fish intended for human consumption, soil, and air. However, while

the screening levels are chemical-specific, California has incorporated multimedia considerations into their use. The screening levels are used in three ways:

Level 1 Compare concentrations to screening levels for each chemical and media (chemical-specific evaluation). If any are exceeded, a more detailed risk characterization is required (Level 2).

Level 2 This approach considers cumulative effects of exposure to a given chemical by different pathways. The ratios of chemical concentration to screening level are summed for each chemical in all media relevant to a hypothetical receptor. If the total for any chemical exceeds 1, a more detailed risk characterization is required (Level 3).

Level 3 Sum ratio of chemical concentration to screening level for all chemicals and all media relevant to a hypothetical receptor (multi-media evaluation). If total for any receptor exceeds 1, a more detailed assessment is required.

All of the above tests must be performed in the early stages of a response action. If none of the above tests show that the risk management criteria are exceeded (and no environmental risk exists), then no further action is required. If the risk management criteria are exceeded, further work is required. In particular, a Soil Remediation Level (SRL) assessment or a complete baseline risk characterization must be performed. Both of these are multi-media approaches. The SRL assessment is a shortened version of a complete assessment that uses conservative default values. If either of these assessments shows that no significant risk to human health exists, "certification" of stabilization or remediation will obtained. If risk management criteria are exceeded, then long term stabilization and final remediation is required. Ultimately, the adequacy of the remediation must be demonstrated by a multi-media risk characterization.

In contrast, **New York** has proposed using a chemical specific, and in some cases, a pathway specific approach. In general, risks are characterized on a chemical and media specific basis by comparison of environmental concentrations to standards and guidelines developed for each media (air, surface water/groundwater, soil, and sediment). The standards and guidelines and implementation protocols have apparently been developed by different programs and are not entirely consistent. For air, measured or modelled concentrations are compared to annual guideline concentrations (AGC). If "many" constituents are present, the sum of the ratios of the concentration to the AGC is developed (the pathway-specific approach). For surface water and groundwater, seven categories of different uses are identified with cleanup levels specific to each category, although many chemical-category combinations have no cleanup level. In this case, one must be developed (by the PRP) using the methodology provided. There does not appear to be a consideration of additive effects within the surface water/groundwater pathways. For soil, initial target soil cleanup concentrations are identified, but they

consider ingestion only. Risks associated with soil pathways are addressed on a case-by-case basis considering the human health, water quality and fish and wildlife. In general, however, the approach is chemical specific.

New Jersey has taken a similar approach to New York in proposing chemical-specific cleanup standards for building interiors, soil and groundwater. For groundwater, the most sensitive categories require natural background (concentrations that would exist in the absence of man-made sources) as the cleanup standard for the most sensitive categories. Many other categories require a site-by-site evaluation. The cleanup standards apply to Class II-A groundwaters (drinking water resources). Risks in those locations are characterized by a comparison of measured or modelled concentrations to cleanup standards. Soil cleanup standards have been developed for residential surface soils, non-residential surface soils and subsurface soils. Risks are characterized by comparison of measured concentrations to cleanup standards. Additive effects within a pathway and multi-media exposures are not considered. However, the state can be petitioned or impose an alternative cleanup standard which can be based on considerations of additive effects.

3.2.2.2 EPA Federal Superfund

EPA 1989 guidance (Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual - Part A (EPA/540/1-89/002) indicates that EPA's approach to risk characterization at Superfund sites is a multimedia pathway evaluation as described in the previous section. Their guidance requires the consideration of media specific standards and guidelines in order to characterize risk, but also the consideration of pathway exposures, as well as multi-media exposures to a theoretical receptor. In addition, a recent directive from the Office of Solid Waste and Emergency Response (OSWER Directive 9355.0-30) indicates that baseline risk assessments (Phase II risk characterizations in MCP terminology) are conducted by considering chemical specific standards and cumulative site risk to an individual using reasonable maximum exposure assumptions for either current or future land use. The cumulative risk estimates are compared to cumulative risk management standards.

The above documents, however, represent national policy. Risk characterization methods used at the regional level are sometimes different. A meeting was held with EPA risk characterization specialists on May 15, 1992 in order to discuss risk characterization methods used at Region I EPA Superfund sites. Region I uses a pathway-specific risk characterization method. Risks are characterized by comparison to pathway specific risk management criteria. Region I is reluctant to adopt the multimedia pathway approach to characterizing risk because they use maximum exposures for each media. (This issue relates to the conservatism of assumptions and will be discussed further in another discussion document.)

3.2.2.3. Other DEP Programs

Risk characterization in other DEP programs primarily occurs in permitting or siting decisions, in addition to the evaluation of existing sources or resources. For the most part, other DEP programs rely on chemical-specific risk characterization approaches through the comparison of existing or projected media concentrations with standards and guidelines. In some cases, additive effects are considered. In particular, contaminated water supplies can be evaluated considering additive effects of the contaminants present. The need for such an evaluation is determined on a case-by-case basis. Further discussion of risk assessment in other DEP programs is provided in Section 5.0.

3.2.3 Advantages and Disadvantages of Alternative Methods

The advantages and disadvantages of the three conceptual alternative methods described in Section 3.2.1 are summarized in Table 3-2. In general, the increasingly detailed methods involve more extensive preparation and evaluation time, but result in a corresponding increase in assurance that all exposure pathways have been considered and that adequate protection of public health has been achieved.

3.3 Recommendations for MCP Risk Characterization Methods

3.3.1 General Description

In considering the objectives of simplicity, consistency and predictability described in Section 3.2, and the methods described above, it is obvious that the current system for risk characterization as a whole is too complex. There are too many methods and the applicability of each method is unclear. It is also obvious that a simpler method for risk characterization needs to be available. In order to address these conclusions, the workgroup proposes to reduce the number of risk characterization methods to two, and to make one of those methods a relatively simple method that will not require quantitative risk characterization for each site. This document is a proposal developed for the purpose of soliciting detailed, substantive comments and to encourage creative fabrication of alternative approaches by commentors. The two methods are briefly described as follows:

Proposed Method 1 Human health risk characterization by this method would involve the comparison of measured or projected environmental concentrations (exposure point concentrations) to a list of chemical-specific, media-specific "cleanup standards". Exceedence of any of these standards (by exposure point concentrations) would indicate the presence or potential for a significant risk to public health. This is a chemical-specific evaluation as described above.

Proposed Method 2 Risk characterization by this method would involve the comparison of measured or projected exposure point concentrations to applicable or suitably analogous standards and the quantitative evaluation of total site risks. This method is the same as the current Method 3.b in the MCP, a multi-media evaluation.

This proposal meets the objectives of simplicity and predictability, but still retains some level of flexibility. It should be noted that the use of either of these methods at a site would require the same level of site characterization, receptor identification, exposure pathway analysis and the development of exposure point concentrations.

We have proposed Method 1 primarily to address the need for simpler methods. However, we propose retaining Method 2 (previously Method 3.b) in order to allow for more detailed assessments if warranted, and to maintain the flexibility in development of cleanup standards that this method allows. In some respects the proposed Method 1 reflects decisions made by regulators in New York and New Jersey to set cleanup standards for certain chemicals in certain specific situations. By allowing the option of Method 2 the proposal retains some of the flexibility and benefits inherent in the California approach.

These methods are distinct alternative risk characterization methods; one or the other method would be used in characterizing the risk to human health posed by the site. However one method can be used to identify the presence of a significant risk (and thus trigger the requirement for remediation) and the other method could be used to demonstrate that a level of no significant risk has been achieved after the implementation of a remedial measure. The Workgroup seeks comment on how the choice of Method may be implemented.

3.3.2 Method 1

3.3.2.1 Framework of Cleanup Standards

The MCP would contain or refer to lists of cleanup levels. It is likely that there would be cleanup levels for soil and groundwater, at a minimum. Cleanup levels may also be necessary or desirable for air (indoor and outdoor), surface water and sediment.

Table 3-2

Advantages and Disadvantages of Risk Characterization Methods

METHOD	ADVANTAGES	DISADVANTAGES
Chemical-specific	* Simple to use and evaluate * Provides quick and consistent method for evaluating site conditions	* Requires upfront development time and maintenance of cleanup levels * Does not consider cumulative effect of multiple exposures; may not be protective of public health
Pathway specific	* Pathway evaluation can be consistent with other programs' requirements * Consistent with Region I EPA practice	* Requires fairly detailed evaluation including quantitative exposure assessment * May not be protective of public health
Multi-media	* Protective of public health * Consistent with EPA national policy	* Requires detailed evaluation including quantitative exposure assessment and pathways analysis

It also seems likely that this method would consist of various lists of cleanup standards applicable to different situations. The situations would be defined by potential exposure scenarios. For example, surface soil cleanup levels could be developed that would be applicable in locations where exposure to children was occurring or was likely to occur given the foreseeable use of the site. Similarly, groundwater cleanup levels could be developed that would be applicable in locations where groundwater was currently or likely to be used as a water supply. The more lists and types of locations considered, the more tailored the applicable cleanup levels can be. However, the number of different lists will have to be limited in order to make the regulations understandable and workable. New Jersey has approximately seven types of locations for which groundwater cleanup levels are defined. They combine a consideration of environmental resources in addition to public health. The list of cleanup levels is only applicable in locations of potential water supply. In some particularly sensitive locations, natural background is identified as the cleanup standard, with the specific background concentrations to be determined on a case-by-case basis. In other locations, upgradient background is specified as the cleanup level, again to be determined on a case-by-case basis. These kinds of considerations could be incorporated into this risk characterization method if protocols are provided for determining such background concentrations.

In order for this method to be available as an alternative to Method 2 at all sites, the lists must be comprehensive. In other words, one of the lists or another set of requirements must be applicable in any given situation. If this is not the case, then presumably the proposed Method 2 would have to be used if no suitable list of cleanup levels is available.

Cleanup levels should be developed for as many substances as possible in order to make this method workable. However, provisions will be needed for situations where no cleanup level is available for a given situation. In order to address this problem, the method could provide procedures for development of cleanup levels when none are available, default cleanup levels, or cleanup levels for chemical classes.

3.3.2.2. Use of Cleanup Levels

In making determinations about the significance of human health risk, the cleanup levels would be used for comparison to exposure point concentrations. If any exposure point concentrations (current or projected) exceeded an applicable cleanup level, it would be concluded that the site poses a significant risk to public health. The cleanup levels could incorporate some consideration of environmental risk, but it is likely that additional evaluation of risk to the environment would be required, as well as risk to safety and public welfare. It is also possible that qualitative evaluation of some human exposure pathways may be required in addition to the consideration of the cleanup levels.

The risk characterization using Method 1 would require an "adequate" site characterization and consideration of the location in order to determine the applicable set of cleanup levels, and to ensure that exposure point concentrations used in the evaluation are representative. (See May 21, 1992 Draft NFA Proposal, Appendix A).

