GUIDANCE FOR DISPOSAL SITE RISK CHARACTERIZATION

In Support of the Massachusetts Contingency Plan

Interim Final Policy #WSC/ORS-95-141

MA DEP LETTERHEAD

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This Interim Final Policy provides guidance for conducting and documenting risk characterizations and related investigatory activities for disposal sites contaminated by oil and/or hazardous material. This information is intended solely for guidance. This document does not create any substantive or procedural rights, and is not enforceable by any party in any administrative proceeding with the Commonwealth. The regulations related to the characterization of risk of harm to health, safety, public welfare and the environment contain both specific and general requirements. In addition to summarizing specific requirements, this document also provides guidance on what approaches the Department considers acceptable for meeting the general requirements set forth in the regulations. Parties using this guidance should be aware that there may be other acceptable alternatives to this guidance for achieving compliance with such general regulatory requirements.

The regulatory citations provided throughout this document are not meant to be, and should not be relied upon to be, a complete list of all the regulatory requirements for risk characterization. Parties undertaking a risk characterization for a site should consult 310 CMR 40.0000 (MCP) for applicable requirements.

This policy supersedes the 1989 version of the *Guidance for Disposal Site Risk Characterization* (Policy #WSC/ORS-141-89) and the 1991 *Suggested Outline, Content and Format of Phase II Human Health Risk Assessment Scope of Work* (Policy #WSC-140-91).

SIGNATURE ON ORIGINAL — **July 28, 1995**

James C. Colman
Assistant Commissioner
Bureau of Waste Site Cleanup

Date

SIGNATURE ON ORIGINAL — **July 28, 1995**

Carol Rowan West
Director
Office of Research and Standards

Date

GUIDANCE FOR DISPOSAL SITE RISK CHARACTERIZATION

- IN SUPPORT OF THE MASSACHUSETTS CONTINGENCY PLAN

INTERIM FINAL POLICY
WSC/ORS-95-141

MASSACHUSETTS DEPARTMENT OF ENVIRONMENTAL PROTECTION

BUREAU OF WASTE SITE CLEANUP
and
OFFICE OF RESEARCH AND STANDARDS

July 1995

FOREWORD

This document provides guidance for conducting risk characterizations pursuant to Subpart I of the Massachusetts Contingency Plan (MCP). This is an update of the 1989 *Guidance for Disposal Site Risk Characterization*, reflecting the changes in the 1993 and 1995 revisions of the MCP.

The risk assessment procedures described herein are intended to be generally consistent with guidance provided by the U.S. Environmental Protection Agency, particularly the *Risk Assessment Guidance for Superfund* (US EPA, 1989) and related material. This guidance includes additional direction concerning the specific requirements of M.G.L. Chapter 21E, the Massachusetts Oil and Hazardous Materials Release Prevention and Response Act, and the MCP. Utilization of this guidance will lead to risk characterizations that are consistent from site to site and remedial decisions that are protective of health, safety, public welfare and the environment.

The increase in the volume of the guidance relative to the document published in 1989 reflects an effort to more fully describe DEP policies and practices. Since DEP no longer exercises direct oversight at all sites, it is necessary to provide more explicit guidance on risk assessment procedures that are acceptable for the purpose of meeting the MCP requirements. The increased volume of the risk assessment guidance does *not* represent an increase in risk assessment requirements. In fact, in many cases, the MCP now makes the risk assessment process much simpler, faster and less expensive than in the past.

This version of the guidance is an ***Interim Final Policy***, meaning that it is being made available to MADEP staff and the general public with the expectation that day-to-day use of this material will provide insight into how the guidance may be improved. The Massachusetts Department of Environmental Protection (MADEP) Bureau of Waste Site Cleanup and Office of Research and Standards are soliciting comments on whether this material provides sufficient guidance to demonstrate that the requirements of the MCP have been met, and on specific technical approaches and requirements described herein. Users of this document are encouraged to submit comments on both its content and format. Any recommendations for making the document more workable would be welcomed. Please submit comments on this document by **December 31, 1995** to:

Nancy Bettinger
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One Winter Street, 3rd Fl
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FOR MORE INFORMATION...

MCP HOTLINE

The *MCP Hotline* is staffed by MADEP BWSC staff with detailed knowledge of the Bureau's regulations and policies. The *Hotline* is reached through the Department's ***Infoline***, a toll-free information service providing answers to general DEP questions, permit application kits, DEP seminar information, Compliance Fee assistance, and referrals to technical experts.

from area code 617 and outside Massachusetts
617-338-2255

from area codes 413 and 508
1-800-462-0444

The ***MCP Hotline*** is the first choice, « 1 », on the ***Infoline***'s menu of options.

MADEP COMPUTER BULLETIN BOARD SYSTEM

The MADEP Office of Research and Standards has established a computer bulletin board system for **24-hour** access to many DEP policies and regulations, particularly related to M.G.L. c.21E and the Massachusetts Contingency Plan.

SETTINGS:

MODEM #:	**617-292-5546**
SPEED:	**up to 14,400 Baud**
DATA:	**8**
STOP:	**1**
PARITY:	**None**

Questions? Call Systems Operator (SYSOP) Michelle Bornstein at 617-556-1052.

STATE HOUSE BOOKSTORE

Copies of the Massachusetts state laws (e.g., M.G.L. Chapter 21E), regulations (e.g., the Massachusetts Contingency Plan), and other publications (e.g., *Background Documentation for the Development of the MCP Numerical Standards*) may be purchased from:

State Bookstore
Room 116
State House
Boston, MA 02133
(617) 727-2834

or

Western Office of the
Massachusetts Secretary of State
436 Dwight Street
Springfield, MA 01103
(413) 784-1376

REGIONAL SERVICE CENTERS

MADEP operates 4 Regional Service Centers to bring information and assistance closer to those who need it. The Service Center in your area is the first place to call or visit for general information, access to DEP documents and files, and environmental education materials. The Centers are located in the four DEP Regional Offices:

Western Region: (413) 784-1100 x 214
Springfield

Central Region:	**(508) 792-7683**
Worcester	**TDD: (508) 767-2788**
Northeast Region:	**(617) 932-7677**
Woburn	**TDD: (617) 932-7679**
Southeast Region:	**(508) 946-2714**
Lakeville	**TDD: (508) 946-2795**

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INTRODUCTION

This document provides guidance for conducting and documenting risk characterizations and related investigatory activities for disposal sites contaminated by oil and/or hazardous material. This information is intended solely for guidance. This document does not create any substantive or procedural rights, and is not enforceable by any party in any administrative proceeding with the Commonwealth. The regulations related to the characterization of risk of harm to health, safety, public welfare and the environment contain both specific and general requirements. In addition to summarizing specific requirements, this document also provides guidance on what approaches the Department considers acceptable for meeting the general requirements set forth in the regulations. Parties using this guidance should be aware that there may be other acceptable alternatives to this guidance for achieving compliance with such general regulatory requirements.

The regulatory citations provided throughout this document are not meant to be, and should not be relied upon to be, a complete list of all the regulatory requirements for risk characterization. Parties undertaking a risk characterization for a site should consult 310 CMR 40.0000 (MCP) for applicable requirements.

This guidance document is intended for use by anyone conducting risk characterizations pursuant to Subpart I (310 CMR 40.0900) of the Massachusetts Contingency Plan (MCP), including those sites considered to be adequately regulated subject to other regulatory schemes pursuant to 310 CMR 40.0110 through 40.0114. In addition to persons conducting risk characterizations at sites, this material may also be of use to persons *reviewing* MCP risk characterizations, persons conducting a risk assessment for other (non-MCP) purposes, and the interested public. The Massachusetts Contingency Plan is a set of regulations for the notification, assessment and remediation of contaminated sites promulgated pursuant to M.G.L. Chapter 21E (c.21E), the Massachusetts Oil and Hazardous Materials Release Prevention and Response Act. The MCP, originally promulgated in 1987, was significantly rewritten in 1993 and 1994 to implement sweeping amendments made to c.21E in 1992. The new program strengthens and expands the role of the private sector and encourages those legally responsible for sites to conduct response actions in a timely way. In addition, the new MCP focuses limited governmental resources on the sites considered to present the greatest potential for harm to health and the environment, and on those tasks the public sector has to perform to ensure that private sector actions are appropriate.

A key feature of the new c.21E program is its reliance on **Hazardous Waste Site Cleanup Professionals** (also called "**Licensed Site Professionals**", or "**LSPs**") to oversee assessment and cleanup actions and to ensure that such actions are performed in compliance with the MCP. LSPs oversee and manage response actions and render opinions that response actions, *including the risk characterization portion of the response action*, meet the MCP's requirements. LSPs are licensed by the Commonwealth and employed by people conducting response actions. The regulations that establish the licensing process and criteria can be found in 309 CMR 1.00 - 8.00. A list of LSPs is available from the Board of Registration of Hazardous Waste Site Cleanup Professionals (telephone: 617-292-5556).

Risk characterization is used in the Massachusetts Contingency Plan to determine whether a remedial response action is necessary and to document that a level of no significant risk of harm to health, safety, public welfare and the environment exists or has been achieved for the site. In this context, the site risk characterization is a decision tool for making remedial decisions in a manner which is both protective of public health and the environment and consistent from site to site. A risk characterization must be performed at each site seeking a Response Action Outcome (RAO), because determining whether a condition of "*No Significant Risk*" exists is a basic requirement of an RAO.

Response Action Outcomes, or RAOs, are the end-points of all response actions conducted under the Massachusetts Contingency Plan, and the documentation that the disposal site has reached an end-point is the Response Action Outcome Statement. RAOs are divided into three main categories (A, B and C) and several subcategories (e.g., A-1, A-2 and A-3) to distinguish between the different types of end-points which may be reached for a given site. Only a Class A-1 RAO, which applies to sites that have been cleaned up to background levels, can be achieved without conducting a quantitative risk assessment. To achieve any other RAO, a risk assessment must be conducted.

While risk characterizations may be performed at any point during the site assessment and remediation process (assuming that sufficient information about the site and the contamination has been gathered) they are typically conducted at two points in the process: (1) as part of a site assessment, to determine whether or not remediation is necessary, and/or (2) following a remedial response action to determine whether the action effectively eliminated significant risk.

The general data gathering and interpretation which must precede the risk characterization is described in the regulations beginning at 310 CMR 40.0904. These activities include investigation of the physical characteristics of the site; identification of the source and extent of the release; characterization of the type, volume, nature, etc. of the released oil or hazardous materials (OHM); identification of applicable soil and groundwater categories; identification of exposure points and the concentration of OHM at these exposure points; and identification of background levels of OHM. While it is beyond the scope of this document to provide detailed guidance on all site investigation activities, **Section 2.0: Site Characterization** provides a discussion of those issues which have the greatest potential impact on the risk characterization process.

Having collected sufficient site information, the risks of harm to health, safety, public welfare and the environment must be evaluated (or characterized). As described in 310 CMR 40.0940 of the MCP, risks of harm to health, public welfare and the environment must be characterized by one of three methods. The Massachusetts Contingency Plan describes these three methods of risk characterization, and this document includes guidance for all three approaches. *In general, only one method should be used for a given disposal site*, although there are circumstances when a combined approach is appropriate. Guidance for selecting the appropriate risk characterization method is contained in **Section 3: Selection of Risk Characterization Method**. Correct choice of the appropriate method is extremely important. Note that the risk of harm to safety is evaluated in the same manner at all sites, no matter which method is used to characterize the risks to health, public welfare and the environment. Guidance on evaluating risk of harm to safety is provided in **Section 4.0: Characterization of Risk to Safety**.

The scope and level of effort of the risk characterization depends upon the complexity of the disposal site and the response action being performed. A Licensed Site Professional may provide ***technical justification*** *(310 CMR 40.0193) for forgoing specific site investigation activities if, in his or her professional judgement, any particular requirement is unnecessary or inappropriate based upon the conditions and characteristics of the site. The LSP must employ* ***RAPS*** *(Response Action Management Approach, 310 CMR 40.0191) in determining whether any such activity is unnecessary or inappropriate.*

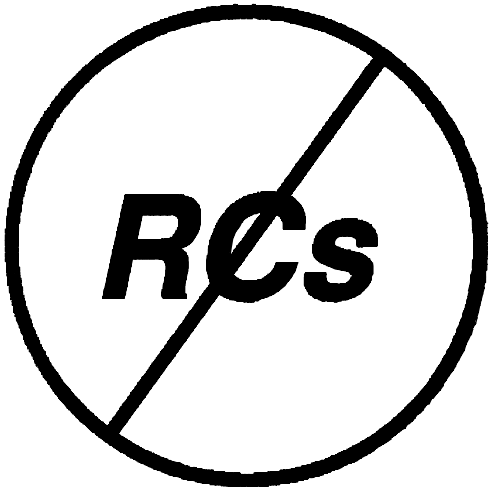
Method 1 risk characterizations (described in the MCP at 310 CMR 40.0970 and in **Section 5.0: Method 1** of this document) compare promulgated lists of soil and groundwater standards to contaminant concentrations detected at the site. Method 2 assessments (310 CMR 40.0980) allow for limited modification of the Method 1 standards based upon site and chemical-specific fate and transport factors. In addition, if MADEP has not promulgated a Method 1 soil or groundwater standard for a chemical, Method 2 may be used to develop values analogous to Method 1 Standards. The use of Method 2 is described in **Section 6.0: Method 2** of this document. Method 3 risk characterizations employ site-specific information (particularly the potential for exposure to contaminants) to independently evaluate the risks of harm to health, public welfare and the environment. The recommended procedures for the evaluation of human health risks are described in **Section 7.0: Method 3 - Human Health**, while the procedures for characterizing the risk of harm to public welfare and the environment are presented in **Section 8.0: Method 3 - Public Welfare** and **Section 9.0: Method 3 - Environmental Risk Characterization**.

There are some site conditions which warrant immediate attention, including early notification to MADEP and the implementation of an **Immediate Response Action** (IRA). Immediate Response Actions must be undertaken to address sudden releases of oil or hazardous material, **Imminent Hazards** and other time-critical conditions identified in the MCP (310 CMR 40.0410). **Section 10.0: Imminent Hazard Evaluations** describes the process by which site conditions may be assessed to determine whether or not an Imminent Hazard exists.

Additional guidance is provided in the Appendices. Appendix A presents a glossary of terms and acronyms used in the MCP and this guidance document. Appendix B presents suggested

default assumptions which can be used to estimate site exposures. Appendix C contains a discussion of the use of probabilistic techniques to characterize risk under the MCP. Appendix D presents guidance on fish tissue sampling. Appendix E provides references for potentially Applicable or Suitably Analogous Standards. Appendices F and G contain outlines of the basic components of Method 1 and Method 2 Risk Characterizations, while Appendix H presents guidance for preparing a Method 3 Scope of Work.

The Misuse of Reportable Concentrations (RCs)



in MCP Risk Characterizations

Reportable Concentrations are <u>ONLY</u> triggers for notification under the Massachusetts Contingency Plan and any other use of those numbers is not sanctioned by the Massachusetts Department of Environmental Protection.

Reportable Concentrations are <u>NOT</u> cleanup standards. The MCP Method 1 Standards are a distinct and separate list of numbers and their use is described in detail in Subpart I of the MCP and Section 5.0 of this document.

Reportable Concentrations are <u>NOT</u> "No Risk" levels. Sites with concentrations of oil or hazardous material below RCs do not trigger notification to MADEP *at that time* but may pose significant risk and require remediation. Information gathered at a later date or through the DEP's Site Discovery Program may result in the need for notification and/or remediation.

Reportable Concentrations are <u>NOT</u> screens to eliminate Contaminants of Concern from a risk assessment. The acceptable approach for eliminating chemicals from further consideration is discussed in Section 2.4 of this document.

1.0 PURPOSES OF RISK CHARACTERIZATION IN THE MCP

As described in Subpart I of the Massachusetts Contingency Plan (MCP), risk characterization is used in the Waste Site Cleanup Program to determine whether a remedial response action is necessary at disposal sites, to identify target cleanup levels in the event that a remedial action is required and to document that a level of no significant risk of harm to health, safety, public welfare and the environment[1] exists or has been achieved for a site. In other words, risk characterization is used to answer the question "***How Clean is Clean Enough?***"

In this context, the site risk characterization is a decision making tool with which remedial decisions may be made in a manner which is both protective of public health and the environment and consistent from site to site. A risk characterization must be performed at each site seeking a Response Action Outcome (RAO): a condition of "*No Significant Risk*" is a basic requirement of an RAO. While risk characterizations may be performed at any point during the site assessment and remediation process (assuming that sufficient information about the site and the contamination has been gathered) they are typically conducted at two points in the process: (1) following a comprehensive site assessment to determine whether or not remediation is necessary, and (2) following a remedial response action to determine whether the action effectively eliminated significant risk.

While the terms "Risk Characterization" and "Risk Assessment" are often used synonymously, there is a subtle difference in their meaning in the regulations. A risk assessment describes, often quantitatively, the potential risks, answering the question, "*What are the risks associated with the contamination at this site?*" An MCP Risk Characterization takes the process one step further: using criteria promulgated in the regulations, the risk characterization answers the question, "*Are those risks significant (important)?*" The standards used to answer that question may be expressed qualitatively, as concentration-based standards or as limits on Cumulative Receptor Risk, depending upon the nature of the risks being evaluated and the risk characterization approach used. Each report presenting an MCP Subpart I Risk Characterization must contain both the documentation of the risk assessment and a clear statement whether or not a condition of no significant risk of harm to health, safety, public welfare and the environment exists or has been achieved. Thus *Risk Characterization* is a process which combines both risk assessment and risk management.

[1] In this document, the capitalized term "*No Significant Risk*" is often used in lieu of the longer "*no significant risk of harm to health, safety, public welfare and the environment*." Reference to single measures, such as "*no significant risk to the environment*," will not use the capitalized form.