The cleanup levels become the minimum requirements for the protection of public health. Cleanup to the applicable levels would be required in order for the remedy to be considered a permanent solution. It is possible that alternatives could be proposed that change the applicability of the cleanup levels used in the risk characterization, for example, deed restrictions could be proposed to limit access. In such a case, a different set of cleanup levels could be applicable for that alternative, or Method 2 could be used to demonstrate that such an alternative represents a permanent solution.

Cleanup levels could also be used in no further action determinations, provided that adequate consideration has been given to the applicability of the cleanup levels in terms of the type of location, and that the characterization of the site has been "adequate". The "no further action" discussion paper goes into these issues further. In any case, cleanup levels and no further action levels should not be different, as their purpose

(identifying environmental concentrations that could pose a significant risk to public health) is the same.

It is possible that cleanup levels developed for Method 1 could also serve as notification criteria, although the implementation of the numbers would be different. This will be discussed further in Section 5.2.1.

3.3.2.3. Pros and Cons of Proposed Method 1

The primary advantage of the use of cleanup levels as a risk characterization method is that it provides a simple and predictable approach to evaluation of risks to public health. In addition, they provide an early and consistent indication of the level of cleanup that the Department is expecting. However, there are a number of limitations to this method:

1. Site specific conditions can be considered only to a limited extent. The fewer sets of cleanup levels, the less variables such as natural background, relevant exposure pathways, site geology, etc. can be considered in the evaluation of risks to public health posed by the site.

2. The cleanup levels ignore additive effects of chemicals and pathways. This may be significant for certain sites. Cleanup levels will also, by necessity, ignore certain exposure pathways in their development. These pathways may be important at certain sites.

3. Increased reliance upon chemical-specific cleanup standards may shift the emphasis from the evaluation of potential human exposures to simple comparisons of raw analytical data. Under the current MCP too little consideration is given to remedial alternatives which prevent or reduce potential human exposure, even though such actions could reduce *Exposure Point Concentrations* to levels of no significant risk. Instead the focus has been on concentration reduction since it is the most straightforward approach to reducing risk, although it may not be the most creative or cost-effective alternative (or even feasible). Promulgated cleanup standards may increase the prevalence of the "*Just give me a number*" mentality.

3.3.3.3. Pros and Cons of Proposed Method 2

The total site risk method is a good complement to the proposed Method 1, as it addresses all of the limitations for the Method 1 proposal identified above. It considers site specific conditions, additive risks of chemicals and pathways, and provides flexibility in terms of cleanup levels and relevant remedial alternatives. Since either method can be selected, if a characterization or cleanup at a particular site is impacted by the limitations of proposed Method 1, the use of proposed Method 2 would address these limitations.

The limitations of the total site risk method are primarily related to its complexity and time consuming nature. The Residential Short Form tool is intended to alleviate this drawback in some circumstances.

3.4 Summary of Recommendations

The Workgroup felt that the most efficient way of soliciting comments on alternative methods of risk characterization was to develop a proposal in a manner which could allow for detailed, concrete comments. While it is the recommendation of the Workgroup to allow human health risk characterization in the revised Waste Site Cleanup process to be conducted by one of two proposed methods, comments on this proposal, suggested modifications or alternative approaches are strongly encouraged by the Workgroup.

Proposed Method 1 Risk characterization by this method would involve the comparison of measured or projected environmental concentrations (exposure point concentrations) to an applicable list of chemical-specific, media-specific "cleanup standards". There may be different lists applicable to different types of locations and site characteristics. The exceedence of any of these standards (by exposure point concentrations) would indicate the presence or potential for a significant risk to public health.

Proposed Method 2 Risk characterization by this method would involve the comparison of measured or projected exposure point concentrations to applicable or suitably analogous standards and the quantitative evaluation of total site risks. This method is the same as the current Method 3.b in the MCP.

The reasons for proposing these changes are to simplify the risk characterization process and to provide a method (proposed Method 1) that allows predictable and consistent results. Proposed Method 2 provides a more flexible approach, which was also considered desirable

by the work group. The proposals detailed above do not represent a major change from the four method approach in the current MCP. Rather it can be viewed as simply the collapsing of the current Methods 1, 2 and 3a into a single method (proposed Method 1) and retaining the site-specific approach of the current Method 3b in the proposed Method 2.

This proposal presents no conceptual disadvantages as compared to the current MCP risk characterization methods for human health. Proposed Method 1, however, would require a considerable effort by the Department to develop the cleanup levels, identify location where they are applicable, and develop detailed protocols for their use. Several other states have implemented similar methods, as described above, and their regulations and guidance regarding these methods are quite complex. In addition, no other state has proposed or implemented sets of cleanup levels that would address all situations. Most have cleanup levels that apply in certain types of locations, but other types require site specific assessment. At this time, the Workgroup is proposing that Method 1 be a complete alternative, in that there would be the option to utilize that method, regardless of the type of location, as long as appropriate cleanup standards have been promulgated by the Department.

3.5 Issues for Comment

Comments are welcome on any aspect of this section of the issue paper. In addition, the work group would like specific comments on the following questions:

1. Does the proposed approach meet the objectives of simplification, consistency and predictability while maintaining some level of flexibility?

2. Is the proposed approach workable, in particular Method 1? (Note: this is hard to answer given that the specific framework for Method 1 has not been laid out).

3. The assumption in the proposal is that Method 1 is comprehensive. However, should the applicability of Method 1 be limited by, for example, the number of chemicals found, the number of media contaminated, or by the presence of certain exposure pathways not considered in Method 1?

   Should the use of Method 2 be restricted? For example, should a choice between Method 1 and Method 2 be given for sites where one chemical is present in one exposure medium? (Such a choice could allow some difference in residual risk level, dependent solely upon the choice of Method.)

In addition there are many questions that will have to be answered in the development of Method 1. Some of them are found below. Any thoughts on these questions would also be useful:

1. What sets of cleanup levels should be developed? Some initial thoughts include surface soils - residential - with and without gardens, surface soils - restricted access areas, subsurface soils, groundwater - water supply areas, groundwater - critical resource areas (that are not water supply areas), groundwater - discharging to surface waters. Keep in mind, that there has to be a list for every circumstance for this method to be comprehensive.

2. Should we incorporate an environmental component into these cleanup levels, even though the primary intent is to characterize human health risks. Doing this wouldn't eliminate the need for separate consideration of environmental risks, but could at least ensure that the minimum needs of an environmental evaluation would be met.

3. On a related issue, should antidegradation considerations be incorporated into the cleanup levels for certain types of areas? This would not likely be a set of concentrations, but a requirement to initiate remediation and to achieve levels, if feasible, in certain sensitive location if concentrations are above natural or area background.

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4.0 RISK MANAGEMENT CRITERIA

4.1 Introduction

While risk assessment and risk management are two distinct processes, how and when they are applied can vary depending upon the application or circumstances. Oftentimes the two steps overlap, but it is still important to recognize the differences. The *risk assessment* gives us information on the level of risk associated with exposures at a site. The *risk management* process defines whether those risks are considered "significant", and whether remediation is required. If remediation is necessary, the risk management process defines the level of remediation required to achieve a *permanent* or *temporary solution.*

Permanent solution is defined in the statute and regulations, and the attainment of a *permanent solution* requires the elimination of "significant risk" of harm to human health, safety, public welfare and the environment for all current and foreseeable future uses of the disposal site and surrounding area. In addition, a *permanent solution* should reduce, to the extent possible, the level of oil or hazardous material in the environment to the level that would exist in the absence of the disposal site - commonly referred to as "background". A *temporary solution* must be implemented if a permanent remedy is not feasible at the present time. A *temporary solution* eliminates "significant risk" until a *permanent solution* is in place. While "Significant Risk" has no universal definition, the enactment of Chapter 21E and the promulgation of the Massachusetts Contingency Plan required that the Department provide a working definition. This definition forms the basis of the risk management decisions at c.21E sites.

Consistent with the statute, a risk management philosophy was developed for the MCP which: (1) recognized the legislative and referendum mandate to protect human health, safety, public welfare, and the environment, (2) was consistent with existing state regulatory programs, and (3) restored sites to background conditions whenever feasible. The MCP risk characterization process was designed to ensure that this risk management philosophy is consistently applied at all disposal sites.

The following sections briefly describe the criteria used in the current MCP and details their use within the existing four Method risk characterization framework which were described in detail in Section 3.1.1. Alternative risk management criteria are proposed for the proposed risk characterization framework described in Section 3.3.

4.1.1 Standards and Guidelines

Chemical-specific standards and guidelines are perhaps the most commonly encountered risk management criteria in environmental regulations. A standard or guideline generally consists of a chemical name and an allowable concentration for the medium of concern. Standards and guidelines often include analytical requirements (frequency of monitoring, specification of analytical method, etc...) as well. Exceedance of a standard or guideline is often presumed to constitute a "significant risk".

The term "*standard*" is generally taken to mean a requirement which is promulgated in regulation, whereas a "*guideline*" is contained in policy or guidance. There is thus a difference in the enforceability of standards vs. guidelines, and this issue is often confused by the promulgation of regulations which specifically call for the use of particular sets of guidelines. One such example is the Massachusetts Groundwater Standards, in which federal and state "Health Advisories" (drinking water guidelines) are specified in 314 CMR 6.07 (3). The use of guidelines in this manner allows for quick revisions of numerical standards in response to new scientific information without the need to promulgate changes to a regulation. Unfortunately such regulations contribute to the perception that guidelines are enforceable, when, in fact, the regulations have the effect of converting the guidelines to standards.

- *An example of a standard:* The Massachusetts Maximum Contaminant Level (MMCL) for Benzene of 0.005 mg/L in drinking water (310 CMR 22.00).
- An example of a guideline: The Office of Research and Standards Drinking Water Guideline (ORSGL) for Acetone of 0.7 mg/L in drinking water.

The methodology used to develop a standard or guideline is not easily summarized as it depends upon the goals and requirements of the program for which they are developed. In general, *standards* consider human health risks, but are often adjusted to account for other considerations including cost, technical feasibility, analytical limitations and background (a *risk-balancing* approach). *Guidelines*, on the other hand, are more likely to be based solely upon human health concerns (a *risk-only* approach). It may be that such a distinction based on risk-management approach is purely coincidental. A standard or guideline which is based all or in part on human health considerations must incorporate more basic risk management considerations specific to the health endpoint of concern (carcinogenic or threshold-type effects). These are described in the following two sections.

4.1.2 Non-Cancer Health Risk Measure: the Hazard Index (HI)

Non-cancer health effects include health endpoints such as Central Nervous System (CNS) disorders, respiratory distress, liver disfunction and death. Carcinogenic effects are evaluated independently as exposure to a chemical may be associated with *both* carcinogenic and non-carcinogenic effects.

For any given chemical associated with non-carcinogenic effects, it is believed that a dose exists *at and below which* no adverse health effects would be expected. Such a level is referred to as a "*threshold dose*". While it is difficult to identify this theoretical threshold dose for any given chemical due to individual variation of response and the limitations of experimental methodologies, it is possible to estimate a human sub-threshold dose at which no adverse effects would be expected. This is done following protocols developed by the scientific community and endorsed by the U.S. EPA. When such a dose is developed and reviewed by the U.S. EPA, it is called a ***Reference Dose*** **(RfD)**. For inhalation exposures, the analogous measure is called the ***Reference Concentration***, or **RfC.**

The Reference Dose (or Reference Concentration) could be considered a "safe" dose, as no adverse health impact would be expected following even an extended (lifetime) exposure to that level of the chemical.

The risk of potential non-carcinogenic health effects following exposure to a chemical is measured simply through the comparison of an individual's (or receptor's) site-related exposure to that chemical and its published Reference Dose. The risk measure is called the ***Hazard Index***, and is described by the equation:

Hazard Index = Estimated Dose / Reference Dose

or

Hazard Index = (Estimated Concentration in Air) / Reference Concentration

A Hazard Index of 1.0 would indicate that the receptor's exposure is equal to the "allowable" exposure level (i.e., the RfD), and it is considered unlikely that adverse health effects would occur. A Hazard Index *greater than* 1 does <u>not</u> imply that health impacts would necessarily be expected: the interpretation of the Hazard Index must consider the appropriateness of the exposure assumptions and the basis of the Reference Dose used in the calculation.

4.2 THE EXISTING PROGRAM

4.2.1 Current MCP Health Risk Management Criteria

The current health risk management criteria in the Massachusetts Contingency Plan are a combination of public health standards and guidelines and measures of quantitative risk (HI and ELCR), as well as policies and sets of cleanup levels. These risk management criteria are specific to the four risk characterization methods (described in Section 3.1.1) used to assess the need for remediation in Phase II, used to (theoretically) develop cleanup requirements, and to demonstrate the elimination of "significant or otherwise unacceptable" risk of harm to health in Phase III and Phase IV.

These risk characterization methods do not address risks to safety, public welfare or the environment. The risk management criteria for each of the existing methods are summarized briefly below, and in Table 4-1. Note that the common element in each of these Methods is the use of any applicable or suitably analogous standards, a requirement of the statute (Section 3.a.(g)).

4.2.1.1 Method 1 (310 CMR 40.545(3)(g) 1.)

Method 1 compares the exposure point concentration (EPC) of each oil or hazardous material to a promulgated applicable or suitably analogous ***standard***. Chemical- and medium-specific standards are the sole risk management criteria employed in this Method. Such standards have generally been developed and promulgated pursuant to one of the MA DEP medium-specific regulatory programs, and reflect the risk management goals of those programs. The most common example of Method 1 risk management criteria are the drinking water standards (Massachusetts Maximum Contaminant Levels) promulgated by the Department's Division of Water Supply in 310 CMR 22.00. Such standards are rarely, if ever, strictly health-based.

4.2.1.2 Method 2 (310 CMR 40.545(3)(g) 2.)

Method 2 would compare the exposure point concentration of each oil or hazardous material to a ***clean-up level*** developed for particular site "types" (such as petroleum sites or coal gasification waste sites) and listed in 310 CMR 800. This Method is currently unavailable as no such sets of clean-up levels have been promulgated.

4.1.3 Carcinogenic Effects: Excess Lifetime Cancer Risk (ELCR)

Unlike the non-cancer effects described above, it is generally assumed that there is <u>no</u> threshold dose for carcinogenicity. In other words, it is believed that ***any*** exposure to a carcinogenic substance is associated with some risk. As exposure increases, the incidence of cancer is expected to increase. This relationship between exposure and cancer incidence is described by one of two measures: the ***carcinogenic potency value*** or the ***unit risk***.

4.1.3.1 Carcinogenic Potency Value (CPV)

The Carcinogenic Potency (or Slope) Value for a chemical is derived by the U.S. EPA's Cancer Assessment Group (CAG). The Potency Value is an estimate of the upper 95% Confidence Limit of the slope of the dose-response curve extrapolated to low doses. For some chemicals, human epidemiologic data (generally from the study of workers) is the basis of an estimate of the carcinogenic potency, although the most common basis of these values is an animal study. The Potency Value is given in units of $(mg/kg/day)^{-1}$.

4.1.3.2 Unit Risk Values (URs)

The Unit Risk is the upper 95% Confidence Limit of the average additional lifetime cancer risk estimated to result from lifetime exposure to an agent if it is in the air at a concentration of 1 $\mu g/m^3$ or in the drinking water at a concentration of 1 $\mu g/L$. These values are used in lieu of the chemical's Potency Value.

For a given chemical, the estimated Excess Lifetime Cancer Risk (ELCR) is considered to be an upper-bound probability of the likelihood of developing cancer *as a result of a given exposure*. It is calculated as the product of an individual's quantified exposure and a measure of carcinogenic potency, as described by the equations:

ELCR = (Lifetime Average Daily Dose) * (Carcinogenic Potency Value)

or

ELCR = (Lifetime Average Exposure Point Concentration) * (Unit Risk)

4.2.1.3 Method 3.a. (310 CMR 40.545(3)(g) 3.a.)

Method 3a risk characterizations employ the following risk management criteria (in *order*):

i. Applicable or suitably analogous public health ***standards*** where they exist;
ii. Public health-or-risk-based ***guidelines*** or ***policies*** approved by the Department where they exist;
iii. Public health-or-risk-based ***guidelines*** proposed by the PRP.

Note: A guideline for an OHM proposed by a PRP is to be set so that the cancer risk associated with the guideline is no greater than 1×10^{-6} and the daily receptor dose resulting from exposure to the concentration specified in the guideline is no greater than 20% of the appropriate Reference Dose or other allowable dose specified by the Department. The 20% factor is a *"source allocation factor"* chosen in consideration that individuals may experience exposures to OHM from sources unrelated to the disposal site under investigation.

Method 3a expands the universe of risk management criteria of Method 1 to include health-based guidelines.

4.2.1.4 Method 3.b (310 CMR 40.545(3)(g) 3.b.)

At the so-called "multi-media" sites, the risk management criteria include:

i. applicable or suitable analogous public health ***standards*** where they exist; ***and***
ii. A Total Site Cancer Risk Limit equal to one in one hundred thousand (1×10^{-5}); ***and***
iii. A Total Site Non-cancer Risk Limit measured as a Hazard Index equal to 0.2.

Under this Method, the use of both standards and quantitative risk assessment insures that any applicable or suitably analogous standards are met while capping the health risk associated with the disposal site.

4.2.2 Development of the Existing MCP Risk Management Criteria

4.2.2.1 Standards, Guidelines and Policies

The risk management criteria used to evaluate risk within the context of the MCP evolved over a period of 12-18 months as the four methods of risk characterization were developed. Having decided to use existing chemical-specific standards and guidelines in Methods 1 and 3a, further risk management criteria were not necessary: any existing standards or guidelines would be used as-is, and any further guideline development

(Method 3a) would be conducted in a manner consistent with the practices of the MA DEP medium-specific Divisions, which include the Division of Water Supply and the Division of Air Quality.

TABLE 4-1

CURRENT MCP
RISK ASSESSMENT METHODS

METHOD (Only one method is applicable at any given disposal site)	RISK MANAGEMENT CRITERIA
1 [40.545(3)(g)1]	• Chemical- and medium-specific applicable or suitably analogous standards.
2 [40.545(3)(g)2]	• Sets of chemical- and medium-specific cleanup levels set forth in 310 CMR 40.800, developed for types of disposal sites.
3.a. [40.545(3)(g)3.a.]	• Chemical- and medium-specific applicable or suitably analogous standards, where they exist; • For OHM for which standards do not exist, health- or risk-based guidelines or policies approved by the Department, where they exist; • For OHM for which standards, guidelines or policies do not exist, a health- or risk-based guideline proposed by the PRP, based on a Hazard Index equal to 0.2 and an Excess Lifetime Cancer Risk equal to one in a million (1×10^{-6}).
3.b. [40.545(3)(g)3.b.]	• Chemical- and medium-specific applicable or suitably analogous standards, where they exist; *and* • Total Site Cancer Risk Limit = 1×10^{-5} (one in one hundred thousand) • Total Site Non-Cancer Risk Limit of a Hazard Index = 0.2

4.2.2.2 Cancer Risk

Once the idea of total site risks (Method 3b) was adopted, the total site risk limits had to be agreed upon. The "Significant Risk" project (MA DEQE, 1988) provided information and perspective for this effort. That project included a survey of health risk decision-making for air permitting, drinking water regulation and hazardous waste sites by regulatory agencies in California, Michigan, New Jersey, New York and Wisconsin and a survey of health risk decision-making by federal agencies including EPA's Office of Air Quality Planning and Standards, Office of Drinking Water, Office of Toxic Substances, and Office of Waste Programs Enforcement (Superfund at that time). Also contacted were the Association of State and Territorial Solid Waste Management Officials, the Public Health Foundation, and the National Governors Association, all of which had conducted or were conducting surveys of state approaches to hazardous waste site evaluation.

There are really three measures of cancer risk which can be part of cancer risk assessment/risk management activities. As reported in Travis et al. (1987), individual risk, size of the exposed population, and population risk may all be (and often are) considered in assessing the managing cancer risks.

Individual risk is an estimate of the probability that an individual (often the most exposed individual) in a population would develop cancer as a result of exposure. The *size of the exposed population*, if it is very small or very large, may heavily influence a decision to not regulate or to regulate an identified exposure. *Population risk* is an estimate of the number of additional cancer cases (often reported as deaths) which could result from exposures to an identified population over some time period.

Obviously, if the population risk is very low (less than 1 additional case per year or much less than 1) a decision not to regulate may be indicated. Work published by Travis et al. (Travis, 1987) suggests that federal regulatory agencies manage cancer risk based on a combination of individual risk and population risk. It appears that the level of individual risk which obviously requires regulation is a function of population risk, with the individual risk level of concern being lower as the population risk increases. That is, the smaller the population potentially affected, the higher the level of individual risk that is considered acceptable. In this case, the "insignificant" individual risk is between 10^{-5} and 10^{-4} for small population risks and between 10^{-7} and 10^{-6} for large population risks.

The Travis et al. article suggests that hazardous waste sites, in general, pose small population risks (because the population exposed is relatively small), and past federal regulatory actions suggest 10^{-4} as an "insignificant" individual risk level for such sites. NOTE: The cancer risk estimates by the federal agencies addressed in Travis et al. are "maximum risk estimates" and may not be directly comparable to risk estimates conducted per MCP associated guidance. For example, individual risks may be estimated using maximum expected exposure concentrations rather than average concentrations.