1.1 DEMONSTRATE NEED FOR A RESPONSE ACTION

A tanker truck overturns on Route 128, spilling gasoline across the highway and into a drainage ditch. *Is a response action necessary?* At many sites regulated under the Massachusetts Contingency Plan the answer is intuitive: it is obvious to the owner/operator, the site manager overseeing the assessment/remediation and to the government regulators involved that remediation must take place. Like this example, many MCP sites result from the sudden release of oil or hazardous material (OHM) and Emergency Response teams are called in immediately to clean up the spill, often to "background" levels.

Unfortunately, the question of whether remediation is necessary is not always so clear. The decision about whether the conditions at a site are serious enough to require remediation requires evaluation of a number of factors such as the possible presence of ongoing releases, the use of the site, the location of the contamination and the concentrations of the oil or hazardous material. One of the primary purposes of promulgating the MCP was to establish a consistent set of rules by which decisions about the need for remedial action could be made. Risk Characterization is one of the tools incorporated into the regulations to assist site managers in making decisions that are both consistent from site to site and protective of health, safety, public welfare and the environment.

1.1.1 Baseline Risk Characterizations

A "*baseline*" is a measure used as a standard for comparison. In environmental regulation, a baseline measure describes the conditions which would exist in the absence of any controls or remedial measures - in other words, the baseline measure describes the "No Action" alternative. Thus, a baseline Risk Characterization describes the health, safety, public welfare and environmental risks which would exist if no remedial actions were taken to address the contamination at a disposal site. Because a baseline risk characterization assumes that no remedial action will take place, the assessment includes an evaluation of both current and future exposures to the unremediated contamination.

At most sites, however, a true baseline risk characterization may never be carried out. The 1993-1994 revisions to the MCP allow preliminary response actions and risk reduction measures to be taken without a formal determination that the contamination at the site poses significant risk. This change was made to the regulations in response to comments that the need for action (and the appropriate type of action) at a site is often evident, and resources should be spent on actually cleaning up sites and reducing risk rather than documenting the need to take such actions. Thus, the first, and only, risk characterization performed for a c.21E site may be to demonstrate that the remedial actions already implemented have achieved a condition of No Significant Risk. In other words, such risk

characterizations describe the "No Further Action" alternative[2]. (The assumption that no further remedial action will take place means that future exposures to any residual contamination must be addressed.) While this approach can greatly streamline the assessment/remediation process, there are potential problems as well. Without an adequate understanding of the site, chemical concentrations and exposure pathways, the initial remedial measures may not be sufficient to achieve a level of No Significant Risk, and further response actions may be necessary. Risk characterizations conducted *before* a remedial measure is carried out can be used to plan cost effective remedial strategies, such as targeting for cleanup those chemicals or exposure media contributing the most risk.

The Risk Characterizations submitted to MADEP to support a Response Action Outcome Statement for a site may be either a baseline or modified baseline evaluation, and the guidance which follows does not distinguish between the two. The difference is only important in so far as the type of RAO (Class A or B) depends upon whether or not a response action has been implemented at the site (310 CMR 40.1035 and 40.1045).

1.1.2 Imminent Hazard Evaluations

Imminent Hazard Evaluations are a specific type of MCP risk characterization which answers the question, "*Is a remedial action required NOW?*". It is a form of baseline risk assessment which typically evaluates the potential risks associated with short-term exposures at a site under current conditions. Imminent Hazard Evaluations are not required at all sites, but are triggered by the presence of conditions indicating the potential for an Imminent Hazard. An Imminent Hazard Evaluation should be conducted whenever information indicating a potential imminent hazard comes to light, which could be at any point in the site assessment/remediation process. Section 10 of this document describes when and how such evaluations are conducted.

1.1.3 Identification of Target Cleanup Levels

When a risk characterization indicates that remediation is needed (i.e., a condition of No Significant Risk has not been achieved) the question "*Is a response action necessary?*" becomes "*When can the response action stop?*" In much the same way that the question is turned around, the risk characterization can be reversed and used to identify target cleanup levels. The equations used to estimate exposure and risk (Sections 7.3 and 7.4) can be applied to combinations of chemical and medium-specific concentrations which would meet the Method 3 Cumulative Risk Limits. (At a given site, there may be an infinite number of combinations which could meet the Method 3 Cumulative Risk Limits, and risk assessment can be used to identify target cleanup levels which maximizes risk reduction

[2] This type of post-remedial action assessment could be thought of as a modified Baseline Risk Characterization, "*modified*" because the remedial measure has altered the initial conditions (changed the baseline.)

and minimizes cost.) The standards promulgated in Method 1 (310 CMR 40.0970), which indicate the need for remediation when exceeded, can also be used as target cleanup levels during remediation, as can Method 2 Standards.

1.1.4 Evaluation of Remedial Alternatives

When remedial alternatives utilizing known technologies are proposed, it is often possible to project the effectiveness of those technologies in reducing contaminant concentrations (and thus exposure point concentrations.) When the capabilities of a given technology are described in terms of likely residual concentrations, then a risk characterization can be performed to determine if that technology is capable of achieving a condition of No Significant Risk at the site. If there is more than one remedial alternative being considered, then the relative effectiveness (particularly the cost effectiveness) of the technologies in reducing risk may be an important factor in choosing among the alternatives.

1.2 RISK CHARACTERIZATION & RESPONSE ACTION OUTCOME (RAO) STATEMENTS

The relevance of risk assessments to Response Action Outcomes is discussed in the Introduction Section, and the regulations specific to Response Action Outcomes (or RAOs) are located in Subpart J (310 CMR 40.1000) of the MCP. This guidance document focuses on *one* of the minimum requirements of a Response Action Outcome: the risk characterization (310 CMR 40.1004(1)(a)). It does *not* present detailed guidance on all of the requirements and procedures for RAOs. The reader is referred to the MCP itself and guidance on a range of topics issued by MADEP (e.g., the MCP Q&A publications) for additional information.

The *Response Action Outcome Statement & Downgradient Property Status Transmittal Form* (BWSC-104) is the form which must be submitted to MADEP along with the documentation which supports the Response Action Outcome. The form itself and written guidance on completing the form are available from MADEP, through the Regional Service Centers and the Infoline.

The general requirements (310 CMR 40.1003 and 40.1020) for achieving a Response Action Outcome include:

- A level of No Significant Risk must exist or have been achieved (Class A and Class B RAOs);
- Achieving an RAO and the submitting an RAO Statement must occur within the deadlines established by the MCP or by the Department;
- An RAO may be achieved and an RAO Statement submitted for any site, disposal site or portion of a disposal site;
- The boundaries of a site or portion of a disposal site to which the RAO is applicable must be clearly and accurately delineated;
- Each source of oil or hazardous material must be eliminated or controlled (for Class A and Class B RAOs); and
- Where feasible, at any disposal site or portion of a disposal site where a remedial action is taken to achieve a Permanent Solution, such actions must achieve or approach background levels of oil or hazardous material.

It is important to note that achieving a level of No Significant Risk is just one of several requirements: it should be thought of as a *minimum* requirement, not the only requirement. Even after a level of No Significant Risk has been achieved, further actions may be necessary to eliminate continuing sources of oil or hazardous material to the environment or to achieve/approach background levels.

Risk assessors and site managers should not focus on the results of the risk assessment to the exclusion of the other requirements of the RAO. A cost effective approach to site management and remediation would ensure that all of the requirements of a Response Action Outcome are considered early in the planning of remedial strategies.

1.3 LEVEL OF EFFORT APPROPRIATE TO THE ACTION TAKEN

Response Action Outcomes may be achieved at any time during the MCP process, from the time of notification to the end of Phase V Operation, Maintenance and Monitoring[3] . The timing of the RAO will depend upon the nature and extent of release and other site-specific factors. In order to achieve an RAO, the RAO Statement must be submitted with evaluations and assessments of sufficient scope and detail to support the conclusion that all the applicable MCP requirements have been met. Recognizing that the scope, detail and level of effort necessary to meet the MCP requirements may vary from site to site, many of the requirements of the regulations are written in terms of Performance Standards rather than laying out specific events which must occur. The performance standards for Response Action Outcomes are listed at 310 CMR 40.1004. The overall performance standard, known as the *Response Action Performance Standard* (RAPS), for work conducted under the MCP is given at 310 CMR 40.0191. Provision is also made for exercising professional judgement to forgo certain site assessment activities based upon technical justification (310 CMR 40.0193.)

[3]The regulations (310 CMR 40.0801 and 40.0810) outline five phases of Comprehensive Response Actions conducted pursuant to the MCP: (a) Phase I Initial Site Investigation, (b) Phase II Comprehensive Site Assessment, (c) Phase III Identification and Selection of Comprehensive Remedial Alternatives, (d) Phase IV Implementation of the Selected Remedial Action Alternative, and (e) Phase V Operation, Maintenance and/or Monitoring.

2.0 SITE CHARACTERIZATION

2.1 CURRENT AND FORESEEABLE USE

This section of the Guidance for Disposal Site Risk Characterization describes the role that site use plays in the characterization of risk under the MCP requirements. Topics which are covered include issues to consider in determining the current and the reasonably foreseeable uses of the site and the surrounding environment, how limitations may be placed on the foreseeable use in order to limit the scope of the risk characterization and remediation, and the soil and groundwater categories established by MADEP as measures of site use.

The risk characterization methods of the MCP are used to establish whether a level of No Significant Risk exists or has been achieved at a disposal site for *any current or reasonably foreseeable uses of the site and surrounding area*. The use of a site and surrounding area determines the activities which occur there and the potential for exposures which could occur there, consistent with the site use. In order to adequately evaluate exposures, the risk characterization must identify and describe the site activities and uses associated with the disposal site and surrounding environment (40.0923). The requirement to consider site use (both current and foreseeable) comes from the definition of "no significant risk" found in M.G.L. c.21E 3A(g). The risk assessment should address all current and reasonably foreseeable uses and activities at the disposal site or in the surrounding environment which could result in exposure to oil and/or hazardous material by human or environmental receptors (40.0923 (1)).

In this document the terms "activity" and "use" are both employed to describe human or environmental pursuits which could result in exposure to human or environmental receptors. As used here, "use" usually refers to the property itself and is generally a broader term than "activity", which is used here to describe actions by a receptor which could potentially result in exposure. Zoning terms, such as "residential", "commercial" and "industrial" are helpful but incomplete descriptors of exposure potential.

Knowledge about the current and foreseeable uses of the site is necessary to identify exposure points and exposure pathways and to classify soil and groundwater. The exposures to be evaluated in a human health or environmental risk assessment depend upon the activities which could occur under the current and foreseeable uses of the land and groundwater at the site.

The MCP recognizes a distinction between the current use of the site and the foreseeable use. "*Current*" is actual or possible given current circumstances, while "*foreseeable*" has not yet occurred, is hypothetical and may yet be changed or avoided. Current uses and activities must be identified and evaluated to be protective of present receptors, and reasonably foreseeable uses and activities must be identified to be protective against potential future exposures which could occur if no action were taken at the disposal site.

2.1.1 Current Site Activities and Uses

Any current site activities and uses that could result in exposure of human and/or environmental (plants, animals and their habitats) receptors must be described in the risk assessment. The current *use* (again, *use* is the broader term) of the site may be consistent with a wide range of site *activities* (*activity* is the narrower term), some of which may happen to be occurring at the time of the risk assessment, but all of which should be identified and assessed as a current activity. For example, if a disposal site with soil contamination is currently used as residential property, the risk assessment should evaluate exposures to children having contact with the soil, regardless of the age of the present residents. The MCP requires that activities which are not occurring at the time of the assessment, but are consistent with the current use of the site, must be evaluated (310 CMR 40.0923(2)).

2.1.2 Reasonably Foreseeable Activities and Uses

The reasonably foreseeable activities and uses should include *any* possible future activity or use (310 CMR 40.0923(3)), with some important exceptions described below. These foreseeable uses must be evaluated in the risk assessment if they would result in greater human or environmental exposures than the current site use: in other words, since the current site use must be evaluated, there is little need to evaluate foreseeable uses which would result in less exposure. (This is an important point in streamlining the risk assessment process, since there are theoretically innumerable possible exposure scenarios. For a given site the risk assessor should quantify the risks only for the most exposed receptors and conclude that receptors experiencing similar exposures but to a lesser degree would face lesser risks than those estimated.)

One of the exceptions to the "*anything is foreseeable*" rule is drinking water. It should ***not*** be assumed that all groundwater is a foreseeable source of drinking water. In determining whether or not the foreseeable use of site groundwater is drinking water, the MADEP criteria listed at 310 CMR 40.0932(4) **must** be used. These criteria were developed by the Commonwealth of Massachusetts for the protection of its groundwater resources. By these criteria, groundwater which is either a current or potential future source of drinking water is categorized as GW-1 and must be protected for this use. Except as described in those criteria *there are no site-by-site exceptions, nor can professional judgement be used to overrule the criteria*. The GW-1 criteria are discussed in more detail below.

Another exception to the "*anything is foreseeable*" rule is that the owner of a property may rule out any hypothetical future site use or activity for that property through an *Activity and Use Limitation* (AUL). AULs are discussed in more detail below. For example, if the present use of a disposal site is commercial with activities which pose limited exposure potential for children, receptor exposures would be evaluated based upon this commercial

use/activity scenario. Exposures evaluated for the future use of the property would include foreseeable residential use with associated activities (including those for children) ***unless*** an AUL is implemented to restrict land use. One possible outcome would be the application of an AUL to ensure that the future use(s) and activities for the property remain consistent with the current use, in which case the current exposures would also be the future exposures.

NOTE: If the risk assessment is conducted prior to implementation of an AUL, but it assumes that certain exposures will be limited by the planned AUL, the risk assessment must clearly state the assumed exposure limitations, and that the results of the risk assessment will not be valid until the AULs are in place.

2.1.3 Activity and Use Limitations

Activity and Use Limitations (AULs) serve several purposes (310 CMR 40.1012(4)). First, they provide notice to future owners of a property, abutters, local officials and MADEP as to what uses and activities are consistent with a level of No Significant Risk at the site. Conversely, they describe conditions under which the site *may* pose a significant risk of harm, and the AUL establishes a duty to evaluate such conditions *prior to* any change in site use. Thus AULs are declarations of the acceptable and unacceptable uses and activities for a site; they are not intended to permanently restrict changes in site use as much as to ensure that any proposed changes are evaluated considering the residual contamination and any increased exposure likely to result from changes in use (310 CMR 40.1080).

An AUL may apply to an entire property, an entire site or to some portion of a property or site. AULs may be used to eliminate entire exposure pathways which would otherwise need to be considered in the evaluation of future site use.

When foreseeable exposures are excluded from a risk assessment because of an AUL, documentation and description of the AUL is a fundamental component of the risk assessment. In such cases the risk assessment is only valid when an adequate and appropriate AUL is in place. Basic issues regarding AUL implementation are presented in a Question and Answer Format.

When would an AUL be used?

- An AUL would be used anytime the risk characterization is performed assuming some restrictions on the use of the site or the activities which would occur there.

- An AUL may be used to limit the number of site uses and/or activities which would otherwise be evaluated as reasonably foreseeable, thereby reducing the scope of the risk characterization. The most common application of an AUL would be to limit the site use and activities to those which are currently occurring. Remediation goals which would achieve a level of No Significant Risk for the current site use would then be acceptable for the foreseeable future.

When are AULs <u>not</u> necessary?

An Activity and Use Limitation is not required if the site is acceptable for unrestricted use. This would include sites where:

- Levels of oil and hazard material are at or below background concentrations; or

- For sites characterized using Methods 1 or 2, the levels of OHM are at or below applicable category S-1 soil standards;

- For sites characterized using Method 3, no limitations on site use were assumed or implied in the risk characterization (e.g., residential use of the site, including unrestricted access to all soil, including soil at depth, is assumed and evaluated).

- residual contamination is located at a depth greater than 15 feet from the ground surface; or

Another situation that does not require an AUL is residual contamination located within a public way or within a rail right-of-way. These areas have been exempted as a matter of policy because the deeds are held differently than those for private property, and are less amenable to the application of AULs.

An AUL is also <u>not</u> required if the groundwater is determined <u>not</u> to be a current or foreseeable source of drinking water, based upon MADEP criteria. While this is a restricted-use scenario, the fact that the criteria used in this determination were developed by MADEP negates the need for an AUL.

An AUL is not required when under current conditions the GW-2 Standards are exceeded and the depth to groundwater is less than 15 feet, but there are no occupied structures on the site. In this situation, an AUL is <u>not</u> required to prevent any future construction at the site. If however, construction were to occur at the site, the future conditions would have to address meeting the GW-2 Standards.

Finally, AULs are not required but may be used to provide notice of the existence of residual contamination at a disposal site where all substantial hazards have been eliminated and where all applicable requirements for a class C RAO have been met pursuant to 310 CMR 40.1050.

Are there any limitations on the use of AULs?

- A planned or proposed AUL may never be used to limit the current use/activities of a site. Note, however, that if an AUL is already in-place and effective, it is part of the current use of the site: any limitations on activity or use which it achieves can be considered in the risk assessment. For example, if a site is currently used as residential property, the risk assessment should evaluate exposures associated with gardening activities such as: direct contact with contaminated soil, incidental ingestion of soil and ingestion of vegetables grown in the soil. If, however, prior to the risk assessment a limitation was placed on the property identifying gardening as a prohibited activity, and that AUL is determined to be effective, then the risk assessment need not evaluate exposures from gardening. If no AUL is in place at the time of the risk assessment, gardening exposures must be evaluated whether or not gardening activities are currently occurring.

Who may place the AUL on the disposal site?