A conscious decision was made in early 1988 to focus the MCP risk management criteria on individual risk since the program deals closely with communities and potentially impacted individuals. It was also decided that the MCP would offer the same level of protection to individuals independent of the size of the exposed population.

The results of the "Significant Risk" Project suggested that regulation of individual carcinogens at 10^{-6} risk was very common and that regulation of total cancer risk for a situation at 10^{-6} or 10^{-5} risk was common. Regulation of non-carcinogenic effects was most often accomplished via enforcement of existing health-related standards and guidelines (occupational limits, drinking water standards and health advisories, etc.).

The total site cancer risk limit of 1×10^{-5} was selected by the DEP work group composed of management and staff from all programs. That group considered the risk management criteria as identified in the Project report, as well as practical considerations such as consistency with other programs.

4.2.2.3 Non-Cancer Risk

The total site non-cancer risk limit, a Hazard Index of 0.2, is a DEP adaptation of an EPA Office of Drinking Water approach. The federal Superfund program considers a Hazard Index greater than 1 (one) to be potentially significant. The Office of Drinking Water at EPA, in developing Health Advisories (allowable drinking water concentrations protective against non-cancer health effects) has routinely allocated only a portion of the allowable human dose to the drinking water exposure pathway. In the absence of chemical specific information about levels of exposure from non-drinking water sources (diet, occupations exposures, other environmental exposures), the Office of Drinking Water has allowed only 20 percent of the allowable dose (or Reference Dose) for a given chemical to come from drinking water exposures.

The Office of Research and Standards suggested, and the DEP workgroup agreed, that a similar "source allocation factor" be employed at c. 21E sites, such that 20 percent of the allowable doses of all OHM would be allowed to be contributed from a site. Therefore, the total site non-cancer risk limit, expressed as a Hazard Index of 0.2, was proposed. The DEP's guidance document (MA DEQE, 1989) describes the general methodology to be used in calculating the Total Site Non-Cancer Risk, emphasizing that simple summation of the chemical-specific hazard indices is a rough-cut screening exercise. The risk assessor had the option to categorize the contaminants by mechanism of action and/or toxic end-point (i.e., target organ) in order to yield more finely tuned risk estimates.

4.2.3 Lessons Learned Since the Implementation of the MCP

A number of lessons have been learned from national developments and the Department's experiences subsequent to the promulgation of the Massachusetts Contingency Plan in October of 1988. Some of the major points are briefly listed below.

i. The U.S. Environmental Protection Agency revised the National Contingency Plan (NCP), and stressed the concept of "*Cumulative Risk*" (40 CFR 300.430(e)(2)(i)(D)), the functional equivalent of the MCP's "*Total Site Risk*". This additivity of risk was more fully described in U.S. EPA guidance, particularly the *Risk Assessment Guidance for Superfund: Volume I* (US EPA, 1989a). The concept of regulations based on cumulative risk is more widespread now than when the MCP was originally promulgated.

ii. The Total Site Non-Cancer Risk estimates are rarely "finely tuned" by mechanism of action or target-organ. This may be due to time or financial pressures on the consulting community, lack of expertise in the consulting community, or inadequate guidance from the Department. In any event, the simple summation of the chemical-specific Hazard Indices to yield a single Total Site Hazard Index is often regarded (incorrectly) as the ultimate regulatory number, rather than a screening tool.

iii. The use of the 20% source allocation factor currently used in the Total Site Non-cancer Risk management criteria may not be necessary due to the consideration of uncertainties in the exposure assessment and the toxicity information used to evaluate risk. No other regulatory program (state or federal) uses a <u>total</u> Hazard Index less than 1.

iv. The distinctions between and the use of promulgated standards, existing public health guidelines and risk-based cleanup levels are often confused, leading to a "hybridization" of the four current methods.

4.3 OTHER PROGRAMS

The risk management criteria used in three other programs (two federal, one state) which resemble the 21E program are briefly reviewed for comparative purposes.

4.3.1 CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act

ARARs: The National Contingency Plan (NCP, 40 CFR Part 300) requires that the Superfund program consider any **applicable or relevant and appropriate requirements (ARARs)** (300.430(e)(2)(i)(A)), and the remedial alternative shall attain the ARARs or provide grounds for waiving the requirement (300.430(e)(9)(iii)(B)).

Non-Cancer Risk: The NCP does not explicitly reference the Hazard Index as a measure of non-carcinogenic risk, but does state that, for non-carcinogenic compounds, acceptable levels are those at which the human population (including sensitive subgroups) may be exposed without adverse effects during a lifetime or part of a lifetime, with an adequate margin of safety" (300.430(e)(2)(i)(A)(1)). National (US EPA, 1989a) and Region I (US EPA, 1989b) guidance discuss the use of the Hazard Index to evaluate non-cancer risk, and the risk is considered to be acceptable if the Hazard Index is equal to or less than unity (1).

Cancer Risk: The NCP (in 300.430(e)(2)(i)(A)(2)) establishes acceptable exposures to be those that represent an individual's cancer risk between 10^{-4} and 10^{-6}. It specifically notes that 10^{-6} level is the "*point of departure*" in developing remedial alternatives in instances involving multiple contaminants or multiple exposure routes.

In addition, section 300.430(e)(2)(i)(D) of the NCP contains provisions to insure that the "*cumulative*" individual cancer risk (due to multiple contaminants or multiple exposures) does not exceed 10^{-4}, *even if the chemical specific ARARs are attained.*

4.3.2 RCRA - Resource Conservation and Recovery Act

Section 3004(u) of the 1984 Hazardous and Solid Waste Amendments (HSWA) to RCRA requires corrective action for releases of hazardous waste or constituents from solid waste facilities. OSWER Directive 9502.00-6D (US EPA, 1989c), *Interim Final RCRA Facility Investigation (RFI) Guidance* describes the second phase of the RCRA Corrective Action Program, the RFI. The purpose of the RFI is to obtain information to characterize the nature, extent and rate of migration of releases of hazardous waste or constituents and to interpret this information to determine whether interim corrective measures and/or further investigation may be necessary.

Health and Environmental Criteria: The guidance presents a set of chemical- and medium-specific health and environmental criteria derived from EPA-established chronic (and in some cases acute) toxicity criteria for ingestion(soil and drinking water) or inhalation exposure routes, and were calculated using a set of intake assumptions for the

various media. These criteria include lists of numbers based on standards, guidelines, non-cancer health effects and carcinogenicity.

Standards and Guidelines: The criteria includes lists of **Maximum Contaminant Levels (MCLs)** for drinking water and **Water Quality Criteria (WQC)**. The WQC exist to protect both marine and freshwater aquatic life and human health through water and fish consumption.

Non-Cancer Risk: The *criteria are based upon standard exposure assumptions* resulting in a dose which is equivalent to the Reference Dose (i.e., the Hazard Index at such a concentration would be equal to unity).

Cancer Risk: The criteria are based upon standard exposure assumptions resulting in excess lifetime cancer risk of 10^{-6} for lifetime exposures to known or probable human carcinogens (Classes A & B). For Class C compounds, the corresponding cancer risk is set at 10^{-5}.

Chemical Mixtures: Chemicals mixtures are evaluated using Hazard Indices generated (for cancer and non-cancer effects) as the sum of the ratios of the site exposure point concentration of the chemical over the chemical-, medium- and health-effect-specific guideline. The guidance states explicitly that contaminant additivity is possible both within a medium and across media.

4.3.3 New Jersey

The New Jersey Environmental Cleanup Responsibility Act (ECRA) authorizes the NJ Department of Environmental Protection and Energy (DEPE) to promulgate standards *"to ensure that the potential harm to human health and safety is minimized to the maximum extent practicable."* The NJ DEPE has recently promulgated rules (N.J.A.C. 7:26D) which contain cleanup standards for contaminated sites. In addition to the chemical- and medium-specific standards, the regulations allow for the development of alternative cleanup standards and deferrals from cleanup standards for specific sites.

Non-Cancer Risk: For chemicals which are not considered to be carcinogenic, the human health-based criterion is calculated from the chronic reference dose or chronic reference concentration, subtracting the average daily intake received from dietary sources. This is the equivalent of setting the sum of each chemical- and medium-specific standard and the dietary intake of that chemical to a Hazard Index equal to one.

Cancer Risk: For chemicals considered to be Class A (Known) or Class B (Probable) Human Carcinogens, the human health-based criterion is calculated from the potency factor or unit risk factor based on an additional lifetime cancer risk of one in a million (1×10^{-6}). For a contaminant considered to be a Class C, Possible Human Carcinogen, the human health-based criterion is calculated based upon its potential non-cancer effects at a Hazard Index equal to 0.1. If there is not sufficient information available to evaluate the non-carcinogenic risk, then the criterion is based upon the chemical's

cancer risk but at an additional lifetime cancer risk of one in a hundred thousand (1×10^{-5}).

4.4 Alternative Risk Management Criteria

A number of DEP staff and representatives of the regulated community have expressed desire to change one or more of the MCP risk management criteria. The most common request for change has been for a change of the Hazard Index limit of 0.2 to a higher value. Fewer comments have been made that the cancer risk limits should be changed. The following sections identify possible changes to the MCP risk management criteria under the proposed modification of the risk characterization process described in Section 3.3. The proposed risk management criteria are discussed below and summarized in Table 4-2.

4.4.1 Standards and Guidelines

Applicable or suitably analogous public health standards would continue to be utilized as risk management criteria for any risk characterization method. They are considered a *minimum* requirement of both proposed Methods. More detailed guidance on the applicability of these standards is recommended, particularly dealing with the groundwater issues. (The applicability of groundwater standards to 21E sites is being dealt with by a separate workgroup.

In addition, in proposed Method 1, chemical-specific cleanup standards would be promulgated by the Bureau of Waste Site Cleanup. Such lists of cleanup standards could be identified in a number of ways, including:

i. The development *de novo* of health- or risk-based standards expressly for the MCP based upon the non-cancer and cancer risk criteria detailed below;

ii. The adoption of existing public health ***standards*** as they currently exist;

iii. The adoption of the health- or risk-based component of existing promulgated public health standards;

iv. The adoption of health- or risk-based guidelines, where they exist; and

v. Some combination of the above four sources.

It would appear that to be consistent with the risk management approach of the statute, that some evaluation of the existing standards take place to identify those which incorporate risk-balancing or which are technology based. On the other hand, the generation of cleanup standards is a resource intensive project which can be facilitated by the adoption of as many existing values as appropriate.

The chemical-specific cleanup standards for proposed Method 1 would not necessarily be a *single* list of numbers. One option available to the Department is to promulgate

a single list of chemical- and medium- specific standards which would be applicable at all locations. These standards would have to be protective of public health for the most sensitive exposures. Another option is to develop multiple lists of standards, each list tailored to a specific site use. The applicability of a given set of cleanup standards would be governed by regulations based upon the Bureau's draft foreseeable use policy. This option would necessarily be more complex than the use of a single list.

4.4.2 Non-Cancer Health Risk Measured By The "Hazard Index"

The Workgroup has considered modifications to the Hazard Index criteria contained in the current MCP before applying them to the proposed two Methods. The Hazard Index criteria would be used in setting proposed Method 1 cleanup standards and as a total risk limit in the proposed Method 2. It is important to keep in mind the distinctions between the use of risk management criteria to regulate single chemicals and to regulate mixtures or multiple exposures. It is not unusual for single-chemical risks and multiple exposure risks to be regulated at different levels (such as in the current MCP cancer risk levels), although this is not currently done for non-cancer risk in the existing MCP.

Unlike cancer risk (where any exposure is associated with an incremental risk), it is assumed that a receptor's exposure must exceed a "threshold" before adverse non-cancer health effects are seen. As described in Section 4.1.2, the Reference Doses which are customarily used in Hazard Index calculations represent estimates of human daily doses to which sensitive individuals could be exposed for an entire lifetime without any anticipated non-cancer health effects. The Reference Dose is thus an exposure level somewhere below the "threshold". Thus exposures somewhat greater than the Reference Dose should not necessarily be expected to induce adverse health effects, as there is a level of conservatism built into the toxicity value itself. In addition, the exposure assessments used to develop standards or evaluate specific sites are generally conservative in nature. The issue of conservatism is addressed in the accompanying issue paper.

The techniques which are used to estimate allowable human doses for sensitive individuals often make use of "no-effect levels" (NOELS) or "lowest observed effect levels" (LOELS) in animals and apply a series of uncertainty factors, often resulting in an allowable Reference Dose which is as much as 1,000 or 10,000 times lower than the allowable dose or lowest harmful dose observed in animals. The use of such factors varies widely, however, depending upon the quality of information available for a given chemical. There are numerous Reference Doses which incorporate smaller uncertainty factors: mercury is one such example, with a combination of uncertainty factors (3 x 10) of 30. The conservative nature of this measure of toxicity is explored more fully in a second discussion document, "Conservatism & Uncertainty In Risk Assessment" (MCP Workgroup, July 8, 1992).

4.4.2.1 Chemical-Specific Standards/Guidelines

The current MCP utilizes applicable or suitably analogous standards and guidelines when available, and (in Method 3a) requires PRP-derived guidelines to be developed using a Hazard Index equal to 0.2.

The origin of the 0.2 value as a "source allocation factor" was described in Section 4.2.2.3. The U.S. EPA Office of Drinking Water (ODW) considers the use of such a factor appropriate for the regulation of public water supplies. A similar factor has been adopted by the MA DEP in setting chemical-specific drinking water guidelines and allowable ambient limits in air (AALs). No state or federal waste site remediation program surveyed made use of an analogous source allocation factor, although they often adopt drinking water standards which incorporate this factor.

The use of a source allocation factor to regulate public drinking water supplies is not unusual considering 2 characteristics of such regulatory programs:

1. **Exposure to a contaminated public drinking water supply is not hypothetical.** Any uncertainty in the exposure assessment concerns the level of exposure, not whether or not exposure is occurring. Thus the conservativeness of the exposure assessment for drinking water is minimized, but potential exposures to *other* contaminated media are not evaluated.

2. **Regulation of public drinking water supplies is typically done on a chemical-by-chemical basis.** There is no mechanism for routine consideration of potential cumulative effects of from exposure to multiple drinking water contaminants.

The source allocation factor is thus used to protect against combined effects both from additional chemicals in the drinking water *and additional exposures to chemicals in other media.*

As proposed, the Method 1 cleanup standards would be potentially applicable at sites with one or many chemicals. In addition, the same standards could be applied regardless of whether exposure were only occurring via one pathway or if the receptor were being exposed to several contaminated media. The standards are required to be protective of the public health in any situation in which they may be applied under the MCP. In this way the proposed Method 1 shares some of the characteristics with the drinking water regulations which led the EPA Office of Drinking Water to utilize a source allocation factor. Other states, such as New Jersey, have developed cleanup standards without using a source allocation factor in the Hazard Index, although the standards are often used in conjunction with some mechanism that would trigger more detailed evaluations at multiple-chemical or multiple-exposure sites (see the discussion of the New York and California programs, Section 3.2.2.1). The Federal Superfund program does not use a source allocation factor in using the Hazard Index on a chemical-specific basis to set target cleanup levels, but it also calls for an evaluation of the cumulative risk posed by the site to insure that the additive effect of the chemical-specific goals are not of concern.

4.4.2.2 Total Site Risk

The current MCP contains a Total Site Noncancer Risk Limit measured as a Hazard Index equal to 0.2. It has been suggested that this "Total Site Hazard Index" could be raised to 1 and continue to be protective and be considered representative of a level of no significant non-cancer health risk. No state (of those surveyed) or Federal waste site cleanup program currently employs a total (or cumulative) hazard index goal less than 1.

As described previously, the Total Hazard Index Limit of 0.2 was adopted from the U.S. EPA Office of Drinking Water's use of a chemical-specific source allocation factor. The adoption of this factor implies that the total risk methodology (the current Method 3b or the proposed Method 1) shares the same goals, strengths, limitations and uncertainties of the chemical-specific regulatory program that initiated its use. With the exception of ODW's use of risk-balancing in setting some drinking water standards, it is clear that the goals of the programs are similar in the most general sense: to protect public health, and (as it relates to this issue) to insure that non-cancer health effects do not result from exposures which fall under the program's regulatory authority. It is clear, however, that at least some of the limitations of the chemical-specific regulatory program are compensated for in the MCP's use of total risk. EPA ODW does not address the cumulative effect of multiple contaminants, whereas the MCP's total risk approach addresses it specifically.

The question remains, however, as to what the Total Hazard Index Limit should be to protect public health and be consistent with a level of "no significant risk". Should some consideration be given to potential exposures which are not site related, and if so, how would that effect the Total Hazard Index Limit? By changing or eliminating the source allocation factor, would there be increased risk of non-cancer health impacts, and would that increased risk be significant? In other words, would increasing the allowable concentrations by a factor of five (5) eliminate any margin of safety built into the Hazard Index calculations?

The U.S. EPA developed the Hazard Index methodology and generates the toxicity information (Reference Doses) used to calculate the Hazard Index. Given the protective nature of most Reference Doses, EPA personnel involved in derivation and review of these reference doses have indicated that a slight exceedance of a reference dose (a Hazard Index greater than 1) would not be likely to produce adverse effects. This suggests that the use of a Total Noncancer Risk Limit of a Hazard Index equal to 1 would be representative of a level of "no significant risk", as it would protect receptors from potential site-related noncancer health impacts.

It remains a question whether OHM exposure from sources other than the site would be sufficient to overwhelm the conservative, health protective nature of the Reference Doses. One alternative is the selection of a source allocation factor falling between 0.2 and 1 to address the non-site related exposures only.

The Federal Superfund program sets target cleanup levels (on a chemical-specific basis) at a Hazard Index equal to 1. A cumulative Hazard Index equal to unity is also a remedial goal, although the EPA risk assessors may use professional judgement on a chemical-by-chemical basis to determine final target concentrations, in recognition of the large margin of safety built into many Reference Doses through the application of multiple uncertainty factors. New Jersey has set chemical-specific cleanup standards at a Hazard Index equal to unity without consideration of additive effects or non-site related exposures.

4.4.3 Cancer Risk

The current MCP provides a target cancer risk level of one-in-a-million for the development of chemical-specific guidelines, and a Total Site Cancer Risk Limit of one-in-a-hundred thousand for the evaluation of cumulative risk. Cancer risk is assumed to be directly related to the concentration of OHM at the environmental levels regulated by the MCP, and exposure at any level to a carcinogenic material is assumed to be associated with some incremental cancer risk. By this assumption, the only concentration of a carcinogenic material associated with "no risk" is a concentration of zero. It is clear when considering cancer risk that a level of "no significant risk" does <u>not</u> mean "no risk".

4.4.3.1 Chemical-Specific Standards/Guidelines

The Excess Lifetime Cancer Risk options for the development of chemical-specific standards (Method 1) are order-of-magnitude differences: 10^{-6}, 10^{-5}, 10^{-4}. The use of the one-in-a-million risk level would provide consistency with existing regulatory programs (MA DEP DWS, U.S. EPA Superfund program's target cleanup levels, etc...). Choice of the 1×10^{-6} would maintain the health-protectiveness of the current MCP. Selection of either of the two higher risk levels would increase the allowable risk associated with residual contamination.

4.4.3.2 Total Site Risk

There are four options under consideration for the risk management criteria for Total Site Cancer Risk in the MCP. Two of these options substitute a risk range for the "bright line" of the risk limit, one would adjust the risk limit, and one would maintain the current (Method 3b) risk limit.

i. Adopt the Total Site Cancer Risk range of 10^{-4} to 10^{-6} used by U.S. EPA Superfund program.

   The benefits of such a change include greater consistency with the federal program. However, it is likely that the upper-end of the risk range would become the *de facto* risk limit. It is perhaps more important to be consistent with the federal *methodology* than to have identical levels of regulatory concern. Finally, the upper-end of this proposed risk range is a level which was considered in 1988 and rejected as being a level of concern and not consistent with a *"permanent solution"*, and is less

health-protective than the current regulations. In fact, the 10^{-4} risk level is used by many regulatory programs (MA DEP Division of Water Supply, U.S. EPA Region III Superfund Removal Branch, U.S. EPA OSWER Directive 9360.1-01) as a level at which *immediate* action would be taken to protect public health. It would be difficult to argue that the same level represents "no significant risk".

ii. Adopt a Total Site Cancer Risk range of one-in-one-hundred thousand to one-in-ten-thousand (1×10^{-5} to 1×10^{-6}).

Again, the benefits and drawbacks of a risk range are the same as in the previous example. Since the upper end of this risk range is the current risk limit, there would be no diminution of health protectiveness, even if the majority of decisions were made at the upper risk level. Adoption of a range which includes more stringent risk requirements would strengthen the health-protectiveness of the MCP. Guidance would need to be developed to describe the circumstances under which the Department would like to see the lower end of the risk range used.

iii. Specify a Total Site Cancer Risk Limit of one-in-ten thousand (1×10^{-4}).

The target cleanup levels in this option could be up to a factor of 10 higher than would currently be allowed. For the reason described for option i, this option must be viewed as being less health protective than the current regulations. Use of a single risk management number would provide for a consistent level of health protectiveness, and it simplifies the enforcement process. It also avoids complex comparisions of alternatives that may achieve very different levels of health protection, as can be the case when the risk management criteria are in the form of a range.

iv. Maintain the existing (Method 3b) Total Site Risk Limit of one-in-one hundred thousand (1×10^{-5}).