The property owner is the only individual who can limit site activities and uses through the use of an AUL. In addition, MADEP may impose an AUL at disposal sites where it has conducted response actions or at sites where the property owner fails to record or register an environmental restriction (see 310 CMR 40.1073).

Although the property owner is ultimately responsible for placing AUL on the site, the decision to use an AUL should be made in consultation with the risk assessor and the Licensed Site Professional (LSP) who can describe the costs and benefits of using this tool.

What information should be included in the AUL?

The contents of the AUL are specified in 310 CMR 40.1071(2) of the MCP. In 40.1071(2)(h) through (k), the regulations describe the *risk-related* information contained in an Activity and Use Limitation, including what uses and activities are prohibited on the property, conditions necessary to maintain a level of No Significant Risk, and a description of the permitted activity and uses.

The AUL must be very specific as to the portion of the disposal site subject to the use restrictions.

How should an AUL be referenced in the risk assessment?

The results of the risk assessment are based upon the exposure assumptions utilized in the process. The exposure assumptions in turn are based upon the current and foreseeable uses of the site. The conclusions of the risk assessment must therefore discuss all limitations in detail. When an AUL is placed on the disposal site, the risk assessment is only valid and applicable in conjunction with the AUL.

What types of AULs exist under the MCP?

The MCP at 310 CMR 40.1070 identifies two types of Activity and Use Limitations: an Environmental Restriction and a Notice of Activity and Use Limitation. The specific requirements for each type of limitation are delineated in the MCP. The technical requirements are somewhat different. The overall purpose of both limitations is, however, to describe the type of use and specific activities that will be allowed at the site, and those activities which are expressly forbidden.

- The general requirements of an Environmental Restriction are delineated in 310 CMR 40.1071 (1). The basic requirements include: submittal to the Department of an AUL Opinion from an LSP specifying the need for the AUL, the activities and uses permitted, prohibited or restricted, and any obligations or conditions necessary to maintain a level of no significant risk. The Grant of Environmental Restriction must be signed by the Commissioner and then recorded with the appropriate Registry of Deeds and/or Land Registration Office.

- The general requirements of the Notice of Activity And Use Limitation are found at 310 CMR 40.1074 (1). The basic requirements include: (1) submittal to the Department of an AUL Opinion with a Response Action Outcome (RAO) Statement specifying the need for the AUL, the activities and uses to be permitted, prohibited or restricted, and any obligations or conditions necessary to maintain a level of no significant risk, and (2) the property owner shall record and/or register any AUL Notice in the appropriate Registry of Deeds and/ or Land Registration Office and within 30 days thereof submit a certified copy to the Department.

What are the Limits on the Use of AULs?

The application of Activity and Use Limitations to a property depends upon the extent to which the property owner wishes to restrict the use of that property.

The application of these limitations to groundwater, however, is somewhat restricted. A groundwater aquifer is a State resource and therefore its foreseeable use is determined by the State and not by the individual property owner. As noted above, the determination of whether or not the groundwater is a drinking water resource (GW-1) is determined in accordance with the criteria listed in 310 CMR 40.0932(4). The only situation in which groundwater that has been classified as GW-1, may be subjected to an Activity and Use

Limitation is when the groundwater is classified as GW-1 solely on the basis of the presence of private drinking water wells within 500 feet (310 CMR 40.0932(5)(d)). An Environmental Restriction (*not* a Notice of Activity and Use Limitation) may be applied to restrict the use of groundwater if and only if:

- the private wells are abandoned;
- the properties previously supplied with drinking water by those wells are tied into a public drinking water distribution system; and
- the affected property owners agree to place an Environmental Restriction on their property.

The properly executed Environmental Restriction must then be recorded. The restriction will serve to prohibit the placement of private wells or to reactivate closed wells on the property in the reasonably foreseeable future.

2.1.4 Groundwater and Soil Categories

The MCP establishes categories of groundwater and soil which should be utilized in characterizing risk posed by a disposal site. Groundwater and soil must be categorized when conducting a risk assessment regardless of the method selected. When utilizing either Method 1 or Method 2 it is necessary to categorize the soil and groundwater so that the appropriate soil and groundwater standards will be used. The groundwater and soil standards for Methods 1 and 2 are listed in 310 CMR 40.0974(2), 310 CMR 40.0975(6)(a)(b) and (c), and 310 CMR 40.0985(6). When conducting a Method 3 risk assessment the soil and groundwater categories should also be identified to aid in the development of exposure profiles and to identify applicable or suitably analogous standards as described in 310 CMR 40.0993(3). Finally, it is necessary to have categorized soil and groundwater prior to placement of any Activity or Use Limitations at the site. Specific guidance on the classification of soil and groundwater at a site is discussed below.

2.1.4.1 Categorization of Groundwater

The MCP identifies three types of applicable groundwater categories in 310 CMR 40.0932, which are described as GW-1, GW-2 and GW-3. These groundwater categories were established to identify groundwater associated with three distinct types of exposures: its use as drinking water, as a source of indoor air contamination, and as a source of surface water contamination. Because these exposures of concern are not necessarily related to each other, they are not mutually exclusive: Groundwater may, at the same time, be used as drinking water, be a threat to indoor air and discharge to surface water, in which case it would be considered to be categories GW-1, GW-2 ***and*** GW-3.

At any disposal site more than one groundwater category may be applicable within the aquifer.

Note also that MADEP assumes that *all* groundwater eventually discharges into surface water, and thereby acts as a source of contamination to that water body. Since the GW-3 Standards are based upon this assumption, the GW-3 Standards are applicable everywhere.

All groundwater is considered to be GW-3.

In addition, there may be disposal sites where groundwater in one area is classified as one category and another area is classified as a different category, even though the groundwater in both areas is part of the same aquifer.

Groundwater Category GW-1

Groundwater GW-1 is considered to be either a current or future source of drinking water, and the MCP describes six criteria (310 CMR 40.0932(4)) which are used to identify aquifers which should be protected for this use. If it is determined that the groundwater at a site meets any *one* of these criteria, its current and foreseeable use must be described as being a source of drinking water. The criteria are:

(a) the groundwater is within a Zone II;
(b) the groundwater is within an Interim Wellhead Protection Area;
(c) the groundwater is within a Potentially Productive Aquifer;
(d) the groundwater is within the Zone A of a Class A Surface Water Body;
(e) the groundwater is located five hundred (500) feet or more from a public water system distribution pipeline; or
(f) the groundwater is located within five hundred (500) feet of a private water supply well that was in use at the time of notification pursuant to 310 CMR 40.0300 and was installed in conformance with any applicable laws, by-laws or regulations.

The terms used in the classification criteria above are defined at 310 CMR 40.0006(11) as follows:

- The ***Zone II*** is defined as "that area of an aquifer which contributes water to a well under the most severe pumping recharge conditions that can be realistically anticipated, as approved by the Department's Division of Water Supply pursuant to 310 CMR 22.00.

- The ***Interim Wellhead Protection Area*** (IWPA) is defined as meaning:

  (1) with respect to public water supply wells and wellfields whose pumping rate is one hundred thousand (100,000) gallons per day or greater and for which the Department has not approved a hydrologically delineated Zone II, the one-half mile (2640') radius surrounding such well or wellfield; and

  (2) with respect to public water supply wells and wellfields whose pumping rate is less than one hundred thousand (100,000) gallons per day and for which the Department has not approved a hydrologically delineated Zone II, the radius calculated by multiplying the maximum pumping rate in gallons per minute for such well or wellfield by thirty-two (32) and adding four hundred (400) feet thereto (i.e. IWPA = (32) (y) + (400); where y = pumping rate in gallons per minute.)

- A ***Potentially Productive Aquifer*** is defined as:

  (a) all aquifers delineated by U.S. Geological Survey (USGS) as a high or medium yield aquifer, except for any portion of a high or medium yield aquifer's surface area that is located in a municipality with a population density equal to or greater than 4,400 persons per square mile (based on the most recent U.S. Census); and
  (b) all aquifers located east of the Cape Cod Canal (Cape Cod), on the Elizabeth Islands, on Martha's Vineyard, or on Nantucket.

  Note (7/95): The Potentially Productive Aquifer (PPA) definition is currently under review. Revisions to the MCP related to PPA designation and GW-1 categorization will be finalized by the fall of 1995. Readers should be sure to consult the latest version of the regulations for changes in this area.

- A ***public water supply*** is defined as "a source of water supply, including, but not limited to, primary, backup and emergency sources, utilized by a public water system." The terms "public water supply", "primary source", and "emergency source" are defined at 310 CMR 22.02.

- A ***private water supply*** is defined as " a well which is utilized by a private water system." The system provides for " piped water for human consumption which has fifteen (15) or less service connections or does not regularly serve an average of at least twenty-five (25) individuals daily at least 60 days of the year."

Note that there is some flexibility in the regulations to consider site-specific factors, but this flexibility is limited to the following conditions. The MCP describes particular situations in which the groundwater which normally would be classified as GW-1 may be otherwise classified. These situations are described at 310 CMR 40.0932 (5)(a)(b)(c)(d), and are summarized below.

- If the groundwater would be classified as GW-1 *solely* on the basis of the groundwater being located within an Interim Wellhead Protection Area, and it can be demonstrated that the groundwater is hydrologically downgradient of the public supply well, or cross gradient and outside the zone of contribution for the public well, or that a hydrogeologic barrier exists between the site and the supply well, then the groundwater need not be classified as GW-1.

- If the groundwater would be classified as GW-1 *solely* on the basis that it is located within a Potentially Productive Aquifer (PPA), it need not be classified as GW-1 if the regional or site characteristics meet MCP criteria for exclusion from GW-1. DEP is currently (7/95) revising the section of the MCP regarding portions of PPAs that need not be classified as GW-1 Readers should be sure to consult the latest version of the regulations for changes in this area.

- If the groundwater would be classified as GW-1 *solely* on the basis of the site being located greater than 500 feet from a public water supply distribution line, it need not be classified as such if any portion of the parcel or facility is within 500 feet of such a pipeline.

- Finally, if the groundwater at the site would be classified as GW-1 because the location is within 500 feet of a private well, it need not be so classified if specific requirements are met such as connecting the properties to a public water supply and registering an environmental restriction on the groundwater. (See the previous discussion of limits on use of AULs).

Groundwater Category GW-2

Groundwater can also serve as a source of volatile contaminants to indoor air, and MADEP established a groundwater category to identify circumstances under which such an impact may be likely. Groundwater will be classified as GW-2 when it is located within thirty (30) feet of an occupied building or structure and the average annual depth to groundwater in the area is fifteen (15) feet or less. ***Note that for certain chemicals (particularly chlorinated hydrocarbons) the GW-2 standards are more stringent than the GW-1 or GW-3 standards.***

Groundwater Category GW-3

All groundwater in the Commonwealth is classified as GW-3. GW-3 standards are based upon discharge to surface water. All groundwater is deemed to ultimately discharge to surface water. ***Note that for certain chemicals (some metals and pesticides) the GW-3 standards are more stringent than the GW-1 or GW-2 standards.***

2.1.4.2 Categorization of Soil

In accordance with the MCP 310 CMR 40.0933 soil at each disposal site must be categorized as either category S-1, S-2 or S-3. The soil categories are based upon the potential for exposure. Category S-1 is associated with the highest potential for exposure and Category S-3 is associated with the lowest potential for exposure. Sites which meet applicable S-2 or S-3, but not S-1, soil standards must implement an Activity and Use Limitation to ensure that the soil category does not change without further assessment/remediation.

When categorizing soil at a disposal site, it is important to note that the category is based upon several factors described below. Any particular disposal site may have more than one category of soil present at the same time.

The factors to be considered in categorizing the site soil include:

1) the type of **receptor** present at the disposal site;
2) the **frequency** of use;
3) the **intensity** of use; and
4) the **accessibility** of the soil.

Each of these factors is discussed briefly in the following paragraphs.

Receptor

The type of receptor at the disposal site must be considered when determining the appropriate soil category. The receptor should be identified as a child or an adult. If both children and adults are present at the site then the soil should be categorized based upon whichever would result in the most stringent soil category (e.g., and if the adult's exposure is more intense, the soil should be categorized based upon the adult's exposures). The MCP defines a child at 40.0933(4)(a)(4) as an individual age 15 or under.

Frequency

Frequency of exposure describes how often a receptor has access to or use of the disposal site. The frequency of use is addressed in the MCP at 40.0933 (4)(a) and is classified as either "high" or "low". When evaluating frequency the risk assessor should be considering how often a receptor comes to the disposal site, *not* how often the receptor comes into contact with contaminated soil (i.e., the frequency term would *not* be reduced if the contamination were located at depth - the depth of the soil in question is considered separately under "accessibility").

Intensity

The intensity of use considers activities which may, by their nature, result in more contact with contaminated soil. Intensity should be classified as "high" or "low". High intensity activities, such as gardening, digging or recreational sports would result in a greater exposure to the soil. Low intensity activities, such as walking could still result in exposure to soil, but to a lessor degree.

Accessibility

The accessibility of the soil relates to the depth of the contaminated soil and whether there is any covering of the soil, by paving, a building or clean soil cover. Soil is classified as either "accessible", "potentially accessible" or "isolated". The criteria for determining which classification is applicable to the soil are identified at 40.0933 (4)(c). Note that in determining that soil is either "potentially accessible" or "isolated" it is assumed that the soil will not become accessible (because no excavation is anticipated or it is assumed that the asphalt surface will remain intact), and these assumptions would be reinforced with an Activity and Use Limitation.

To assist in categorizing soil, a matrix is provided in the MCP at 40.0933(9). This Table is reproduced on the following page.

SOIL CATEGORY SELECTION MATRIX - HUMAN EXPOSURE POTENTIAL

Accessibility ↓ of Soil ↓	RECEPTOR CHARACTERISTICS							
	CHILDREN PRESENT				ADULTS ONLY PRESENT			
	HIGH FREQUENCY		LOW FREQUENCY		HIGH FREQUENCY		LOW FREQUENCY	
	High Intensity	Low Intensity	High Intensity	Low Intensity	High Intensity	Low Intensity	High Intensity	Low Intensity
ACCESSIBLE (SURFICIAL) SOIL 0 <= 3' (unpaved)	**CATEGORY S-1**			**S-2**	**S-1**	**CATEGORY S-2**		
POTENTIALLY ACCESSIBLE SOIL 3 <= 15' (unpaved) or 0 <= 15' (paved)		**CATEGORY S-2**			**S-2**	**CATEGORY S-3**		
ISOLATED SUB-SURFACE SOILS > 15' or under the footprint of a building or permanent structure	**CATEGORY S-3**							

* - Category S-1 also applies to any accessible soil where the current or reasonably foreseeable use of the soil is for growing fruits and vegetables for human consumption.

2.2 DETERMINING THE NATURE AND EXTENT OF CONTAMINATION

This section provides guidance on determining the nature, extent, distribution and severity of contamination for the purpose of assessing exposures at disposal sites. Exposure assessment is only one of the many purposes for which chemical data is collected at 21E sites. Other applications include delineating the extent of contamination, identifying contaminants, comparing site concentrations with background levels. These and other applications are discussed briefly in Section 2.2.2 to show how different types of data are used in site assessments and to put the data quality needs of the risk assessment into perspective. However, the emphasis in this chapter is on the data needed for the risk assessment itself.

This chapter is also limited to data on environmental contaminant concentrations. Other kinds of data are often used in risk assessments, particularly in evaluating plant and animal exposures. Examples of such parameters include the hardness of surface water and the organic carbon content of sediment. Such supplementary parameters are described in more detail in Section 9.0. This section applies primarily to chemical concentrations in environmental media, such as soil and groundwater.

The Massachusetts Contingency Plan (MCP) sets investigation and cleanup requirements in terms of a general performance standard, rather than detailed procedural directives. The performance standard is referred to as Response Action Performance Standard (RAPS). The MCP (310 CMR 40.0191(1)) states that the Response Action Performance Standard is the level of diligence reasonably necessary to obtain the quantity and quality of information adequate to assess a site and evaluate remedial action alternatives, and to design and implement specific remedial actions at a disposal site to achieve a level of No Significant Risk....". Thus, the investigation and cleanup measures may vary from site to site, but in each case they must be sufficient to meet the goal of determining and achieving a condition of "No Significant Risk".

2.2.1 Data Quality Considerations

A comprehensive discussion of data quality issues and criteria is presented in EPA's *Guidance for Data Useability in Risk Assessments* (subsequently referred to as the *Useability Guidance*). Although that document was written for remedial investigations at Federal Superfund Sites, the principles of data quality evaluation contained in it are broadly applicable. Data quality considerations should underpin the development of sampling plans and the selection of analytical methods for all MCP site investigations.

Much of this section is taken directly from the *Useability Guidance*. That guidance outlines criteria that can be used to evaluate the adequacy and applicability of data in a risk assessment. The data quality criteria include:

Data Sources

Data from various sources may be used in a typical site investigation. Examples of sources of analytical data are: (1) **Fixed (stationary) laboratory analyses**, which provide detailed information for a wide range of analytes, and are critical to quantitative risk assessment and site characterization, (2) **Field laboratory analyses**, which are performed using instruments and procedures equivalent to fixed laboratory analyses, and can provide defensible data if equivalent quality control procedures are implemented, and (3) **Field screening techniques**, which are usually performed to provide a preliminary estimate of the type and concentration of chemicals of concern. Different labs may also be considered different sources. Data sources must be comparable for data to be combined for use in quantitative risk assessment.

Documentation

Sampling and analysis procedures must be documented thoroughly and accurately in order to verify that the analysis was conducted as reported, and that the data are reliable. Four types of documentation generally produced in support of analytical data are:

- Sampling and analysis and quality assurance plans;
- Standard operating procedures, the use of which assures consistency in sampling and analysis and reduces the level of error associated with data collection;
- Field analytical records which document the analytical procedures and quality assurance measures used in field analysis, as well as the data obtained from such projects. (Note: fixed laboratory analytical records are normally maintained by the labs themselves, and are not generally reproduced for individual projects unless requested);
- Chain of custody records, which establish the history and handling of each sample from collection to analysis. Chain of custody reports do not affect the quantitative estimates of risk, but provide some of the information necessary for all interested parties to have confidence in the data and the risk estimate.

Analytical Methods and Detection Limits

The term detection limit is often used without qualification, but it is a very general term. There are several methods of calculating the detection limit, and the method used in the risk assessment should always be specified in the report. Types of detection limits include:

- Instrument detection limit (IDL) includes only the instrument portion of detection, not sample preparation, concentration/dilution factors, or method specific parameters;

- Method detection limit (MDL) is the minimum amount of an analyte that can be routinely identified using a specific method;

- Sample quantitation limit (SQL) is the MDL adjusted to reflect sample-specific action, such as dilution or use of a smaller sample aliquot for analysis due to matrix effects the high concentration of some analytes;

- Practical quantitation limit (PQL) is defined in the SW846 Methods and is the lowest level that can be reliably achieved within specified limits of precision and accuracy during laboratory operating conditions.

The project manager should specify to the laboratory what type of detection limits are to be reported. **The sample quantitation limit (SQL) should be reported whenever possible**. The SQL is the *actual* detection limit for the specific sample and analysis being reported. The MDL or PQL, which are reported more often, are typical values for the method, but may not represent the actual detection limit for the analysis under consideration.

For the risk assessment, analytical methods with detection limits well below concentrations of potential concern should be selected. When chemicals are reported at concentrations near the detection limit, the data have a greater possibility of containing false negative and false positive results. If detection limits of conventional methods are near concentrations of concern for the chemical(s) being evaluated, then an analytical chemist should be consulted to assist in identifying alternative methods. The Useability Guidance presents a comprehensive discussion of the possibility of false positive or false negative results when the confidence limits of the detection limits overlap or fall above the confidence limits of the concentrations of concern.

Data Quality Indicators

Data quality indicators provide quantitative measures of data quality. Those suggested in the EPA *Useability Guidance* are summarized below:

Completeness - indicates whether the range of contaminant concentrations, the suite of contaminants detected and the extent of contamination in environmental media at the site are fully represented in the data set;

Comparability - relates to whether data sets from different sources or different time periods are equivalent;

Representativeness - refers to the extent to which the data used to estimate exposure point concentrations define the true nature, extent and concentrations of the contaminants of concern to which receptors may be exposed;

Precision - is a measure of data variability introduced by measurement error, which is governed by a combination of sample collection and analytical factors;

Accuracy - provides a measure of the closeness of the reported concentration to the true value.

Each of these indicators has different meanings for sampling than for analysis. A comprehensive discussion of the implications of each indicator is presented in the EPA *Useability Guidance*. The quality of data with respect to these indicators is an important factor in determining its useability for risk assessment purposes.

2.2.2 Selection of Analytical Methods

Analytical Methods and Procedures

The precision, accuracy and sensitivity of different analytical procedures vary widely. Furthermore, some laboratory settings are more amenable than others to implementing and documenting rigorous quality assurance/quality control (QA/QC) procedures. Analytical procedures can be divided into 3 general categories: (1) procedures conducted in commercial fixed (stationary) laboratories, under established quality assurance programs, with well documented QA/QC procedures, using published analytical protocols; (2) procedures conducted in field (mobile or temporary) laboratories, using the same equipment and protocols as are employed in fixed laboratories; and (3) field screening techniques, which generally involve compromises in analytical procedure and overall data quality. This differentiation is useful for the purposes of this document, but is not a universally accepted categorization.

Under these definitions, field laboratory procedures are essentially equivalent to fixed laboratory methods with respect to analytical methods, equipment and conditions, sample preparation, QA plan and QC procedure, and documentation of QA/QC procedures, operating conditions and personnel qualifications. Although there are exceptions, data from analyses done in commercial (fixed) laboratories are usually preferable to data from field labs because the latter generally do not operate within an established quality assurance program. As a result, extensive project-specific quality assurance documentation and review is needed to demonstrate equivalency with fixed lab data. (Note that under this definition, most of the gas chromatography work that is currently conducted in the field falls into the screening category, and is not considered field analysis.)

Compared with protocols carried out in fixed or field laboratories, screening methods involve some procedural compromises or shortcuts. One example of such a shortcut is

using measurements of concentrations in one medium to estimate concentrations in a different medium, as is done in headspace screening of contaminated groundwater or soil. Another shortcut is the use of sample preparation/extraction techniques that are less rigorous than those followed in a laboratory. One very common compromise is the use of simple instrumentation that does not produce substance specific results, for example organic vapor analyzers. Such techniques save either time or money or both, but lead to compromises in overall data quality.

The Massachusetts Contingency Plan clearly supports the use of professional judgement in selecting the analytical method most appropriate for a specific purpose. In Section 310 CMR 40.0017, the MCP states:

> *Procedures and methodologies employed for the collection and analysis of ... samples shall consist of:*
> *(1) methods published by the Department, EPA....*
> *(2) modification of published methods...*
> *(3) unpublished methods, including screening methods, provided that such methods are scientifically valid and are of known and demonstrated level of precision, accuracy and are completely described and documented in response action submittals.*

When faced with a choice of potentially applicable analytical methods (for example the 500 or 600 series methods for groundwater analysis), project managers should exercise professional judgement consistent with the RAPS provisions of the MCP in selecting the appropriate method. Cost is an important factor, but it should not be the primary consideration. Above all, the quality of the data must be adequate for the specific purposes for which it will be used.

With respect to data quality indicators listed in the preceding section, field screening methods can differ substantially from fixed or field laboratory procedures. Screening procedures often produce data of adequate quality with respect to only a limited number of data indicators. However, **not all of the listed data quality indicators are relevant to every decision point in a site assessment.** Although the overall quality of data from a screening method may be compromised, these data may nevertheless be of adequate quality and provide the information needed for some purposes.

In addition to differences in data quality indicators, **screening techniques often differ from fixed and field laboratory procedures in sensitivity and specificity**. Specificity is the ability of the technique to differentiate between a certain substance and other similar chemicals. Sensitivity is the ability of the technique to detect contaminants at the lower end of the range of concentrations of concern, and is expressed by the detection limit.

The most important factors to consider in determining the applicability of data from a particular screening technique are:

* Sensitivity
* Specificity
* Comparability
* Precision
* Accuracy

The factors on this list will be referred to as "data quality characteristics" throughout the remainder of this document. **The applicability of screening data at a particular decision point depends on the match between the data quality characteristics of the screening data in question and those that are relevant to the decision point of concern.** The following paragraph describes the disposal site decisions for which analytical data are used. For different decisions, the relevant data quality indicators and data quality characteristics may vary.

Site Assessment Decisions

In the site assessment process, there are several decision points, or assessment components, where data are applied. These include:

(1) determining the presence or absence of contamination at a site or a portion of a site; delineating the extent of contamination;
(2) identifying the contaminants present;
(3) comparing site concentrations with background concentrations;
(4) deciding where to focus sampling efforts;
(5) estimating exposure point concentrations;
(6) monitoring remediation processes; and
(7) verifying remediation effectiveness.

Each of the first three decision points listed above are basic components of the risk assessment in that they define and limit the scope. For example, the determination of where contamination is present and absent (delineating the extent of contamination) is a basic component of the exposure assessment. Although such decisions are often thought of as being separate from the risk assessment, the validity of the risk assessment depends in part upon correctly identifying and delineating the extent or the contamination.

The fifth decision point listed here, estimating exposure point concentrations, is more commonly thought of as *the* decision point that relates site investigation activities to the risk assessment. In principle it is no more important than determining the presence or absence or delineating the extent of contamination. Nevertheless, as discussed in the following section, the data quality requirements for estimating exposure point concentrations are generally more stringent than for some of the other site assessment

decisions.

Applicability of Screening Data to Site Assessment Decisions

To decide whether a specific screening method is a technically sound approach at any point in a site assessment, one has to think about exactly what kind of information is needed to answer the specific question. The assessor must determine whether the data quality characteristics of the screening data match the data quality needs for the decision point in question.

By definition, every screening method has certain limitations relative to standard laboratory techniques. If the limitations of a proposed screening method are not relevant to the question at hand, then the screening data are *effectively equivalent to lab data for the purpose in question*.

For example, suppose that data were needed to determine the bounds of the area contaminated by specific substances. From a regulatory perspective, the most important data quality characteristics are analytical sensitivity to the contaminants of potential concern. The detection limit of the selected method should be lower than the lowest concentration of concern, so that the probability of false negatives is decreased. The precision should be good enough so that analytical variability does not produce false negatives for sampling locations where the concentration is actually substantially higher than the detection limit. A screening procedure that is sufficiently sensitive and precise should provide data essentially equivalent to commercial laboratory data for the purpose of determining where the contamination is present and where it is absent. For some contaminants at some sites, depending on the extent and reliability of site history information, characteristics such as specificity, comparability, and accuracy may not be important considerations for determining the presence or absence of a contaminant. The problem of delineating the extent of a release is similar to determining the presence or absence of contamination, and the same considerations apply.

From MADEP's viewpoint, screening methods are frequently useful (supplementing fixed lab data) at decision points related to *delineation* of contamination, but seldom applicable for decisions related to *characterization* of contamination. MADEP considers all of the data quality characteristics listed in the preceding section relevant to characterizing contamination, while a more limited subset of data quality characteristics may be relevant for delineating contaminated areas. Two of the decision points presented in the preceding section, *estimating exposure point concentrations* and *comparing site concentrations to background levels*, always require complete characterization of contamination; therefore these determinations cannot be accomplished using screening techniques. In general, **MADEP considers screening techniques not applicable to the estimation of exposure point concentrations or to the comparison of site concentrations to background.**

2.2.3 Sampling Plans

Implementation of a sound sampling plan and selection of appropriate analytical methods are both essential for site characterization that is adequate for risk assessment purposes. The preceding sections focused on the selection of appropriate analytical methods. This section focuses on the development of an appropriate sampling plan.

Sample collection and analysis may be done at a site for a number of reasons. All of these objectives should be explicitly considered in the sampling plan and discussed in the site investigation report. Often, the data needs of the risk assessment are overlooked in the early stages of the site investigation process. As a consequence, site sampling efforts often do not produce the data necessary to characterize exposures at a disposal site. The sampling plan should ensure the collection of data which can adequately characterize exposures at the disposal site. To that end, potential exposure points and the activity patterns of potential receptors at the site in question should be identified when the sampling plan is being developed. If exposure patterns are considered only after sampling has been completed, the data collected may not provide sufficiently accurate exposure point concentration estimates, and further sampling may be needed. Ideally, the risk assessor's involvement in a project should begin with the sampling plan development stage. If not, the risk assessor must retrospectively evaluate the representativeness of the samples for exposure assessment purposes.

Composite Samples

As discussed in the chapter on *Exposure Point Concentration Estimation*, composite samples may provide an efficient way of estimating the average concentration of the subsamples. However, important information about the subsample concentrations is lost. The range of concentrations cannot be determined from a composite sample, because the highest concentration contributed by a subsample is diluted by mixing with samples of lower concentrations. Furthermore, since the highest concentrations are not detected, hot spots or areas of unusually elevated concentrations may not show up in the data. Thus, while compositing may be an efficient way to obtain an average, it generally does not provide complete information on the range and distribution of concentrations within the area sampled.

Contaminant Distribution Considerations

In addition to determining the areal extent of contamination and the range of concentrations present at the site, the distribution of contaminant concentrations must also be assessed. The sampling plan should be developed in a way that takes into account the need for characterizing the distribution of contaminant concentrations.

For evaluating soil exposures, the average concentration within the exposure area is generally used as a surrogate for time weighted average exposure point concentrations (See *Estimating Exposure Point Concentrations*, Section 7.3.4.5). Systematic or random sampling approaches are generally preferable for evaluating the areal distribution of contaminant concentrations. However, for site assessment purposes other than risk assessment, biased sampling is often conducted. If samples are collected so that certain areas are more heavily represented in the sample set, a weighted average can be used. Weighted averages can compensate for unevenly distributed sampling locations when calculating the exposure point concentration. The *Estimating Exposure Point Concentrations* section of this document presents guidance for calculating an area-weighted average in cases where sampling locations are not distributed randomly or evenly throughout an exposure area.

Hot Spot Identification

Hot spots are a special case of non-randomly distributed concentrations. They are relatively small areas with relatively high contaminant concentrations. The MCP (310 CMR 40.0006) defines Hot Spot as follows:

> *Hot Spot means a discrete area where the concentrations of oil or hazardous material are substantially higher than those concentrations in the surrounding area. A hot spot shall be identified based on consideration of both the concentrations of a chemical within a contaminated area and the spatial pattern of that contamination. The areal extent and spatial pattern of a hot spot may be determined through the analytical results from multiple samples taken within the area, or the results of limited sampling in combination with other knowledge about the release, such as the presence of discoloration, odors or a defined source area. In all cases, a discrete area where the concentration of oil or hazardous material is greater than one hundred times the concentration in the surrounding area shall be considered a Hot Spot. Discrete areas where the concentration difference is greater than ten but less than one hundred shall be considered a Hot Spot unless:*
>
> *(a) there is no evidence that the discrete area would be associated with greater exposure potential than the surrounding area; and*
> *(b) a site-specific evaluation indicates that the area should not be considered a Hot Spot considering the concentration(s), and distribution(s) of oil or hazardous material, background variability, and/or appropriate statistical analyses. In no case shall concentrations of oil or hazardous material equal to or less than an applicable Method 1 standard be considered indicative of a hot spot.*

In other words, a discrete area where the concentration is greater than ten times the concentration in the surrounding area is a hot spot unless both of the above conditions hold true.

The sampling density needed to detect and delineate a hot spot depends mainly upon its size, and will vary from case to case. An elevated concentration at a single sample location does not necessarily constitute a hot spot. However, elevated concentrations in a single sample may be indicative of the presence of a hot spot, and may warrant further sampling in that area. In deciding whether an exceptionally high result should trigger additional sampling, the investigator should consider: (1) the density of the existing sampling locations; (2) the magnitude of the spike relative to the concentration variability in the nearby samples; and (3) site history.

As discussed in the *Estimating Exposure Point Concentrations* section, hot spots should be evaluated as additional, individual exposure points. The potential for hot spots to exist on the site should be considered in planning the sampling locations and sampling density.

2.2.4 Characterizing Future Environmental Conditions

If changes in contaminant distribution are anticipated based on fate and transport evaluations, the extent of contamination under future environmental conditions may have to be evaluated in addition to present conditions. Future concentrations cannot be measured and must be modeled. Modeling will be discussed in somewhat greater detail in the chapter on *Exposure Point Concentration Estimation*.

Although biodegradation may be an important attenuation mechanism at some sites, predicting degradation rates that will actually occur in the field at a specific site is difficult. The application of degradation rates observed under controlled laboratory conditions to field conditions can lead to significant underestimation of future concentrations. The assumption that the concentrations will be decreased at a certain rate by biodegradation is discouraged for risk assessment purposes.

2.2.5 Analytical Data Presentation

As specified in 310 CMR 40.0835, the documentation supporting the risk characterization should describe the nature and extent of contamination, including a characterization of sources, nature, and vertical and horizontal extent of contamination at the disposal site; presence and distribution of any non-aqueous phase liquids; tabulation of analytical testing results; and, where appropriate, characterization of background concentrations of oil and/or hazardous materials at the site. Further, the documentation of the risk assessment should contain summary tables which clearly indicate which oil or hazardous materials at or from the disposal site have been identified in each medium at the disposal site and in the surrounding environment. A separate table or set of tables should be presented for each environmental medium. These tables should also present the range of reported concentrations for each OHM detected at the disposal site and in the surrounding environment.

Laboratory data reports should be included in the documentation for the risk assessment. The detection or quantitation limits should be reported as the "Sample quantitation limit", or SQL. The SQL is defined as the method detection limit adjusted to reflect sample-specific action such as dilution or use of a smaller sample aliquot for analysis due to matrix effects or the high concentration of some analytes (EPA 1992). The inclusion of "less than quantitation limit" results in exposure point concentration calculations is discussed in the section on *Estimating Exposure Point Concentrations*.

2.3 BACKGROUND

This section of the ***Guidance for Disposal Site Risk Characterization*** contains a discussion of the term "*background*" and its applications in the characterization of risk at a disposal site. The determination of representative background levels for a disposal site is an explicit requirement of the Massachusetts Contingency Plan (310 CMR 40.0835(4)(f) and 40.0904(2)(b)). This information is used for the determination of the extent of the release of oil or hazardous material, for the risk characterization process itself, and for making clean-up decisions. Despite the numerous important decisions which are based upon knowledge of background conditions for a site, in the past there has been insufficient emphasis on the collection of adequate background samples. The need for identifying background concentrations, including the collection of accurate and reliable data, is reinforced by virtue of the multiple applications of this information. The discussion in this section addresses the regulatory definition of "*background*" and the various uses of background information under the MCP. This section also provides specific guidance on the use of generic background levels published by MADEP, the collection of background data for a variety of media and the comparison of site data sets to "*background*" data sets. Simply put, this section provides the information and guidance needed to answer the following questions:

- *Why is background data important in the MCP and how is it used?*
- *Are the background data collected for the disposal site truly representative of background conditions for the site?*
- *Are the <u>site</u> concentrations reported (for one or more chemicals) consistent with background conditions for the disposal site?*

Ideally, the risk assessor will be involved in the development of the site sampling plan and will have significant input on where and when to collect samples for the site risk characterization. There will, however, be situations where the site data has already been collected, in which case, the risk assessor should review this information (including the background data), discuss its adequacy with the site manager and recommend additional data collection if necessary. The risk assessor must have confidence that the data collected are representative of the site and the site background conditions if this information is to be meaningfully used in the risk characterization process.