No Change. This option shares the benefits and problems associated with the use of a single risk management criterion (described above), and does not reduce the health-protectiveness of the MCP. The process by which this Limit was identified is described in Section 4.2.2.2.

TABLE 4-2

ALTERNATIVE MCP RISK ASSESSMENT METHODS

METHOD (*Either* Method may be chosen to evaluate a given disposal site.)	*RISK MANAGEMENT* CRITERIA ALTERNATIVES
1 [The applicability of Method 1 could be limited by the number of *OHM* or some measure of the complexity of the site]	Chemical-, medium- and use- specific standards published (or referenced) in the Massachusetts Contingency Plan. There are alternatives for identifying such standards, and they could include: • Chemical- and medium- specific applicable or suitably analogous standards (or guidelines), where they currently exist; *and* • For OHM for which standards (or guidelines) do not currently exist, health- or risk-based standards developed for the MCP based on: ▸ 3 Options for Excess Lifetime Cancer Risk:

EXCESS LIFETIME *CANCER RISK* =	(a) 1×10^{-6}	(b) 1×10^{-5}	(c) 1×10^{-4}

▸ 3 Options for Non-Cancer Risk, as measured by the Hazard Index:

HAZARD INDEX =	(a) 0.2	(b) 1	(c) A Value Between 0.2 and 1

2	• Chemical- and medium- specific applicable or suitably analogous standards, where they exist, *and* • Total Site Risk management criteria for cancer and noncancer risk: ▸ One of 4 Options for Total Site Cancer Risk (TSCR) Limit:

(a)	(b)	(c)	(d)
TSCR range 10^{-6} -> 10^{-4}	TSCR range 10^{-6} -> 10^{-5}	TSCR 10^{-4}	TSCR 10^{-5}

▸ One of 3 Options for Total Site Non-Cancer Risk Limit, expressed as a Hazard Index:

(a)	(b)	(c)
Hazard Index equal to 0.2	Hazard Index between 0.2 and 1	Hazard Index equal to 1

4.5 SOLICITATION OF COMMENTS AND RECOMMENDATIONS

4.5.1 Recommended Human Health Risk Assessment Method

Section 3.0 of this document described the current risk assessment methodology and outlined alternative methods to characterize risk. The conclusion of that section recommended the adoption of a two-Method approach combining the ease of chemical-specific cleanup levels and the flexibility of a total risk approach.

As a starting point, recommendations for modification of the risk management criteria should be made on the assumption that the changes recommended in Section 3.0 will made to the risk characterization methods. Combined suggestions for alternative risk assessment methods and risk management criteria are also welcome.

4.5.2 Recommended Human Health Risk Management Criteria

At this time the Workgroup has not made recommendations for the risk management criteria to be used with the proposed risk assessment methods. Instead, the Workgroup solicits proposals based upon the preceding discussions and any other information which might be submitted to support suggested proposals. Commentors are encouraged to use Table 4-2 as a guide for possible risk management criteria options, but they should not be limited to those presented in the table.

4.5.2.1 PROPOSED METHOD 1

Human health risks would be characterized for each oil or hazardous material (OHM) at or from the disposal site by comparing estimated exposure point concentrations of the OHM to lists of chemical- and medium-specific standards published (or referenced) in the MCP. There are several options for identifying such standards, and the Workgroup seeks comments on these alternatives.

- Method 1 standards could include concentrations adopted directly from existing chemical-specific public health standards and guidelines.

  Should *any* existing public health standards/guidelines be adopted?

  What criteria should be used to select the appropriate standards and guidelines?

  Please suggests lists of existing standards/guidelines which would be considered appropriate for adoption as Method 1 standards, and provide justification for their inclusion.

  Please indicate any existing standards/guidelines which would *not* be considered appropriate, and justify their exclusion from Method 1.

  How should the BWSC consider existing public health standards/guidelines which incorporate risk-balancing or a technology-based approach? Should the risk-based

component be used or should the standard be adopted as-is? If, as a general approach, such standards are adopted in their existing form, is there an upper limit to the risk associated with such standards which would cause you to exclude a particular standard from Method 1?

- Many (if not all) of the proposed Method 1 standards would be generated *de novo* for the MCP.

  Based upon the discussions in this document, what risk management criteria should be the basis of such standards? - for noncancer risk (Hazard Index)? -for cancer risk (Excess Lifetime Cancer Risk)? Please provide justification that your recommended criteria represent levels of "no significant risk".

  Should analytical limitations (detection limits) be considered in setting such standards? If so, in what way? Is this consistent with the risk-only risk management approach of the MCP?

  Method 1 standards would be used to characterize the risk of harm to human health only, and would serve as health-based cleanup standards. Are there any other considerations which could/should be incorporated into Method 1 standards without changing their health-risk focus?

- As proposed, Method 1 standards would be identified for some universe of chemicals. These standards would be developed for different environmental media (soil, drinking water, surface water, air...), and sets of standards could be developed for different site uses (Residential, Commercial, Industrial, Agricultural, etc...). The development of Method 1 standards could represent a significant commitment of DEP resources.

  Can the development of such standards be accomplished in a step-wise fashion?

  What chemicals should be addressed by the effective date of the revised regulations?

  How would you suggest the Department prioritize the chemicals for the development of cleanup standards?

  For which environmental media should the Department develop Method 1 cleanup standards? Is there a way to prioritize the development of standards for different media?

  Should Method 1 standards be developed for specific site uses? If so, please describe (in as much detail as is appropriate) the specific use scenarios which you would suggest. How would you rank the importance of these uses for the development of standards?

- As proposed, Method 1 would be an available option at any type of site without the current restrictions based on single- vs. multi-media contamination.

  Should the choice of Method 1 be completely without restrictions? Is there any type of site which you would consider to be too complex for the use of Method 1? Assuming the potential for additive effects resulting from exposure to multiple chemicals, should there be an upper limit to the number of contaminants at a site eligible to use Method 1? Would it make sense to require simple sites (one or two chemicals in one or two exposure media) to utilize Method 1?

4.5.2.2 PROPOSED METHOD 2

Human health risks would be characterized for each oil or hazardous material (OHM) at or from the disposal site by comparing estimated exposure point concentrations of the OHM to any applicable or suitable analogous public health standards. In addition, for each receptor identified for the disposal site, the Excess Lifetime Cancer Risk associated with all theorized exposures to all OHM would be summed and this cumulative value compared to a Total Site Cancer Risk Limit. For non-cancer risks, for each receptor identified for the disposal site, the hazard indices associated with all theorized exposures to OHM displaying the same mechanism of action, health-endpoint, and/or shared target-organ would be summed and this cumulative value compared to a Total Site Noncancer Risk Limit expressed as a Hazard Index.

- The proposed Method 2 utilizes existing applicable or suitably analogous public health standards as a minimum requirement, identical to the existing requirement of Method 3b.

  Please comment of the use of these promulgated standards as a factor in the health risk characterization method.

- Similar to the current Method 3b, the proposed Method 2 utilizes a cumulative risk approach which would specify total cancer and noncancer risk levels at or below which would be considered a condition of "no significant risk".

  Do you consider the current (Method 3b) risk management criteria to be *under-* or *over-protective*, or an appropriate level of health protection?

  Based on the discussions in this document, what risk management criteria should be used for this Method? - for noncancer risk (Hazard Index)? - for cancer risk (Excess Lifetime Cancer Risk)? Please provide justification that your recommended criteria represent levels of "no significant risk".

  The use of a risk range similar to that employed by the U.S. EPA is considered to be difficult to implement effectively due to a tendency to rely upon the extremes of the range for regulatory decisions. Is there a mechanism by which such a range could be effected by the Department in a revised program with little or no Departmental oversight?

- As proposed, Method 2 would be an available option at any type of site without the current restrictions based on multi-media contamination.

  Should the choice of Method 2 be completely without restrictions? Is there any type of site for which you would consider Method 2 to be too complex? Are there any types of sites which should *always* be required to use Method 2?

- *Risk Assessment ShortForms* (computerized risk assessments) are being developed to streamline the site-specific risk assessments which would be performed under Method 2 (and the current Method 3b).

  Please describe (in as much detail as possible) the specific scenarios for which you would want the Department to develop *ShortForms*. How would you rank the importance of these scenarios in order to prioritize this work?

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5.0 RISK ASSESSMENT/RISK MANAGEMENT IN OTHER MA DEP ACTIVITIES

5.1 Introduction

Decisions made in the Waste Site Cleanup Program Redesign regarding the risk management approach, risk characterization methods, and risk management criteria are not made in a vacuum. Many, if not all of the Department's regulatory programs incorporate considerations of risk of harm to health, safety, public welfare and the environment, although such considerations are not always as explicit as they are in the Waste Site Cleanup program. DEP staff, the regulated community and the general public are aware of the requirements of the different programs, and a change in one approach can have direct (or indirect) implications throughout the Department.

It is important to keep in mind that any programmatic differences are likely due to different statutory goals and objectives. If dissimilarities do exist, it is important to be aware not only of the nature of the differences, but also of their source. The Department should be able to explain with confidence the various approaches taken to meet the goals of its numerous regulatory programs.

This section briefly describes the role of risk characterization in components of the waste site cleanup process and redesign, and other DEP programs. It will identify dissimilarities and issues that will need to be addressed if the recommendations contained in this issue paper are adopted.

5.2 Bureau of Waste Site Cleanup

The risk characterization methods and risk management criteria discussed previously are intended for use in Phase II of the MCP to determine the need for remediation, in Phase III to evaluate the theoretical reduction in risk envisioned by various alternatives, in Phase IV to document that remediation has achieved a "level of no significant risk", and at other points where determinations of "no significant risk" are needed. The following sections describe other aspects of the MCP process (existing or redesigned) where risk characterization and risk management decisions are made, and where changes may be required based on the proposed changes in Phase II.

Table 5-1 briefly summarizes each program's use of risk assessment and risk management.

5.2.1 *Release Notification*

Site notification regulations are currently being drafted by an internal WSC workgroup as part of the program redesign effort. A discussion paper and proposal were prepared earlier this year.

One of the objectives of the notification criteria is to require notification of releases that could pose a significant risk. This objective is consistent with the risk management approach mandated by M.G.L. c. 21E and described in Section 2.0 of this document. It should be noted that the site notification requirements are not limited to the risk of harm to human health, and the discussion which follows is applicable only to the health-risk component of the reporting requirements.

The reportable concentrations (RCs), developed as part of the notification criteria, incorporate specific risk characterization methods and risk management criteria. At this time, the methods are consistent with the current Method 3.a. and the applicable risk management criteria specified in the MCP. If the proposed changes to the risk characterization Methods are adopted, the reportable concentrations may need to be revised to consider the risk management criteria for Method 1 (discussed in Section 4.0). As proposed, the new Method 1 criteria would be similar to that of the current Method 3.a.