It is important to recognize that many anthropogenic chemicals (particularly some chlorinated organic compounds) are expected to have nondetect background concentrations, as these compounds, while common at c.21E disposal sites, are otherwise rare in the environment. Generally speaking, background levels are most important for the various naturally occurring metals found in the environment. It is also quite common to detect "*background*" levels of polycyclic aromatic hydrocarbons (PAH's) in soil, especially in urban areas. Except when MADEP published background levels are used, background should be dealt with on a site-by-site basis and should be medium-specific.

2.3.1 The Concept of "Background" in the Massachusetts Contingency Plan

2.3.1.1 Definition: 310 CMR 40.0006

In order to discuss the use of background data under the Massachusetts Contingency Plan the regulatory definition of the term is important:

> *Background* means those levels of oil and hazardous material that would exist in the absence of the disposal site of concern which are:
>
> (a) ubiquitous and consistently present in the environment at and in the vicinity of the disposal site of concern; and
>
> (b) attributable to geologic or ecologic conditions, atmospheric deposition of industrial process or engine emissions, fill materials containing wood or coal ash, releases to groundwater from a public water supply system, and/or petroleum residues that are incidental to the normal operation of motor vehicles.

The regulatory definition of background makes clear that the term is not limited to "*pristine*" conditions, and that the Department recognizes that historic human activities have resulted in the presence of some chemicals in the environment. Such non-pristine conditions must meet the conditions described in *both* of the clauses [(a) and (b)] of the definition, however. It is important to note that, under this definition, oil or hazardous material from one release ***cannot*** be considered background for another release[1].

2.3.1.2 Background & Permanent Solutions

Under the MCP, *Permanent Solutions* are implemented to achieve a level of No Significant Risk at a disposal site. The definition of a Permanent Solution is given at 310 CMR 40.0006.

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[1] The January 1995 revisions to the MCP included provisions to address situations in which a property is located downgradient of a property which is the source of the release of oil or hazardous material. The owner or operator of that downgradient property may establish *Downgradient Property Status* pursuant to 310 CMR 40.0180. These provisions were established in recognition of the fact that, while the upgradient source is not "background" for the downgradient property, the owner/operator of the downgradient property has limited ability to implement a Permanent Solution at that site.

Definition

Permanent Solution means a measure or combination of measures which will, when implemented, ensure attainment of a level of control of each identified substance of concern at a disposal site or in the surrounding environment such that no substance of concern will present a significant risk of harm to health, safety, public welfare or the environment during any foreseeable period of time.

The implementation of a Permanent Solution (or the *achievement* of a permanent Solution) is the equivalent of conducting a Response Action to achieve a level of No Significant Risk or to control or eliminate sources of oil or hazardous material for a foreseeable period of time. (Note that in the MCP the term Response Action could also include the assessment of a site, but such assessments are not the equivalent of implementing a Permanent Solution.)

The regulations also require that, where feasible and to the extent possible, a Permanent Solution reduce the levels of oil or hazardous material in the environment to background (310 CMR 40.0190(5) and 310 CMR 40.1020(1)). This concept of reducing contaminant concentrations as close to background as possible whenever remedial actions are implemented at a site derives directly from the statute (M.G.L. c.21E, §3A(g)) and it is explicitly incorporated in the basic performance standard of the MCP: the *Response Action Performance Standard*, or RAPS (310 CMR 40.0191(1) and (3)(c)).

It is important to understand that the requirement to achieve or approach background levels (where feasible) is separate from the risk-based requirements: if it is feasible to go beyond the minimum requirement of eliminating significant risk, there is a statutory obligation to do so.

The word "*feasible*" is prominent in this MCP requirement, and the criteria to be used in establishing feasibility are described at 310 CMR 40.0860. Note that while these criteria are found in a section of the MCP which describes the requirements for conducting Phase III Comprehensive Response Actions, the evaluation of the feasibility of achieving background is a requirement at *all* sites where one or more remedial actions (e.g., Release Abatement Measures, or RAMs) are undertaken to achieve a Permanent Solution (310 CMR 40.1020), *even if the Response Action Outcome is achieved before Phase III*. Draft guidance addressing the feasibility issue is under development, with an external review draft expected by July, 1995. Please consult the MCP Hotline for the status of that guidance.

The site background levels become the cleanup goals of the response action if it is feasible to achieve those levels. The proper determination of background levels is necessary both for conducting the feasibility evaluation and for those levels to be used as cleanup criteria.

Achieving Background Levels Is Considered Feasible *unless*:

→ The remedial alternative is not technologically feasible (technological feasibility criteria found in 310 CMR 40.0860(5))

→ The costs or risks associated with the remedial alternative would not be justified by the benefits (cost/benefit analysis criteria found in 310 CMR 40.0860(6))

→ Experienced individuals are not available to implement the remedial alternative

→ The alternative would necessitate off-site land disposal and no facility is available

→ The elimination or control of the *source* of OHM is not achievable by the person conducting the response action

Summarized from 310 CMR 40.0860(4): consult the regulations for exact wording and more detail.

2.3.1.3 Background & Response Action Outcomes (RAOs)

Response Action Outcomes, or RAOs, are the end-points of all response actions conducted under the Massachusetts Contingency Plan, and the documentation that the disposal site has reached an end-point is the Response Action Outcome Statement. RAOs are divided into three main categories (A, B and C) and several subcategories (e.g., A-1, A-2 and A-3) to distinguish between the different types of end-points which may be reached for a given site.

When a Permanent Solution has been implemented at a disposal site, a Class A Response Action Outcome applies to the disposal site (310 CMR 40.1035). The subcategories of the Class A RAO are described at 310 CMR 40.1036. As noted in the discussion above, the implementation of a permanent solution must be accompanied by an evaluation of the feasibility of reducing OHM levels to background, and thus *all* Class A RAO Statements must either document the extent to which site conditions have been reduced to background (for Class A-1 RAOs) or demonstrate that the achievement of background is not feasible (for Class A-2 and A-3 RAOs). This requirement is found at 310 CMR 40.1056(2)(e).

Since Permanent Solutions are not implemented at sites eligible for Class B or Class C Response Action Outcomes, an evaluation of the feasibility of returning the site to background conditions is not required.[2]

[2] Sites eligible for a Class B RAO do not have to implement a Permanent Solution as no remedial actions are necessary to achieve a condition of No Significant Risk. Sites eligible for a Class C RAO have implemented measures to eliminate substantial hazards at the disposal site until such time as a Permanent

Background & RAO's

A-1 RAO:	**Achieves Background.** RAO Statement demonstrates that background cleanup goals are met.
A-2 & A-3 RAO's:	**Background levels determined to be infeasible.** RAO Statements includes infeasibility demonstration.
Class B & Class C RAO's	**Feasibility of Background analysis not required.** Permanent Solutions are not implemented at these sites.

The fact that the background feasibility requirement is only triggered at sites eligible for Class A RAOs is logical in that, if remediation is taking place at a site, the incremental cost of going beyond the risk-based requirement may be small relative to the cost of the remedial action; the remedial workers are already mobilized, plans are already in place for the treatment or removal of remediation wastes, etc.. Thus, in planning the remediation activities consideration should always be given, *up front and early in the process*, to approaching background conditions. If, on the other hand, no risk-based remediation is necessary and no remedial action plans are developed, the regulations and the statute do not require actions to be taken solely for the purpose of restoring background conditions.

2.3.1.4 Background and Activity and Use Limitations (AULs)

Limitations on site use may be part of the package of response actions taken to achieve a level of No Significant Risk at a disposal site. The MCP provides specific tools, called Activity and Use Limitations, described at 310 CMR 40.1012. These limitations and their relationship to the risk characterization process are described in more detail in Section 2.1.3 of this guidance document. There are two points to make concerning the relationship of AULs and background:

(a) Activity and Use Limitations are not required where the concentrations of oil or hazardous material have been reduced to background (310 CMR 40.0923(3)(b)1 and 40.1012(2)(a)); and

(b) For the purposes of the requirements of Response Action Outcomes only, Activity and Use Limitations are not considered a "remedial action" (310 CMR 40.1046(3)) and thus the implementation of an AUL does not, in and of itself, trigger the requirement to evaluate the feasibility of reducing concentrations of OHM to

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Solution becomes feasible.

background.

2.3.1.5 Background in the Risk Characterization Process

The Department focuses assessment and remediation resources on contamination which is attributable to a release of oil or hazardous material and which has the potential to pose significant risk of harm to health, safety, public welfare or the environment. To this end, chemicals which are present at levels consistent with background are removed from the risk characterization process: they are, by definition, at a level of No Significant Risk (310 CMR 40.902(3)). Conversely if a chemical is present at concentrations above background, then it cannot be so eliminated. Thus, background data is one factor used to identify *Contaminants of Concern* (Section 2.4) for the risk characterization.

Taking this argument further, if all chemicals reported in a given environmental medium (such as groundwater) are present at background levels, then exposure to that medium does not have to be evaluated in the risk characterization. Finally, if *all* chemicals in *all* media at the site are present at background, *or if they have been reduced to background levels through some response action*, then a risk characterization is not required (310 CMR 40.0901(3) and 40.1020(2)) as a level of No Significant Risk is deemed to exist. Therefore reducing contaminant concentrations to background levels can minimize the assessment required at a disposal site, which may potentially lower costs at some sites, particularly for recent, discrete releases.

The risk assessor must determine what contaminants are consistent with background concentrations and document why it is appropriate to drop these contaminants from the process. An accurate determination of background concentrations is essential to enable the risk assessor to make a critical decision as to what compounds will be carried through the risk assessment process. If background has not been adequately characterized the risk assessor might not be able to eliminate from further assessment those chemicals which are consistent with background and ultimately these chemicals will be unnecessarily carried through the risk characterization. In the alternative, chemicals which should be included in the risk assessment might be wrongly dropped out if background concentrations are inappropriately identified. Either result carries with it the potential for additional cost and effort that could be eliminated.

2.3.1.6 Background and Technical Justification

The following guidance on gathering and evaluating background data is written to address issues which arise at a wide array of disposal sites, from the simple to the complex. The level of detail of this guidance should not obscure the fact that the scope and level of effort of the risk characterization (including background issues) depend upon the complexity of the disposal site and the response action being performed (310 CMR 40.0903(1)).

At many sites, particularly those resulting from sudden and discrete releases of oil or hazardous material (i.e., "spills"), knowledge about the release and the extent of the response action may be used with only limited analytical information to draw conclusions

about background levels. For example, it may be unnecessary to determine background conditions for a fuel oil spill which was quickly contained and completely cleaned up. Knowledge about the quantity of fuel spilled (*is it all accounted for?*), the location of the spill (*was it on pavement or in a well defined area?*) and the nature of the material (*would it have penetrated the soil to great depth? is it soluble in water?*), the nature of the remedial action performed and the results of any confirmatory sampling (*field screening? laboratory analyses?*) could be used to conclude, **based upon professional judgement**, that the spill was remediated to background levels.

Note that such flexibility is inherent in the MCP; the regulations contain language (310 CMR 40.0193) which allows a Licensed Site Professional (LSP) to forgo specific site investigation activities, "*if, in his or her professional judgement any particular requirement is unnecessary or inappropriate based upon the conditions and characteristics of a disposal site.*" The basis of such a technical justification would be described in the pertinent submittal to MADEP. The technical justification should be documented in sufficient detail to enable a reviewer/auditor to evaluate the decision to forego the requirements in question.

2.3.2 Identification of Site Background Conditions

As demonstrated above, background conditions should be considered in selecting contaminants of concern, planning remedial response actions, implementing Permanent Solutions, and evaluating the feasibility of reducing concentrations to background. The project manager should consider the importance of the background information when planning the data collection to ensure that adequate resources are devoted to gathering this information. The risk assessor should reinforce the need for obtaining background information and demonstrate how this information can be properly used. The following guidance is provided to assist in the characterization of site background concentrations, including both the use of MADEP published generic background levels and the establishment of site-specific background concentrations.

As will be seen in the sections which follow, it accomplishes little to collect a single sample and declare the chemical concentrations in that sample as "*background*" for the disposal site. Reported concentrations (both background and release-related) may vary over a wide range due to the heterogeneity of the environmental medium, natural variation or the presence of "*hot spots*", or the vagaries of the analytical methods employed. A single sample is no more than a random estimate of what "typical" background concentrations might be. Sufficient data is required to provide the site manager and risk assessor a sense of the average or likely concentrations as well as the variation in levels expected. Ideally, distributions of site-background data should be compared in some fashion to distributions describing the site-release concentrations, although there are circumstances under which a streamlined approach is justified. The important site-decisions made based upon the background data should not be undermined by an inadequate characterization of

background. When site-specific background data is sought, it is imperative that a well thought out sampling plan for each medium be developed. When MADEP published lists of generic background levels are used it is important that data be used as described by the Department. The risk assessor must have a high level of confidence that the information collected to establish background is representative of background conditions at that location.

2.3.2.1 MADEP Derived Background Levels

Historically, MADEP has considered the use of published generic background levels to be an option of last resort, when obtaining site-specific data was not possible. The data which comprise such generic background lists may not be representative of Massachusetts conditions and/or are not comparable to the data obtained at disposal sites. Typically they are collected over a large geographic region, including areas which would not be representative of Massachusetts conditions (e.g., the USGS data (Shacklette, 1984) often submitted to the Department can be narrowed down to data representative of "Eastern U.S. Soils".) Compilations of generic background levels may also include data taken from a number of sources, with internal variation of sample collection, handling and analytical techniques. Thus, the risk assessor should avoid using any list of generic background levels which has not been specifically recommended by the Department.

MADEP recognizes the utility of published background levels, however. The use of published lists of background concentrations can streamline the site assessment and risk assessment process, particularly to provide justification for dropping chemicals from further consideration in the risk assessment. Such values could also be used as target cleanup levels when a Class A-1 RAO is sought, or could serve as the basis for a feasibility analysis submitted as part of a Class A-2 or A-3 RAO. The Department has initiated an on-going project to identify and publish generic background concentrations which would be acceptable for use in c.21E assessments. The first such list, *MADEP Background Soil Concentrations,* is presented below. Additional lists will be made available through the MADEP Bulletin Board as they are developed. Current plans includes the expansion of this list to include polycyclic aromatic hydrocarbons and the publication of a similar list for urban locations.

MADEP Background Soil Concentrations

Table 2.1 presents the list of Massachusetts Background Soil Concentrations which may be used in lieu of site-specific background levels as part of a c.21E assessment. These values were judged by MADEP staff to be sufficiently representative of Massachusetts non-urban (i.e., suburban and rural) locations that the use of these values at c.21E sites would be protective of public health and the environment.

Table 2.1

MADEP BACKGROUND SOIL CONCENTRATIONS

These soil concentrations are derived from a database of background samples taken from rural and suburban locations. The values represent total metal concentrations. These values may be generalized to urban locations pending the publication of a MADEP list of typical urban background levels.

Chemical	Soil Concentration mg/kg	Chemical	Soil Concentration mg/kg
Aluminum	13,000	Lead	99
Antimony	1.4	Magnesium	4,900
Arsenic	17	Manganese	300
Barium	45	Mercury	0.3
Beryllium	0.4	Nickel	17
Cadmium	2	Selenium	0.5
Chromium	29	Silver	0.6
Cobalt	4.4	Thallium	0.6
Copper	38	Vanadium	29
Iron	17,000	Zinc	116

These concentrations represent the 90th percentile values from the collected data set. A high (e.g., 90th) percentile was chosen in order to insure that chemicals which are truly present at background levels would be correctly identified as such. By using a high-end background concentration (90th percentile) as a point of comparison for all site data, DEP recognizes that some contaminants that are actually elevated may wrongly be treated as background concentrations. The consequences of these errors, however, will

not be serious because the 90th percentile levels of the metals listed here are not associated with significant health risks. There may be other substances for which this simplified approach is not appropriate. Table 2.2 presents a more detailed summary of the data used to select the MADEP Background Soil Levels.

It is important to note that a higher (e.g., 95th) percentile value was *not* chosen based upon MADEP staff judgement that the data set used as the basis of this analysis may be biased towards the higher concentrations. The data set was developed from reports submitted to MADEP under the c.21E program. Samples identified in the reports as being representative of "background" at the site under investigation were compiled and analyzed. The data thus collected could have been influenced by some of the following intentional/unintentional biases:

(a) the samples were taken in the vicinity of disposal sites and may in fact have been affected by the contamination at the sites;
(b) historically at c.21E sites, background samples are more likely to be taken (and reported to MADEP) in areas with relatively high background levels; samples are less likely to be taken if the concentrations at the site are so low that they are "obviously" background;
(c) it is possible that some samples taken as background at sites were not included in reports submitted to MADEP;
(d) high background samples at sites may have been mistaken for contaminated samples and not identified as "background".

The use of these values in a c.21E risk characterization is discussed in Section 2.3.3. These values are intended for use in determining whether levels of metals at **non-urban 21E sites** are consistent with background. They are not necessarily appropriate for use at urban sites or for use in meeting the regulatory requirements of other programs.

2.3.2.2 Background Sample Collection and Analysis

Site-specific background determinations are necessary for chemicals not included in the list(s) of generic MADEP Background Concentrations. Site specific background determinations may also be made where it is believed that site-specific background may, in fact, be higher or lower than the published Massachusetts values. For many chemicals, including chlorinated organic compounds, expected background levels would be non-detect, and the risk assessor may adopt a background concentration of zero (or ND) without further analysis.

When site-specific background levels are needed, the collection of adequate data to define background conditions requires consideration of the number of samples to collect, the sample location and the sample collection methodology and timing. When site concentrations are to be compared to background, a characterization of background

conditions is needed for each media sampled as part of the site investigation. Under most circumstances, background is characterized by collecting site-specific environmental samples.

Background sample collection and sample analysis methods should be consistent with those for other site-related samples. For example, if surficial soil samples are being collected in a source area with a hand auger, then the same technique should be used to collect background samples. In addition, background samples should be handled in the same fashion as site samples. For example, if groundwater samples are collected and filtered on-site, the background groundwater samples should be filtered as well. Use of the same sample collection technique and preparation will limit differences in results which are potentially attributable to sample handling. Additional information on sampling methods and analyses is contained in Section 2.2, *Determining the Nature and Extent of Contamination*.

Background and site samples should be collected concurrently whenever possible, to ensure that the analytical results are comparable. This is particularly important for media where concentrations may vary or fluctuate with time, such as groundwater, surface water and indoor or ambient air. By collecting the samples at the same time, you can attempt to control for seasonal variations, changing weather conditions and possible effects associated with the fate and transport of contaminants in the environment.

Timing is less of an issue when the medium and contaminants are more stable in the environment, such as metals in soils at depth, where background concentrations are likely to remain more constant over time. Nevertheless, collecting and analyzing both site and background soil samples at the same time in the same way will reduce the chance of introducing differences in the results that are just artifacts of sampling and analysis procedures and are not actually representative of site conditions.

Collection of both background and site samples should be conducted in accordance with *Environmental Sample Collection and Analyses*, set forth in 310 CMR 40.0017.

Table 2.2

DETAILS OF THE MADEP BACKGROUND SOIL DATA SET

		Range of Values		Mean Values		→ Percentiles →		
Chemical	Number of Samples	Maximum mg/kg	Minimum mg/kg	Arithmetic mg/kg	Geometric mg/kg	50th mg/kg	90th mg/kg	95th mg/kg
Aluminum	30	24,000	387	8,165	5,536	7,800	13,000	16,000
Antimony	90	22	< 0.002	0.9	0.2	0.34	1.4	4.8
Arsenic	139	99	< 0.1	8.2	4.7	4.8	16.7	24.5
Barium	64	104	0.42	22.2	15	15.7	45.2	52.8
Beryllium	103	1.6	0.03	0.25	0.21	0.23	0.39	0.53
Cadmium	127	5.9	< 0.01	0.8	0.43	0.29	2.06	3.4
Chromium	147	105	0.02	15.2	10.3	10.6	28.6	38.8
Cobalt	10	4.7	< 0.5	1.7	0.8	NC	4.4	4.5
Copper	103	160	< 0.5	16.3	7.7	7.3	37.7	56.1
Iron	30	50,000	444	9,579	6,031	7,200	17,000	22,500
Lead	141	326	1	39.2	19.5	19.1	98.7	158
Magnesium	30	11,000	< 250	2,141	1,028	1,300	4,900	6,700
Manganese	30	460	< 3	140	81.5	110	300	365
Mercury	107	1.4	< 0.0002	0.13	0.043	0.066	0.28	0.43
Nickel	103	48	< 0.5	7.7	4.6	5.1	16.6	22.7
Selenium	93	4.6	< 0.0005	0.32	0.1	0.17	0.5	1
Silver	117	82	< 0.003	0.92	0.09	0.07	0.58	0.91
Thallium	71	5	< 0.005	0.41	0.1	NC	0.6	1.65
Vanadium	30	46.6	< 1	13.6	7.6	10.3	28.5	38.5

Table 2.2

DETAILS OF THE MADEP BACKGROUND SOIL DATA SET

		Range of Values		Mean Values		→ Percentiles →		
Chemical	Number of Samples	Maximum mg/kg	Minimum mg/kg	Arithmetic mg/kg	Geometric mg/kg	50th mg/kg	90th mg/kg	95th mg/kg
Zinc	112	190	3.52	42.6	29.3	27.7	116.4	131.2

Number of Background Samples

A sufficient number of samples must be taken to allow a meaningful comparison of background concentrations to site concentrations. Generally speaking, **more** background samples are required if:

- there is high variation in the concentration of analytes in the background data set (indicated by a coefficient of variation greater than 50), *or*
- if contamination exists in more than one medium, *or*
- if small differences (small minimum detectable relative difference in inferential statistical tests) between site concentrations and backgrounds may be of concern. When it is acceptable not to detect small differences between background concentrations and site concentrations, fewer samples are required.

When an argument is being presented that remediation of a site is unnecessary because the site concentrations are consistent with background (i.e., when a Class B RAO is sought), or that a permanent solution has been achieved because site concentrations have been reduced to background concentrations, a sufficient number of background samples must be collected to support this assertion. The specific number of samples needed depends in part upon the method used to compare the results.

A number of documents have been prepared by USEPA which describe approaches to determining what is an adequate number of samples. A particularly useful publication is the *Guidance for Data Useability in Risk Assessment* (USEPA, 1992), hereafter referred to as *Guidance for Data Useability*. An understanding of basic statistics is helpful in determining background sample size. In the section which follows, entitled **Approaches to Comparisons with Background**, a brief explanation of common statistical terms is provided. It may be helpful however, to refer to a basic statistics text (such as Cochran, 1977; Green, 1979; Snedecor, 1980) for additional information and a more detailed presentation.

The *Guidance for Data Useability* contains equations (in its Appendix IV) that can be used to calculate the minimum number of samples required to achieve specific statistical goals, such as levels of *power*, *confidence* and *minimum detectable relative difference* (MDRD). It is clear from discussions in environmental statistics texts that the range of chemical concentrations reported is as important as the magnitude of the concentrations when making background-to-site comparisons. The *Guidance for Data Useability* gives specific examples to demonstrate the influence that variability among samples has on the number of background samples required at a site.

When considering the number of background samples needed to evaluate

variability in the background data, the users of either common sense or statistics will conclude that one or two samples are generally insufficient.

It is important to remember that not all background samples will need to be analyzed for all analytes. In order to minimize costs and streamline this assessment, those analytes that exhibit a low degree of variability would require fewer background samples to be analyzed. Thus, a cost saving could be obtained if only the analytes with a high degree of variability are analyzed for in every background sample.

Selection of Background Sample Locations

Background samples are collected to assess the levels of contaminants that would exist in the absence of the disposal site of concern, which are ubiquitous and consistently present in the environment at and in the vicinity of the disposal site of concern, and are attributable to geologic or ecologic conditions, atmospheric deposition of industrial process or engine emissions, fill materials containing wood or coal ash, or petroleum residues that are incidental to the normal operation of motor vehicles" (310 40.0006). Background samples should be collected in locations that are relatively undisturbed, unstained and unlikely to have been used for handling or storing oil or hazardous materials, or to have been affected by oil or hazardous materials migrating to that location. The sampling location should be based upon similarity of the medium and environmental conditions at the background area and the disposal site's conditions.

The location(s) selected to collect background samples may be either inside or outside of a property boundary. The risk assessor should allow for additional time when scoping this task if access to a property is, or could be, an issue. There may be situations, particularly in some urban and heavily industrial areas, where a suitable location is not available on an adjacent property, and background samples must be collected further from the site. Background samples should not be collected off-site in areas affected by another disposal site.

A review of any existing historical records and the current environmental setting, along with physical observations and field screening data, can be used to select an appropriate location for a site-specific background sample. This type of information should be readily available from the site project manager, as this is basic information for most site investigations.

All available historical records regarding the use of oil and hazardous materials at the disposal site and in the local area should be reviewed. Some typical examples of such records might include, but are not limited to, records available from the Massachusetts DEP, the United States Environmental Protection Agency (USEPA), the local Board(s) of Health, the local Fire Department(s) and the local Water Department. It is also helpful when possible to obtain historical aerial photographs of the disposal site.

The environmental setting may provide information on where to collect a background sample, such as the upgradient direction for groundwater or the upstream direction of a river. Conversely, the environmental setting may indicate locations where background samples should not be collected, such as a surface area affected by runoff from the disposal site.

In the field, physical observations can often provide a great deal of information. Observations of staining, odors, soil disturbances or stressed vegetation should eliminate an area from consideration as a possible location to collect background samples. Field screening data can also be evaluated to locate a background area. Background samples should not be collected in areas of elevated screening data. In general, optimal locations for collecting background samples are areas where minimal current or past human activity has occurred. For example, in a rural or suburban area, a mature stand of trees may provide an area of relatively undisturbed soil. However, be aware that just because field screening results are negative and the area where the samples were collected appeared undisturbed, one cannot always be absolutely certain that the area actually represents background conditions, and has not been affected by oil or hazardous material. If site-specific background concentrations are high relative to typical background levels, a decision to use those data to make a background determination must be justified by other geological or historical information.

Media-Specific Background Considerations

Many of the factors that are important in determining background conditions are media-specific. A discussion of media specific background considerations is addressed below.

Groundwater

Background groundwater samples should be collected from an area which is hydraulically upgradient of the disposal site. The background location should be an area which is believed to be unaffected by other releases. The depth of geological strata from which the background samples are collected should be consistent with the sampling depth for the site samples, such that the samples are obtained in the same water-bearing unit. For example, when sampling overburden wells, the background samples should not be collected in the bedrock aquifer. Groundwater flow direction should be considered separately for each water bearing unit when locating background sampling locations, since the upgradient direction may be different for different units.

The question of whether the groundwater samples in general should be filtered is addressed in the Section on Exposure Point Concentration. The only issue pertaining to filtering background samples is that of consistency. Therefore, whether background groundwater samples from the disposal site should be filtered is dependent upon whether the site groundwater samples were filtered.

Soil

Background soil samples should be collected from an area where soil conditions are similar to the soil samples collected for the site investigation, excluding the impact of the site in question. Soil can be classified into groups based upon physical characteristics. This classification is routinely conducted by a geologist during field investigations. The physical characteristics most commonly evaluated include grain size, color, moisture content, organic carbon content, gradation and plasticity.

It is important to consider sampling depth when collecting background soil samples. Surficial soil samples are much more likely to be affected by atmospheric conditions and industrial processes than soil samples collected at depth. It may be necessary to collect background samples at various depths at a site to adequately characterize background conditions.

It is useful to take a soil core sample and examine bedding patterns to see if there has been much soil disturbance. This will help determine if composites on selected horizons (e.g. 0 - 5 cm depth) are most appropriate.

Surface Water

The collection of background samples in a surface water body will vary depending upon the type of water body. In the case of rivers and streams the background samples should be collected from a physically similar location upstream of the site in an area were site contaminants are unlikely to migrate. When a pond or lake is impacted by oil/hazardous materials (OHM), a background sampling location may be available in the same water body at a distant location from the site. If however, the entire pond has been affected it may be necessary to investigate collecting background samples from a similar pond in the same drainage basin. When a "reference pond" is used, special consideration should be given to morphological characteristics such as size, depth, surface water turnover rate and geology, and to lake trophic status as often judged by color, pH, chlorophyll a content, biological standing crop and diversity.

When selecting any surface water location for collecting background samples the surrounding conditions should always be compared to conditions at the site. Some factors to consider include: industrial development in the area, presence of roadways, culverts or run-off areas. The Massachusetts Department of Fisheries, Wildlife and Environmental Law Enforcement maintains historical records of activities of many water bodies in the state which are invaluable for determining historical impacts to the water bodies. In addition, field screening techniques may be helpful in determining if the background surface water characteristics are similar to the surface water conditions at the site. Some field screening techniques commonly used include pH, conductivity, dissolved oxygen and temperature. Of course, it is important to note

that some of these parameters may be altered as a direct result of the OHM from the site, which is why they can be used to indicate non-background conditions. It may also be helpful to collect the background samples at water depths similar to those selected for site sampling.

Sediments

Many of the factors considered in the collection of surface water samples hold true for the collection of background sediment samples. However, in addition to those issues it is also important to consider sediment conditions such as color, organic carbon content, grain size, gradation and redox status. Also, where possible, the current velocity and the depositional conditions should be considered when identifying a background location.

Ambient Air

Background ambient air samples can be collected to analyze for the presence of particulate matter, for specific chemical constituents, or both. Obviously, the choice will be determined by the sampling design used to collect the site samples.

Of primary importance in ambient air sampling is the predominant wind direction for the area. Background samples should be collected in the upwind direction of the site. It is therefore necessary to collect information on predominant wind direction prior to and during the collection of the site and background samples. Locating multiple samplers around the site will improve the chances of collecting adequate background sampling data.

Seasonal variation should also be considered. Both site-related and background air concentrations may fluctuate seasonally, so it is important to collect both types of samples at the same time.

Another important consideration in collecting background data is distance from the site. By collecting background samples at an increased distance from the site the likelihood of interference from the site itself can be decreased. This does have a cost however, since likelihood of having comparable conditions also decreases as you get further away from the site. This may result in increasing the likelihood of impacts from sources that do not impact the site.
It is of particular importance that background ambient air samples be collected at the same time as site samples are collected because the potential for mixing and changing conditions is so great. When possible the sampling plan should control for these types of potential confounding variables.

It may be appropriate to collect some preliminary information on the site and the surrounding area prior to actual ambient air sampling, such as identifying other

potential sources of air contamination in the area, determining predominant wind direction and conducting some preliminary field screening.

Indoor Air

The collection of background samples for indoor air presents some unique and different problems, as compared to the collection of other background media. In each of the previously discussed situations it was recommended that site specific background samples be collected. In the case of indoor air, it may not always be best to base background air concentrations on site specific samples. There are numerous factors which can result in differences between site indoor samples and background indoor air samples. A primary issue is locating an appropriate background sampling location. It is generally not appropriate to utilize an upper level of a structure to collect background samples, because lower concentrations of the same contaminants elsewhere in the building may just be indicative of lower concentrations of the site contaminants. In lieu of using the same building to collect indoor air samples, background samples could be collected in a similar structure. However, regardless of how similar the structures are there are a number of factors that can lead to erroneous background samples, such as:

- differences in building construction and design;
- differences in building age and tightness;
- differences in building construction materials;
- differences in building ventilation;
- differences in volatile compounds present in the structures, unrelated to the disposal site of concern;
- different effects from outdoor ambient air conditions; and
- different depths to the groundwater table.

In general, when sampling indoor air, the sampling plan should include an outdoor sample to determine if the chemicals are unique to the indoor air.

In some cases, it may be more appropriate to use literature values to establish background levels for indoor air. There are recent publications available which may be referenced, including Shah and Singh (1988) and Stolwijk (1990).

The use of published values from the literature may present equally problematic conditions. Shah, for example, compiled indoor air data which had been previously collected. The studies that contributed data were originally done for a variety of purposes. The environment sampled might be either a residential setting or a workplace environment. Moreover, differences exist between the sampling techniques utilized, the duration of the sample collection and the analytical methods employed. The risk assessor should determine the suitability of using any published data set and recognize that limitations exist for this approach to background as well. These

limitations should always be discussed in the text of the report.

Table 2.3 provides a summary of medium-specific information which should be considered when selecting background sample locations.

Table 2.3

CONSIDERATIONS IN THE SELECTION OF BACKGROUND SAMPLE LOCATIONS

MEDIUM		BACKGROUND SAMPLE CONSIDERATIONS	
General	• records review • OHMs at site	• visual observations • field screening
Soil	• geologic unit • use and extent of fill	• sample collection depth • soil characteristics
Groundwater	• flow direction • seasonal fluctuations	• different water bearing units
Surface Water	• seasonal fluctuations • flow direction • water quality characteristics	• morphological characteristics • sampling depth in the water column
Sediments	• deposition • surface water flow direction	• sediment characteristics • seasonal fluctuations
Ambient Air	• predominant wind direction	• seasonal fluctuation • distance from site
Indoor Air	• building construction • construction materials	• depth to groundwater • presence of smokers/indoor storage of sources

2.3.3 Comparing Background Levels to Site Data

As described in Section 2.3.1, many decisions made during the assessment and remediation of c.21E disposal sites depend upon a comparison of site conditions to background concentrations. Determination of whether site conditions are consistent with background can be reliably made with appropriate statistical techniques.

It should be assumed that a detected chemical is present above background concentrations unless it can be otherwise

demonstrated.

2.3.3.1 Comparison of Site Data to MADEP Published Background Levels

The Department has established generic background soil levels at non-urban sites for twenty metals, as described in Section 2.3.2.1, and may publish additional values in the future. When comparing these generic background levels to site data, the risk assessor may conclude that the concentrations of an oil or hazardous material is consistent with background conditions if all the site data are equal to or less than the MADEP Background Level for that chemical.

All Site Data ≤ MADEP Background Level

If the analytical results from **one or more** site samples are greater than the established MADEP Background Level, then the risk assessor may either: (a) collect site-specific background data in an attempt to establish that the site data is, in fact, consistent with background conditions, *or* (b) conclude that the chemical is present at levels greater than background concentrations and proceed with the site risk characterization. However, **in any case where site concentrations are substantially higher than the MADEP background levels, the risk assessor will bear a relatively heavy burden of proof in using site specific data to demonstrate consistency with background, and the site specific evaluation will be closely scrutinized in any DEP review.**

2.3.3.2 Comparison of Site-Specific Background Levels to Site Data

The sampling design and number of samples necessary to compare the site contaminants to background chemical levels are determined by the distribution of contaminants, the analytical variability, the statistical methodology used for the comparison, and the variation in contaminant levels at the study and background sites (as described in Section 2.2). In order to eliminate or minimize bias from the site-to-background comparison a valid sampling design and appropriate test statistic should be used. It is advisable (and cost effective) to consult with a statistician *before* sampling to determine the sampling design, number of samples, and the appropriate statistical test for your particular situation. While the specific statistical method needed to compare site to background contamination levels will vary according to each evaluation, an outline of what is expected in the comparison of site-to-background contaminant levels and a discussion of the critical factors which must be considered are provided in this section.