It is possible that the chemical- and medium-specific concentrations developed for use as cleanup levels in proposed Method 1 could also serve as notification criteria, although the implementation of the numbers would be different. For notification purposes, the proposed Method 1 concentrations could be compared to ***any*** data available, and ***any*** exceedence would trigger an obligation to notify the Department and would lead to further investigation. In contrast, the use of the proposed Method 1 concentrations in NFA determinations or in the current Phase II would compare the cleanup levels to *representative exposure point concentrations*, which could be generated from data collected during the comprehensive site investigation. Consideration of non-human health risk issues would have to be incorporated in such a proposal.

In addition to the specific risk characterization methods used, there is an issue of consistency in which different situations are evaluated throughout the process. In other words, types of releases or locations that are identified as being of greater concern at the time of notification, should be consistent with the types of releases or locations that are of concern in other points in the process. This issue relates to the risk characterization assumptions that are utilized for different scenarios. For example, if it is determined that sole source aquifers are subject to more stringent notification requirements since it is assumed that this water could be ingested, this assumption should be carried through the process. The only exception to this may be that more conservative assumptions are made early in the process (for notification), and later phases allow a more specific evaluation of this issue and site specific assumptions.

5.2.2 Imminent Hazard Determinations

As part of the program redesign, a WSC workgroup is preparing guidance for Imminent Hazard determinations under the MCP.

Imminent hazard determinations can include (but do not necessarily require) a quantitative evaluation of human health risk similar to that in a Phase II assessment. The current MCP envisions a qualitative approach to this evaluation, as described in 310

CMR 40.542(2). Even if a more quantitative approach were taken to this issue, the risk characterization methods and risk management criteria proposed in this document would not necessarily be applicable.

The statute stipulates a different standard for imminent hazards for the significance of the risk: it specifies that imminent hazard is a hazard that poses a significant risk if it were present even for a short period of time. Presumably this implies that human health risks associated with short duration exposures should be evaluated in order to identify the existence of an imminent hazard. As a result of the temporal differences in definition, the evaluation of risk for an imminent hazard requires different exposure assumptions than would generally be used in a Phase II assessment, and thus the Method 1 concentrations (based upon long-term exposure) would not be applicable (Analogous lists of numbers *could* be developed for the purposes of evaluating imminent hazards). A Method 2 assessment could consider the exposure differences, but it is also possible that different risk management criteria could be developed for imminent hazard determinations.

The guidance for quantitative imminent hazard determinations can be developed in a manner generally consistent with the proposals outlined in this paper, although some differences in approach and risk management criteria are expected.

5.2.3 No Further Action Determinations

As part of the program redesign a WSC workgroup has prepared a proposal and discussion paper for No Further Action Determinations.

An objective of a no further action determination, according to the May 1992 Discussion Document, is to document that a level of no significant risk exists or has been achieved. This objective is consistent with the risk management approach mandated by M.G.L. c. 21E.

The NFA process also incorporates specific risk characterization methods and risk management criteria. At this time, the process is consistent with the current MCP Methods 3.a and 3.b. and the applicable risk management criteria. If the proposed Methods 1 and 2 and the modifications to the risk management criteria are adopted, some changes to the NFA process would be required. The most significant change is that the Method 1 cleanup levels would replace the proposed NFA single-media cleanup levels. As described earlier, these cleanup levels would be available for use at any type of site and would not be restricted to single media situations.

5.2.4 Tier Classification

The tier classification system is intended, in part, to identify the sites that pose a greater risk than other sites in the differentiation of Tier I sites from Tier II sites, and the identification of Category A, B, or C sites within Tier I. This objective is consistent with the risk management approach mandated by M.G.L. c. 21E. The classification scheme does not incorporate quantitative risk assessment, but uses a qualitative

evaluation approach that is intended to provide a relative representation of risk. The scoring system incorporates considerations of risks to human health, safety and the environment; and the need for DEP oversight.

The specific risk characterization methods used in Phase II should not impact the scoring system, nor should the risk management criteria chosen for those methods. However, if Method 1 were adopted, it may be desirable to incorporate the cleanup levels into the scoring system in some way.

The assumptions or degree of conservatism used in the Phase II risk characterization should, however, be reflected in the scoring system. For example, if a sole source aquifer is viewed in Phases II, III and IV as requiring cleanup to levels based on an assumption of drinking water ingestion, this assumption should be reflected qualitatively in the scoring conducted in the site classification. Similarly, if exposure point concentrations for soil exposures in a Phase II risk characterization are based on concentrations detected in the top 2 feet, this assumption should also be reflected in the site scoring procedure.

It should be noted that the current scoring proposal incorporates a concept that is not considered in the current or proposed risk characterization methods or management criteria: **population risk**. The methodology scores a site based on population within 1/2 mile of the site and the number of persons served by a public drinking water supply. These aspects of the scoring system imply that the number of people potentially affected (population risk) should be a factor in determining the appropriate level of oversight for the assessment and remediation of that location. The use of population risk in this system is not intended to imply that the significance of risk is dependent upon population size. The current and proposed risk characterization methods are based solely on individual risk and not population risk. It may be appropriate to rank a site based on population risk, but it should be recognized that at this time population risk has no bearing on whether or not a site would require remediation, or the extent of remediation required.

5.3 Other DEP Bureaus

Other DEP bureaus utilize risk characterization and management in two contexts. First, several DEP divisions are responsible for setting and enforcing environmental standards and guidelines. By their nature, standards and guidelines represent single media, single pathway risk characterization methods, similar to the proposed Method 1 risk characterization described in this document. Second, other DEP divisions are responsible for siting and/or permitting decisions, and other site-specific evaluations. These decisions may utilize standards and guidelines alone (similar to the proposed Method 1), or they may consider *total risk* (or *cumulative risk*), similar to the proposed Method 2. It is important to keep in mind, however, that other DEP programs have different authorities and legislative mandates than does the Waste Site Cleanup program. As a result, other programs may be required to utilize different risk management approaches (many are required to use risk balancing), risk characterization methods, and risk management criteria.

The following sections will briefly discuss the use of risk characterization and risk management in the development and use of standards and guidelines and in any site specific decisions made by other bureaus.

5.3.1 Bureau of Resource Protection

5.3.1.1 Drinking Water Standards

The drinking water regulations (310 CMR 22.00) are intended to "promote the public health and general welfare", and to ensure that water provided is "safe, fit and pure to drink". In this regard, these regulations establish Massachusetts Maximum Contaminant Levels (MMCLs) for microbiological, inorganic, organic, turbidity, and radionuclide contaminants. For the most part, drinking water standards promulgated by U.S. EPA (Maximum Contaminant Levels - MCLs) are adopted without change.

MCLs are developed using a risk balancing approach. Potential risks are weighed against economic issues (costs of treatment) and technological feasibility (availability and effectiveness of treatment methods). These standards are applicable to public water supplies, and the costs and feasibility are considered in that context. It should be noted that the balancing of these components might be different in the context of a waste site cleanup, when the costs, feasibility and effectiveness of a treatment technology might not be constrained in the same way as when considered in the nationwide context of water suppliers. The MMCL and MCL for total trihalomethanes is a good example of this risk balancing. The MMCL is set at a cancer risk in the range of 10^{-3} to 10^{-4} as a result of the risk balancing approach. Trihalomethanes are produced in water treatment upon chlorination to reduce hazards associated with microbiological contaminants. The standard applies to community water supplies serving more than 10,000 individuals. It was developed by considering the costs of treatment, the potential risks associated with exposure to trihalomethanes, and the benefits achieved by treatment of water supplies with chlorine. Clearly, this analysis is different than what is required under the mandate of M.G.L. c. 21E in terms of what would pose a significant level of risk to persons using water supplies contaminated by trihalomethanes from a site.

5.3.1.2 Drinking Water Guidelines

Drinking water guidelines are developed in Massachusetts by the Office of Research and Standards. They are used in the evaluation of existing water supplies, and in the siting of new water supplies in a manner similar to that described above for drinking water standards. They are, however, developed using a risk-only management approach and risk characterization methods similar to Method 1 proposed here.

5.3.1.3 Evaluation of Water Supplies

Existing water supplies are routinely evaluated by the Division of Water Supply in order to determine whether they are in compliance with 310 CMR 22.00. A risk characterization step is performed by comparing the required monitoring data to applicable standards and guidelines, as described above.

MMCLs are used to evaluate existing water supplies by comparison to annual averages, generally based on quarterly sampling. Public water supply systems exceeding MCLs are deemed "out of compliance", but action is not necessarily taken. 310 CMR 22.13 requires that systems utilize "best technology, treatment techniques, or other means, which the Department finds are generally available, taking costs into consideration" in order to achieve MCLs. If using these techniques, compliance still cannot be achieved, the Department can grant a variance if they (in consultation with the Department of Public Health) determine that granting the variance will not result in an unreasonable risk to health. This risk/characterization risk management approach represents risk balancing and requires the consideration of cost in considering whether additional treatment is appropriate, or whether a variance should be granted. In addition, the consideration of a variance in based on an "unreasonable risk", a different standard than "significant risk". No specific risk management standards are specified, and evaluation of "out of compliance" water supplies and variances are conducted on site specific basis.

In addition to the single chemical approach of comparison of monitoring data to MCLs, the regulations (310 CMR 22.07(3)(i) specify that where one or more VOCs are detected but no MCL is exceeded, the Department may specify appropriate measures to be taken by the water supplier. This implies that the Department develop chemical-specific guidance (ORS guidelines), or it may conduct an evaluation of a water supply considering multiple chemicals. No specific risk management standards are specified in the regulations for this approach. However, the "*Guide to the Regulation of Toxic Chemicals in Massachusetts Waters*" developed by the Office of Research and Standards provides guidance in this regard. It specifies that the risk characterization method will be pathway specific (consider cumulative effects of multiple chemicals), and the risk management criteria to be used in the evaluation of water supplies are standards and guidelines and a total ELCR of 10^{-5} and a Hazard Index of 1. However, the Division of Water Supply uses risk balancing in order to determine whether or how to respond to a particular situation. Their specific risk balancing approach is not documented in policy or regulation.

5.3.1.4 Groundwater Standards

314 CMR 6.00 establishes the Massachusetts Groundwater Quality Standards. These standards consist, in part, of groundwater classifications and groundwater quality criteria necessary to sustain the designated uses. Drinking water standards and guidelines are adopted as groundwater standards for Class I and Class II groundwaters, which are considered potentially potable waters. The risk characterization/risk management approaches used in the development of these standards are discussed above. Class III groundwaters are designated for uses other than as a source of potable water supply. Most groundwaters in the state are currently classified as Class I. Class III designations require the submission of a petition in the context of an existing or proposed discharge to the groundwater. Criteria for Class III groundwater are developed on a site-by-site basis.

The Bureau of Waste Site Cleanup and the Bureau of Resource Protection have established a joint Workgroup to study the applicability of groundwater standards under the Massachusetts Contingency Plan.

5.3.1.5 Groundwater Discharge Permits

The groundwater standards are intended to be used in the consideration of groundwater discharge permits in order to ensure that the designated uses and groundwater quality will be maintained. 314 CMR 40.607(2) specifies that the Division of Water Pollution Control will establish discharge limits in the permit. The division is required to consider natural background conditions, to protect existing adjacent and downgradient uses, and must not interfere with the maintenance and attainment of beneficial uses in adjacent and downgradient waters. No other specifics as to discharge permit limits described.

The consistency issue with groundwater discharge permits does not specifically relate to the standards themselves, but their application. Method 1 may set cleanup levels for locations where there is a current or potential use of groundwater as a water supply. These locations may not be the same as the locations designated as Class I or II groundwaters under 314 CMR 6.00. As a result, remediation to groundwater standards may not be required in some locations, but in these same locations discharge permits (at least for new sources) may require compliance with groundwater standards.

5.3.1.6 Surface Water Quality Standards

Regulations embodied in 314 CMR 4.00 establish the Massachusetts Water Quality Standards. These regulations specify the most sensitive uses for which the various waters of the Commonwealth shall be enhanced, maintained and protected, prescribe the minimum water quality criteria necessary to sustain the designated uses, and specify how the existing water quality can be achieved and the existing water quality can be maintained. For toxic pollutants (similar to hazardous materials specified in M.G.L. c. 21E), according to 314 CMR 4.05(5)(e), DEP adopts EPA's Ambient Water Quality Criteria (the Gold Book) as recommended limits. These criteria consider both human health and aquatic effects and are strictly risk-based; that is, there is no consideration of economic or feasibility issues in the setting of these criteria. However, site specific limits can be developed by considering other sources, such as drinking water standards and guidelines, and fish action levels. Some of these other sources, particularly drinking water standards and fish action levels, incorporate risk balancing into their development.

5.3.1.7 Surface Water Discharge Permits

The Division of Water Pollution Control controls discharge of pollutants to assure that surface water quality standards of the receiving waters are protected and maintained or attained. Discharge permits specify water quality based effluent limitations. For toxics, these limits are developed through consideration of the recommended limits, as discussed above, and in some cases site-specific limits. In addition, these regulations have antidegradation provisions, which require that the existing level of quality in certain waters (high quality and other significant resource waters) be maintained unless

specifically approved by the Division of Water Pollution Control. New or increased discharges to Outstanding Resource Waters (including Public Water Supplies) is prohibited. Variances to these restrictions can be allowed based on economic and feasibility considerations.

The Massachusetts Water Quality Standards Implementation Policy for the Control of Toxic Pollutants in Surface Waters (February 23, 1990) states that risk balancing is appropriate in setting discharge limits. It specifies that "the health-based concentration shall be used as a goal for discharge limits. The Division reserves the right to consider costs and availability of waste treatment technologies when applying the health-based number to effluent limits."

As a result of the antidegradation provisions and the risk-balancing approach, site-specific water quality standards and effluent limits may be inconsistent with cleanup levels developed under c. 21E. This statute and the MCP do not explicitly specify an antidegradation approach, except in the provision that requires the consideration of the feasibility of permanent solutions that will achieve background conditions.

5.3.1.8 Land Application of Sludge and Septage

310 CMR 32.00 allows the land application of sludge and septage for beneficial purposes (to provide nutrients to growing vegetation or to improve the quality of soil for the purposes of growing vegetation) in a manner that will protect public health and the environment from possible contamination which could occur from pathogens, metals or toxic chemical compounds. As such, it inherently has a risk-balancing basis, the balancing of risks to public health with the benefits to be gained from land application, both from the use of the nutrient material and from the diversion of this material from traditional waste streams. In this sense, the balancing which occurs in this program is somewhat different than programs that balance the benefit of public health protection with the negative cost and feasibility considerations.

The regulations specify Maximum Allowable Concentrations for metals and PCBs in sludge to classify the material as Class I, II or III, and specifies conditions that must be met in obtaining an Approval of Suitability for the sale, distribution or use of the sludge or septage. The Maximum Allowable Concentrations were proposed in 1982 ("*Recommended Limits for Land Application of Sludge*", Memorandum to the MA DEQE Sludge Task Force from FiFi Nessen, 2/18/82) based on the consensus of the Committee for Establishing Application Rates. This committee was comprised of MA DEQE staff, academicians and soil scientists. While scientific data from the literature was considered, quantitative health risk assessment was not performed. The regulations do not describe specific risk levels as targets for the Maximum Allowable Concentrations. Proposed modifications of these regulations in 1991 utilized quantitative risk assessment as one factor in a decision to increase the allowable level of cadmium in Type I sludge.

5.3.2 Bureau of Waste Prevention

5.3.2.1 Hazardous Waste

The Department's Division of Hazardous Waste and M.G.L. c. 21C incorporate risk characterization/risk management into a number of programs. Overall their mandate is to protect public health, safety, and welfare, and the environment, similar to that of c. 21E.

The identification of substances that are considered hazardous wastes (310 CMR 30.100) is done primarily on the basis of consideration of the characteristics of the substance or waste. In this context, the risk characterization is limited and does not specifically consider potential exposure situations. The one exception to this is the maximum concentrations set for the toxicity characteristic leaching procedure (TCLP). These regulatory levels are set as a function of the drinking water standards, and as such implicitly incorporate an assumed drinking water exposure pathway and the risk balancing components of the drinking water standards described above.

The technical standards for hazardous waste facilities (310 CMR 30.600 also contain some implicit risk characterization/risk management provisions. The closure requirements require the removal or decontamination of waste residues, or the control of migration of hazardous constituents. Practical considerations are a facet of the closure requirements, incorporating a risk-balancing approach into the closure decision-making.

Groundwater protection is an important component of the hazardous waste regulations (310 CMR 30.660). Concentration limits are specified which, when exceeded, require a corrective action program. Facility licenses specify which groundwater protection standards apply. These groundwater protection standards can be based on background, specific maximum concentrations set forth in regulation (drinking water standards and risk balancing), or an alternate concentration limit. In setting the alternate concentration limits the factors to be considered include site specific considerations that relate to actual exposures that may occur, but do not include economic or feasibility considerations.

5.3.2.2 Ambient Air Quality Standards

310 CMR 6.00 establishes ambient air quality standards for Massachusetts. Primary standards define levels of air quality that are protective of public health. Secondary ambient air quality standards are protective of public welfare from known or anticipated adverse effects of a pollutant. These standards are adopted federal standards which were developed using a risk balancing approach, considering the potential human health risks as well as potential costs and feasibility.

5.3.2.3 Allowable Ambient Limits

The Division of Air Quality Control's (DAQC) legislative mandate (M.G.L.c. 142, Sections A-E) is to prevent the occurrence of conditions of air pollution and to facilitate the abatement of such conditions when and where they occur. DAQC's air toxics program was developed under that mandate to control emissions. Allowable ambient limits (AALs), as described in the Office of Research and Standards publication *The Chemical Health Effects Assessment Methodology and The Method to Derive Allowable Ambient Limits* (1990) are guidelines to be used in the evaluation of stationary sources. The AALs were developed using a risk-only approach and do not consider economic or feasibility issues, or quantitation levels. These chemical-specific concentrations are set at a cancer risk level of one in a million or a level equal to 20% of a level at which no adverse (noncancer) health impact would be expected, even if the exposure were to occur continuously over a lifetime.

As described in a 1989 *Air Toxics Implementation Update*,

> "DAQC integrates an air toxics review with its more traditional permit evaluation. DAQC requires new or modified sources of air contaminants to demonstrate the application of **Best Available Control Technology** (BACT), and assess, through computer modeling, the ambient concentrations caused solely by that source's emissions. These modelled concentrations are then compared to the AALs to determine whether there may be potentially unacceptable risks associated with that particular source."

The ability to meet AALs is *one* factor in the decision to grant a permit.

5.3.2.4 Air Permits/Plan Approvals

The Division of Air Quality Control is responsible for preventing the occurrence of the conditions of air pollution, and with abating such conditions when they occur (310 CMR 7.00). Air pollution is defined as the presence in ambient air of air contaminants that are or potentially could be injurious to health, (among other characteristics). Plan approvals are required for new sources, and the demonstration that the new source would not result in air quality exceeding Massachusetts or National Ambient Air Quality Standards is necessary for plan approval. Emission limitations are set in regulation for new sources, and no plan approval will be granted if these limitations would be exceeded. In addition, the emissions from the facility must represent Best Available Control Technology (BACT). Decisions made on new sources can be considered both risk balancing and technology based. While the decision-making process does not explicitly allow considerations of cost or feasibility, the air quality standards incorporate cost and feasibility considerations.

The Department may require reconstruction, alteration or repair at existing facilities when it is determined that the facility is causing or contributing to a conditions of air pollution, as defined above.

5.4 Conclusion

Table 5-1 presents a summary of the use of risk management, risk assessment and risk characterization criteria within the Department. Many of the regulatory programs which promulgate chemical-specific standards incorporate some form of risk-balancing. Such decisions can be made on a chemical-by-chemical basis reflecting specific costs and benefits which must be weighed, including technical feasibility and cost. Many of the risk-balancing decisions are have been made at the federal level and adopted by the Commonwealth. The Drinking Water Standards is one example.

Table 5-1
Summary of Risk Characterization/Risk Management

PROGRAM		DEFINED RISK CHARACTERIZATION /RISK MANAGEMENT APPROACH	UTILIZE RISK CHARACTERIZATION	UTILIZE RISK MANAGEMENT
BWSC	Release Notification	yes	Chemical specific	Risk-only
BWSC	Imminent Hazard	Only in general terms	Generally qualitative	Risk-only
BWSC	NFA	yes	Chemical specific and multimedia	Risk-only and risk balancing
BWSC	Tier Classification	Only in general terms	Generally qualitative	Not Applicable
BRP	Drinking Water Standards	yes	Chemical specific	Risk Balancing
BRP	BRP - Drinking Water Guidelines	yes	Chemical specific	Risk-only
BRP	Evaluation of Water Supplies	Partially	Chemical specific and multimedia	Risk Balancing
BRP	Groundwater Standards	yes	Chemical specific	Risk-only and risk balancing
BRP	Groundwater Discharge Permits	no	Chemical specific	Unclear
BRP	Surface Water Quality Standards	yes	Chemical specific	Risk-only and risk balancing
BRP	Surface Water Discharge Permits	yes	Chemical specific	Risk balancing
BRP	Land Application of Sludge	only in the most general terms	Chemical specific	Risk balancing
BWP	Hazardous Waste	no	Only in general terms	Not Applicable
BWP	Air Quality Standards	yes	Chemical specific	Risk Balancing
BWP	AALs	yes	Chemical specific	Risk-only
BWP	Air Quality Permits/approvals	no	Chemical specific	Unclear

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