Summary Statistics

Summary, or descriptive statistics for both site and the background samples should be provided in a table in the risk assessment report. (The data used to calculate the statistics should be clearly referenced and available. These are typically found in appendices to the actual site or risk assessment.) The table should provide the descriptive statistics for the site and background levels of each contaminant, including the *number of observations, the*

median, minimum, maximum, mean, standard deviation, and *geometric mean* (see glossary of statistical terms, Table 2.4). It is useful to include in this table the frequency and limits of detection as well.

Table 2.4

Statistical Measures Used In Comparing Data Sets

Measures of Central Tendency for the Data Set

Mean:	the arithmetic average, calculated by summing the values and dividing by the total sample size
Geometric Mean:	the antilog of the arithmetic mean of a log-transformed data set
Median:	the 50th percentile value; half the values in the data set are above the median and half the values are below
Mode:	the value that occurs most often in the data set

Measures of Variability or Spread in the Data Set

Range:	a single value which represents the difference between the largest value in the distribution and the smallest value
Extremes:	the 2 ends or limits of a data set; the lowest and highest values
Percentile:	the percent of individual values below a particular value
Variance:	a measure of variation among individual values; it is calculated as the average squared deviation from the mean
Standard Deviation:	the square root of the variance
Standard Error:	the uncertainty or variability around a mean or the standard deviation around the mean
Coefficient of Variation:	the standard deviation expressed as a percent of the mean; SD/mean X 100 =CV

The median and mean (arithmetic and geometric) indicate the middle or central level of the contaminant, and allow for a comparison of the difference in the central value between site and background. The range (minimum to maximum) and standard deviation measure the spread and variability in the contaminant levels among the samples, and aid in the assessment of the differences in central values between the site and background. Three to five background samples may be sufficient in some cases to calculate these summary statistics, but more are recommended to make final judgements if the conclusions are ambiguous.

Descriptive statistics may be used to compare the background data set with the samples from the disposal site. This method of assessment should be conducted when the number

of background samples is insufficient to achieve the specified power for an inferential procedure (see discussion below).

Note: In ORS' experience, the use of professional judgement by the risk assessor considering all relevant site information (including historical use of the site, etc...) and simple summary statistics is less likely to lead to erroneous conclusions than the use of a formal inferential statistical test with small data sets. For example when site conditions are truly above background, the risk assessor is less likely (than a statistical test with insufficient power) to erroneously conclude that the site conditions are consistent with background.

Generally speaking, the data sets should be comparable in size to provide meaningful comparisons. *[This should not, however, be interpreted to mean that the number of site samples must be limited to the number of background samples taken...]* When making comparisons based upon professional judgement, the risk assessor cannot rely upon objective statistical measures (such as power and confidence) to validate the conclusions. Therefore, it is important that the thought process employed is described and well documented so that the reader may evaluate whether the conclusions are proper. (In other words, when exercising professional judgement, the professional should document how and why those judgements were made.)

When comparing summary statistics, a measure of central tendency and a measure of spread should be compared and interpreted. MADEP recommends comparing the *median* and *maximum* values of each data set to evaluate whether the site concentrations are consistent with background levels. For values that are lognormally distributed, the median is considered the appropriate measure of central tendency to use when comparing distributions, because it is better than the arithmetic mean for representing the location of the lognormal distribution, and it is less heavily influenced by the skewed values in the data set.

Since these comparisons are typically one-sided, meaning that, from a regulatory perspective MADEP is concerned only if the site concentrations are above background levels, the high end of the observed concentration range (i.e., the maximum value) is recommended as an indicator of the spread in the data.

- If this pair of summary statistics (the median and the maximum values) for the site data set are greater than the corresponding values from the background data set, then it should be concluded that the site data are not consistent with background.

- Conversely, if both values of this pair for the site data are equal to or less than the background values, then it may be concluded that the site data are consistent with background.

This analysis becomes problematic when the comparison of the median values yields the opposite result from the comparison of the maximum values. For such cases, *and only for such cases*, MADEP recommends a tolerance limit of 50%:

- If the median value of the site data is less than or equal to the median value of the background data, and the maximum value of the site data is no more than 50% greater than the maximum value for the background data, then it may be concluded that the site data is consistent with background.

- Conversely, if the maximum value of the site data is less than or equal to the maximum value of the background data, and the median value of the site data is no more than 50% greater than the median value for the background data, then it may be concluded that the site data is consistent with background.

Thus, slight differences in a measure may not result in a conclusion that a chemical is a contaminant of concern. This tolerance factor is *not* intended to imply that slight exceedances of background levels are acceptable, but that, given the sampling uncertainty which exists, such results may be indistinguishable from background levels. Remember that if the site median and maximum values *both* exceed the corresponding background levels (regardless of the magnitude of the differences), then that is sufficient evidence in this simple approach to conclude that the site data is greater than background levels.[3]

If the risk assessor or site manager believes that an incorrect conclusion is drawn due to statistical uncertainty, the option is always available to reduce that uncertainty through the collection of additional background samples and/or performing an inferential statistical test as discussed in the next section.

The option of summary statistic comparisons has been included for cases when the background and/or site data sets are not large enough for an acceptable inferential statistical test. Nevertheless, adequate sample sizes are needed to make reasonable decisions. The number of samples that is sufficient depends on a variety of factors, including site geology, the mixture of contaminants present, and the variability in the concentrations of the contaminants of potential concern. It is not possible to specify the optimal sample size a priori. However, these "rules of thumb" are offered to provide rough indication of what DEP is likely to

[3]This approach is recommended because it is simple to implement. It does not have a statistical basis, in that the data distributions are not accounted for in a quantitative manner. Nevertheless, applying this simple rule is unlikely to lead to significant risk assessment/risk management errors. True background concentrations are expected to exceed the MADEP derived values by 50% or more only in exceptional cases.

consider adequate. In order to assess both the central tendency and the variability of the background concentrations at a location, a minimum of three (3) must be taken for each contaminated medium. This value is considered a bare minimum for a small, simple release at a small (< 3 acres) site. For a slightly larger (less than five acres) but still simple site (in terms of geology and number and distribution of chemicals) where the nature of the contamination is not complex, five (5) samples is considered the minimum. For larger, more complex sites, more background samples would be more likely to provide a defensible result.

Statistical uncertainty due to inadequate sample size can <u>never</u> be used to justify a conclusion that the site conditions are consistent with background.

It is also useful to graphically depict the site and background data sets, using the data points, histograms or box plots, to support this comparison.

Summary statistics can provide a fair assessment of site contamination, but a statistical test utilizing a sample size large enough to provide appropriate power to detect reasonable difference in the data is necessary to demonstrate that site concentrations are truly consistent with background levels.

Inferential Statistics

The "*gold standard*" for comparisons of site and background data is the use of a statistical test. Statistical tests utilizing a sample size large enough to provide appropriate power, confidence and minimal detectable relative difference provide conclusive determinations about the relationship between site concentrations and background levels. A statistical test of the hypothesis that the contaminant levels at the site do not significantly differ from the background levels, if done properly, is the most conclusive evidence of that chemical concentrations at the site are consistent with background levels.

An inappropriate statistical test (too small a sample size producing too low of a confidence level and/or too little power) is insufficient to demonstrate that site concentrations are consistent with background levels. Inappropriate statistical methods and/or insufficient sample sizes are no better than simple assessment of summary statistics, and may even lead to a false conclusion that would not be drawn from the summary statistics.

While cost is a consideration when using the proper sample size and design to evaluate contaminant levels at a site relative to background, it may prove cost effective to spend more money in the preliminary assessment, rather than investing in an inappropriate solution based on incomplete information and then having to redo the project after further analysis reveals flaws in the original site assessment.

There are numerous statistical methods that could be used for comparing site and background contamination levels. These methods can be generally divided into two categories (parametric and nonparametric), and selection of the appropriate method depends on the distribution of the contaminant data. Nonparametric tests have more relaxed assumptions than parametric tests but they tend to be less sensitive to differences between data sets than parametric tests. For this reason, parametric tests, when applicable, are preferred for comparing site and background data. Nonparametric tests such as the Wilcoxon Rank Sum Test or the Kruskal-Wallis Test can be used effectively, however, and may be appropriate in some cases for comparisons of site data to background levels. Risk assessors are referred to published texts on nonparametric statistics, such as Conover (1971) or Hollander (1973).

One of the assumptions of many parametric tests is that the data are normally distributed. There are several tests (for example: Shapiro and Wilk, 1965; Royston, 1982) to assess whether data are normally distributed, all of which need ten samples or more to have much validity. If the data are not normally distributed, there are a number of transformations which could be used to achieve normally distributed data. The log transformation is commonly used, and is often appropriate for contaminant data. If the contaminant data are normally distributed and if the other assumptions of the parametric statistics are met, then parametric statistical comparisons are more sensitive to differences in contaminant levels between locations than nonparametric tests. Snedecor (1980) provides clear summaries of parametric tests (such as the t-test and ANOVA test) and compares them to some nonparametric tests.

When a parametric test is based on a comparison of the means of two distributions, the means must represent members of normal distributions. The underlying concentration distribution (of individual data points) need not be normally distributed. Therefore, for parametric tests that compare means, it may not always be necessary to transform

lognormally distributed data before employing the statistical test.

The risk assessor or statistician conducting the analysis must determine whether to apply a statistical test to the available data, to identify the most appropriate and sensitive test, and to assure that the underlying requirements and assumptions of the test are met. The data sets encountered in environmental sampling at disposal sites are never ideal, because the sample sizes are always small for statistical purposes and the distributions of values are never perfect normal or lognormal distributions. Therefore, an extensive understanding of the principles and practice of statistics is needed to apply inferential techniques appropriately.

Every report using a statistical test for site contamination should contain a discussion of the power, confidence level, and the minimum detectable relative difference between the site and background contaminant levels. These should be considered before sampling a site, because they are the criteria, along with a measure of the variability in contaminant levels, that the risk assessor (or a statistician) needs to determine the requisite number of samples for the analysis. They also inform the site manager or reviewer about the validity of the conclusions, or the likelihood of drawing erroneous conclusions from the analysis of site data.

Assuming that the null hypothesis is defined by the statement "*There is no difference in contaminant levels between the site and background*", the three performance criteria of interest; **power**, **confidence** and **Minimum Detectable Relative Difference** are described in Figure 2.1. (If the null hypothesis is reversed, "There is a real difference between the site and background data", then the discussion of power which follows would be applicable to the confidence level, and vice versa.)

The ideal analysis of background and site data provide close to 100% power at a very high confidence level (also near 100%). Such ideal conditions are unlikely to occur at c.21E sites, however, so the risk assessor must consider which factors are *most* important so that the analysis will result in credible conclusions. From a regulatory viewpoint, the power of the analysis is of primary importance. The power of inferential techniques applied to data at typical hazardous waste sites is expected to range from 50% to over 90%. If the power of a test is lower than 60%, the results should not be considered conclusive, and should not be taken as evidence that site concentrations are consistent with background levels. For non-urban sites where concentrations substantially exceed DEP published background levels, the risk assessor bears a heavier burden of proof, and the power of the test should be greater than 90% to justify a conclusion that site concentrations are attributable to background. Sites where there is geological or historical information that explains the higher levels are considered exceptions to this rule.

Power (1-β) should be as high as possible so that the analysis correctly identifies site conditions which are greater than background levels. At a minimum, power should be as high as necessary to draw a conclusion.

Low statistical power could result in the erroneous conclusion that a truly contaminated site poses no significant risk of harm because it was consistent with background conditions when, in fact, a risk assessment should be conducted to evaluate potential risks. Analyses performed with low statistical power could therefore inadvertently jeopardize public health.

The confidence level is of lesser importance in this specific statistical application as Type I errors would result in chemicals present at background levels being evaluated in the risk assessment. Such an error would not pose a risk to health or the environment.

Power is not an independent variable, however. The power of a statistical test depends upon three related factors:

(1) the acceptable α, or Type I error. The power of a test can be increased if α is increased (i.e., if the confidence level is decreased). In the extreme, however, reducing the confidence level in order to increase the power of the analysis defeats the purpose of this assessment as it would be rare to conclude that a chemical is present at levels consistent with background. Type I error should not be greater

Figure 2-1

Important Parameters for Statistical Comparisons

Examples assume the null hypothesis being tested is: "There is no difference in contaminant levels between the site and background."

Confidence Level: The confidence level is 1 - α (times 100 for a percentage), where α (alpha) is the (one-sided) probability of concluding that the site chemical concentrations are greater than background when, in fact, the site concentrations are consistent with reported background levels. Alpha is also known as Type I error, or the probability of rejecting the null hypothesis when it is true (i.e., a false positive). The confidence level is the probability of correctly concluding that the site concentrations are consistent with background, and this level should be as close to 1 (or 100%) as possible.

Power: Power is 1 - β (times 100 for a percentage), where β (beta) is the probability of concluding that the site concentrations are consistent with background when, in fact, the site concentrations are greater than background. Beta is also known as the Type II error, or the probability of accepting the null hypothesis when it is false (i.e, a false negative). Power (1-beta) is the probability of rejecting the null hypothesis when it is false, or the probability of correctly concluding that the site concentrations are greater than background levels. Power should be as close to 1 (or 100%) as possible.

MDRD: The minimum detectable relative difference is the percent difference required between the site and background contaminant levels.

Sample Size: The number of samples in a data set.

than 0.5.

(2) the minimum detectable relative difference (MDRD). Since it is easier to detect larger differences in data sets than it is to detect slight differences, the power of a test can be increased by increasing the MDRD. In specifying the MDRD, the statistician (or risk assessor) is specifying how far above background the chemical concentration would have to be before it is considered important. An analysis using an extremely high MDRD would be meaningless, however, as the increased statistical power would be gained at the cost of missing sites with potentially significant contamination. The Minimum Detectable Relative Difference (MDRD) achieved should be no greater than 50% of the median value of the background data set (in a test of log-transformed data sets the MDRD should translate into an increment no greater than 50% of the median value of the untransformed background data set.)

Table 2.5
Types of Erroneous Conclusions When Comparing Site and Background Data Using Inferential Statistics

Assumes the null hypothesis (H_0)being tested is:
"There is no difference in chemical concentrations between site and background."

	Actual Condition	
Conclusion from statistical analysis	Chemical concentration greater than background (H_0 is false)	Chemical present at background concentrations (H_0 is true)
Chemical concentration is greater than background (Reject H_0)	*correct conclusion* $1 - \beta$	incorrect conclusion Type I error α
Chemical present at background concentrations (Accept H_0)	incorrect conclusion Type II error β	correct conclusion $1 - \alpha$

(Table modified from Glantz, 1981)

(3) the number of site and background samples which have been taken. The simplest way to increase the power of a statistical test is to increase the number of background and/or site samples. The number of site and background samples should be approximately the same to maximize the power for a given total number of samples. Note that increasing the number of samples will also increase the confidence level of the test as well.

The risk characterization report should include the calculations of power and confidence for the statistical test conducted, and a discussion of the implications of the results of those calculations. The Minimum Detectable Relative difference should be identified, and that value should be small enough to be sure that sites with contamination above background levels will likely be identified.

The risk assessor should explicitly consider these factors when discussing data needs with the site manager (i.e., when determining the necessary number of site and background samples). The EPA's Guidance for Data Useability discusses in detail the relationships between alpha, beta, minimum difference, data set variance and how to estimate sample size.

2.4 CONTAMINANTS OF CONCERN

All chemicals detected at the site should be considered contaminants of concern and should be carried through the risk assessment process, unless there is a specific, justifiable rationale for dropping the contaminant from the quantitative risk characterization. The selection of contaminants of concern should be evaluated in light of the specific conditions associated with each individual disposal site. The risk assessment report should document the process of identifying the contaminants of concern, and it should list the chemicals that are identified for both the human health risk assessment and the ecological risk assessment. The specific basis for eliminating a chemical detected at the site from the list of contaminants of concern should be clearly delineated in the text of the report.

All oil and hazardous material detected at a site should be included in the risk assessment unless one of the following conditions is true:

- The chemicals are present at a low frequency of detection and in low concentrations; or
- The chemicals are present at levels which are consistent with "background" concentrations for the area and there is no evidence that their presence is related to activities at the site; or
- The chemicals are field or laboratory contaminants.

Each of these rationales will be discussed individually.

NOTE: It is important to recognize that the term "contaminant of concern" is not synonymous with the term "indicator chemical". The latter term, was previously used by the EPA when a particular chemical was used as an indication of the presence of or risk posed by other contaminants at the site. The EPA no longer advocates the use of indicator chemicals because the practice may not accurately reflect the total site risk and in general may detract from the accuracy of the risk assessment. The EPA now recommends the use of chemicals of potential concern *[Risk Assessment Guidance for Superfund Volume 1 Human Health Evaluation Manual, Interim Final, December 1989].*

2.4.1 The Role of the Risk Assessor

The data collected at the site must be reviewed by the risk assessor. Once the analytical data are determined to be sufficient for risk assessment purposes, the contaminants of concern can be identified. As a general rule, the sampling data is likely to be sufficient if the samples are sufficiently representative of the exposure area; the data quality conforms with the guidance in Section 2.2: the samples have been collected and handled in accordance with standard procedures for the collection methodology; and the samples were

analyzed at a certified laboratory in accordance with appropriate laboratory methodologies and established protocols, including the criteria for environmental sample collection and analyses set forth in 310 CMR 40.0017.

2.4.2 Very Low Frequency of Detection and Concentration

Substances detected at very low frequencies *and* concentrations may be omitted from the risk assessment process. The purpose of this criterion is to eliminate from a risk assessment any substance that is not present consistently enough or at high enough concentrations to contribute to exposure.

Low Concentrations

The term "very low concentration" refers to the concentration of the chemical relative to the method detection limit. For the chemical to be identified as a contaminant of concern it must be present in a concentration above the detection limit. As the chemical concentration approaches the method detection limit however, the level of confidence in accurate quantitation decreases. The method detection limit (MDL) is the smallest concentration of a chemical which can be accurately measured considering the instrumentation and background noise. The EPA defines the MDL as three times the standard deviation of seven replicate spiked samples run according to the complete method. A further discussion of detection limits is included in the section of the guidance entitled *Extent of Contamination*.

For use in the risk characterization process, the *EPA Guidance for Data Useability in Risk Assessment* recommends the use of sample quantitation limit (SQL), which is the MDL adjusted to reflect sample-specific action, or the MDL itself. In general, the risk assessor should evaluate the type of detection limit identified in the site data as a part of an evaluation of the overall quality of the data. Instrument detection limits should never be considered appropriate for use in the risk assessment. Use of the MDL is appropriate and use of method reporting limit or the practical quantitation limit (PQL), the MDL multiplied by a factor of 2 to 5, may be appropriate. The use of the PQL is generally acceptable, unless the PQL is unusually high. The risk assessor should consider the site specific conditions in deciding if the use of the PQL is appropriate.

The risk assessor may have to decide whether or not to use qualified data in the risk assessment. The data may be qualified due to concerns regarding chemical identification, chemical concentration, or both. One of the most commonly encountered types of data qualifiers are "J" values, utilized in the EPA Contract Laboratory Program (CLP). The use of a J value may indicate that the identification of the contaminant is uncertain or approximate or that the concentration of the contaminant in the sample is uncertain or approximate. The *USEPA Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual, Interim Final, December 1989 (RAGS)* recommends the use of J-qualified concentrations, but cautions that care should be exercised if the risk is being

driven by the qualified data results.

When the risk assessor has determined that the detection limit presented is appropriate and the concentration of the analyte is very close to that detection limit, the next step is to determine the frequency of detection of the analyte at the site.

Very Low Frequency

The frequency of detection will be evaluated at each disposal site based upon the total number of samples collected, the sampling design and the total area sampled. In order to establish that the frequency of detection is very low, the risk assessor should first determine that the total number of samples collected was adequate to characterize the extent of contamination at the site.

There is no established number for what constitutes very low frequency of detection, but in general this number should be limited to one or two samples. This number will be a function of total sample size and as such it would not be appropriate to consider contaminants detected in one to two samples as very low frequency when the total sample size was only five or six samples. Generally speaking, unless there are at least ten samples, very low frequency ought not even be discussed.

It is also critical when considering total sample size that the samples included in the total were collected in the same medium and that, within that medium, the conditions are similar. For example, to determine that the frequency of detection of a contaminant is very low in soil samples collected at the site, the risk assessor should compare these samples to other soil samples collected at comparable depths in an area where the soil has similar characteristics (grain size, etc).

When determining whether the frequency of detection of a particular contaminant is very low at the site, it is also important to consider the spatial relationship of that sample relative to other samples at the site. For example, a contaminant may only be detected in 2 out of 20 total samples, but those two samples might be located in a particular portion of the site and may represent a localized area of contamination. The MCP 40.0924 (2) requires that localized "hot spot" areas be dealt with as distinct exposure points. A hot spot is defined in the MCP at 310 CMR 40.0006 and is discussed in greater detail in Section 2.2 of this guidance.

Finally, a chemical should not be ruled out as a contaminant of concern, even if the levels are detected in very low concentrations and very low frequency, when there is historical or present use of the chemical at the disposal site. In this situation, it is not possible to definitively conclude that a chemical detected in only a small number of samples is not associated with use of that chemical at the site; therefore it should be carried through the risk assessment.

2.4.3 Background

Once the presence of oil and/or hazardous materials has been documented at a disposal site, the risk assessor must evaluate the list of chemicals in relation to background conditions.

> *Background* is defined in the Massachusetts Contingency Plan (MCP) 310 CMR 40.0006 as:
>
> Those levels of oil and hazardous materials that would exist in the absence of the disposal site of concern which are:
>
> (a) ubiquitous and consistently present in the environment at and in the vicinity of the disposal site of concern; and
>
> (b) attributable to geologic or ecologic conditions, atmospheric deposition of industrial process or engine emissions, fill materials containing wood or coal ash, and/or petroleum residues that are incident to the normal operation of motor vehicles.

When chemicals are present at levels which are consistent with background and there is no evidence that the presence of that chemical is related to disposal at the site, then those chemicals need not be carried through the quantitative risk assessment process. The guidance addresses the determination of consistency with background in much greater detail in Section 2.3 on *Background*.

2.4.4 Field or Laboratory Contaminants

Contamination may be introduced into a sample during sample collection, transport or laboratory handling and analysis. A variety of quality control samples such as equipment blanks, trip blanks and method blanks should be collected and analyzed to determine whether contaminants are being introduced by field or laboratory practices rather than as a result of the release. A careful review of quality assurance and quality control data should be conducted as part of an investigation to avoid including chemicals attributable to sampling or laboratory activities in the assessment, while ensuring that chemicals which are site-related are not eliminated from further evaluation. When assessing the potential

for field or laboratory contamination the risk assessor should consider:

- the concentrations of chemicals detected in both the environmental and the blank samples;
- the types of contaminants detected in the samples, with particular attention to chemicals commonly used in a laboratory ; and
- historical information regarding chemical use at the site.

The Office of Research and Standards (ORS) recommends that when the concentrations detected in the site samples are higher than the concentrations detected in the quality control samples, the chemicals should either be considered contaminants of concern, or new samples should be collected. In the alternative, when the concentrations detected in the quality control blank samples are comparable to the concentrations detected in the site samples, those contaminants may be eliminated from a quantitative risk assessment, unless those contaminants are otherwise associated with the site based upon other evidence, such as a history of prior use of that chemical, or associated chemicals, at the site. In this situation, it may also be prudent to return to the site and collect both the site and the quality control samples again. Although it is acknowledged that this is not always possible, this step will aid in determining the actual source of the contaminant.

Table 2.5 identifies the recommended procedure for dealing with contamination in the blank quality control samples.

Table 2.5

CONTAMINANT CONCENTRATION	RECOMMENDED INITIAL EVALUATION	ALTERNATIVE EVALUATION
Site Sample >Blank	Resample	Include in the Risk Assessment as a Contaminant of concern
Site Sample ≤ Blank	Resample if deemed necessary	Eliminate based upon other evidence, such as site history and the nature of the contaminant

Although the EPA has established guidelines to use when comparing results from analysis of blanks and of environmental samples, **this approach is generally not recommended** for screening out chemicals at 21E sites. EPA guidelines were developed for use at large Superfund sites where the data sets are generally quite large. ORS does not recommend the EPA approach because of the small sample size frequently encountered at 21E disposal sites. If the risk assessor chooses to use the EPA approach, technical justification for this

approach should be provided. However, when resampling to confirm the presence or absence of the contaminant is possible, this is often the best alternative for determining whether the contaminant is present as a result of the release, or if it was introduced during sample collection or handling.

2.4.5 Lead as a Contaminant of Concern

The presence of lead at a site is often problematic because of the way that lead is regulated under MGL c.21E and the MCP. Lead is considered a "*hazardous material*" and as such is regulated under MGL c. 21E. A release or threat of release of lead can result in classification as a site, in accordance with MGL c. 21E Section 2. There is, however, a distinction between the definitions of *site* and *disposal site* under MGL c. 21E, and the distinction is important in that some of the requirements set forth in the MCP apply only to disposal sites and not to all sites. A site is defined as:

> *"...any building, structure, installation, equipment, pipe or pipeline, including any pipe into a sewer or publicly-owned treatment works, well, pit, pond, lagoon, impoundment, ditch, landfill, storage container, motor vehicle, rolling stock, or aircraft, or any other place or area where oil or hazardous material has been deposited, stored, disposed of or placed, or otherwise come to be located. The term shall not include any consumer product in consumer use or any vessel." (MGL c. 21E section 2)*

A disposal site is similarly defined, however, there are a few differences that should be noted. A disposal site is defined as:

> *"...any structure, well, pit, lagoon, impoundment, ditch, landfill or other place or area, excluding ambient air or surface water, where uncontrolled oil or hazardous material has come to be located as a result of any spilling, leaking, pouring, abandoning, emitting, emptying, discharging, injecting, escaping, leaching, dumping, discarding or otherwise disposing of such oil and/or hazardous materials. The term shall not include any site containing only oil or hazardous materials which are: lead-based paint residues emanating from a point of original application of such paint; resulted from emissions from the exhaust of an engine; are building materials still serving their original intended use of emanating from such use; or resulted from a release of source, byproduct or special nuclear material from a nuclear incident, as those terms are defined in 42 USC Sec. 2014, if such release was subject to requirements with respect to financial protection established by the Nuclear Regulatory Commission under 42 USC. Sec. 2210." (MGL c. 21E Section 2, emphasis added)*

As a result of the definitions of site and disposal site, releases of lead in the form of lead-based paint residues and/or from automobile exhaust are exempted from notification under the MCP (310 CMR 40.0317(8)). However, since lead is a hazardous material regulated under the statute, a Response Action may still be required at sites where such material has been released (310 CMR 40.0370).

Thus, when lead contamination is present in an environmental medium, it should be considered a contaminant of concern for the purposes of the risk characterization, regardless of its origin. At sites where no other notification requirement is triggered, however, persons undertaking response actions to address lead from lead-based paint or automobile exhaust would not be subject to the submittal requirements, approvals, or fees specified in the MCP (310 CMR 40.0370(2)).

2.4.6 Additional Issues for Consideration

2.4.6.1 Toxicity Screening

The Department does not recommend the use of toxicity screening to eliminate chemicals prior to the risk assessment at a disposal site. The use of EPA's concentration-toxicity screen, as described in the *Risk Assessment Guidance for Superfund Volume 1 Human Health Evaluation Manual (Part A), December 1989 section 5.9.5* is not recommended. The risk assessment process itself considers toxicity in estimating risks; it would be premature to eliminate contaminants before the risk assessment is performed.

ORS does not recommend the practice of screening out contaminants based upon this criteria despite the fact that they are not toxic at low doses and high concentrations are not usually associated with exposures at disposal sites. At some level even essential human nutrients may have adverse effects. If chemicals are eliminated based upon their being classified by the risk assessor as essential human nutrients, the report should contain a thorough discussion of the technical justification for taking such a step. In the alternative, the chemicals should be carried through the risk assessment process.

A contaminant of concern should not be screened out based solely upon human health risk considerations. Some chemicals which might be considered unimportant in the assessment of human health risk may still present a risk to the environment or to public welfare. The potential effects of contamination should be evaluated comprehensively through the quantitative risk characterization process.

The risk assessor may need to generate different lists of Contaminants of Concern to address risks to human health and the environment, and these lists should be clearly identified in each section of the assessment.

2.4.6.2 Chemical Species

When identifying contaminants of concern it may be important to consider specific states of the chemicals. Depending upon the specific state of the chemical that is present at the site, there may be different health or environmental effects associated with the chemical. This phenomenon is commonly encountered with differences in oxidation states of metals, where changes in oxidation states can result in changes in absorption or toxicity. For example,

hexavalent chromium is more toxic than trivalent chromium. In addition, some compounds may degrade over time and products of degradation may have different toxicity parameters than the parent compound. The risk assessor should consider these factors and may want to discuss these issues when identifying the contaminants of concern.

2.4.6.3 Groups of Compounds

When reviewing the analytical data available for the disposal site some of the data may be presented for groups of compounds rather than for each individual component. Data on groups of compounds is not generally useful in the risk assessment process. Toxicity information used to estimate risk is compound specific; therefore, therefore the estimation of risk associated with exposure to compounds that are identified as a group can be highly inaccurate or impossible, and as a result is not generally recommended. The individual chemicals are the Contaminants of Concern, but for simplicity's sake may be described as groups of compounds in discussions within the risk assessment. The Dose Response Section of the guidance addresses this issue in greater detail.

One of the most commonly detected groups of compounds at disposal sites are total petroleum hydrocarbons (TPH). For a further discussion of TPH data at disposal sites see the *Policy for the Investigation, Assessment, and Remediation of Petroleum Releases - Interim Site Investigation Protocol Document, WSC-401-91 (4/91), and the Interim Final Petroleum Policy: Development of Health-Based Alternative to the Total Petroleum Hydrocarbon (TPH) Parameter, June 1994.*

2.4.6.4 Tentatively Identified Compounds

When gas chromatography-mass spectrometry (GC-MS) is used to analyze for the presence of organic compounds, the instrument is calibrated for certain chemical standards. These standards represent the target compounds which are being analyzed in the samples. When compounds are identified in the sample, but the GC-MS instrument was not specifically calibrated for those compounds, they are designated as tentatively identified compounds (TICs). The mass spectrum of the sample is compared to a computerized library of mass spectra, but since there is no standard calibrated for the TIC, the identification is less certain than for target compounds. The *EPA Data Useability Guidance Document* identifies several techniques which can be employed to increase the confidence in identification and quantitation of TICs:

- the TIC data should be reviewed by an analytical chemist trained in the interpretation of mass spectra and chromatograms;

- the identification of the TICs should be checked against the chromatographic retention indices or relative retention times;

- the TICs should be compared to available site information regarding past use of the site and chemicals associated with prior uses of the site;

- the sample could be re-analyzed using a specific standard.

Another advisable step is to evaluate whether the TIC is likely to be associated with other compounds detected at the site. The result may support the tentative identification or may aid in making a decision regarding the need to re-sample.

The risk assessor may be able to classify the TICs as belonging to a particular class of compounds, such as aliphatic hydrocarbons or polycyclic aromatic hydrocarbons, and as such can qualitatively discuss the significance of these TICs. When dealing with the TICs qualitatively the impacts on cumulative site risk and overall uncertainty should be discussed. The data should be reviewed by an experienced analyst to obtain an "order of magnitude" estimate of the concentration, prior to any discussion of qualitative risk posed by the TICs.

The purpose of this discussion is not to encourage the risk assessor to identify more TICs at sites, but rather, to provide guidance on how TICs that are identified can be dealt with at a site. The risk assessor should note when he/she specifically requests the identification of the TICs at the site, as opposed to a situation where the TICs were just identified as a part of the comprehensive site investigation. The risk assessor must use his/her professional judgement in dealing with TICs, especially when the TICs are potentially associated with a significant health risk. The concentrations of TICs v. concentration of identified compounds should be discussed in terms of the overall risk associated with the site.

2.4.6.5 Comparison to Regulatory Standards & Guidelines

A chemical should not be ruled out as a contaminant of concern because it is below a standard regardless of the risk characterization method used. It is appropriate to compare individual exposure point concentrations to standards when conducting a Method 1 or Method 2 risk assessment, as this is the actual risk characterization process for those methods. However, when conducting a Method 3 risk characterization, screening substances out of the risk assessment because they are below applicable or suitably analogous standards is not appropriate. In Method 3 it is appropriate to compare the exposure point concentrations at the site to applicable or suitably analogous standards, but that is only part of a Method 3 characterization. The contaminants of concern must also be carried through the risk assessment process to comply with the MCP and determine if a level of no significant risk has been reached. Therefore, even if the contaminant concentration is below the Massachusetts Drinking Water Quality Standards promulgated

in 310 CMR 22.00 the chemical should be included as a contaminant of concern and carried through the Method 3 Risk Assessment process.

2.4.6.6 Comparison to Reporting Concentrations

The Reporting Concentrations (RCs) should only be used to determine whether a release needs to be reported to the Department. It is not appropriate to eliminate chemicals as potential contaminants of concern, based upon the fact that the concentrations are lower than the RC for the particular chemical.

2.4.6.7 Mobility, Persistence, and Bioaccumulation Potential

When identifying contaminants of concern at a disposal site it is not appropriate to eliminate them from the risk analysis based upon physical or biological properties that suggest reduction of the chemical in the future.

2.5 SIGNIFICANT FIGURES

The risk assessor should keep in mind the accuracy and precision of the environmental data, toxicity information and exposure assumptions used in the course of an MCP Risk Characterization. Environmental measures such as Exposure Point Concentrations, calculated Method 2 standards, and estimated cancer and non-cancer risks are continuous variables whose *exact* values are unknown and unknowable. Such values should be expressed in as many significant figures as is appropriate.

There are conventions for determining the appropriate number of significant figures and how to round the 20-digit value calculated by a spreadsheet to the appropriate number of significant figures.

2.5.1 What Is A Significant Figure?

In general, significant figures (digits) in a number include the left-most non-zero digit to the right-most digit written

Thus: 241
24.1
0.00241, and
2.41 E-2

all have three significant figures.

Terminal zeros may be significant or may be used solely to fix the decimal point (the number 240 may have two or three significant digits) and such numbers can be written in scientific notation to explicitly denote the number of significant digits (2.4 E+2 would have two significant digits while 2.40 E+2 would have three).

2.5.2 Rounding Off Values to the Appropriate Number of Significant Figures

Rounding off of values to the appropriate number of significant figures should occur as the last step of the calculations, and should *not* follow each stage of the calculations.

Rounding a number to the appropriate number of significant figures involves dropping one or more digits to the right of the last significant figure. When more than one digit is to be dropped, the rounding off should be done as a block and not one figure at a time:

- When the first digit dropped is less than 5, the last digit retained should remain unchanged.
- When the first digit dropped is greater than 5 then 1 is added to the last digit retained.
- When the first digit dropped is equal to 5, then 1 is added to the last digit retained *if* that digit is odd.

When adding or subtracting numbers, the answer should contain digits only as far as the first column containing a significant figure:

Examples:

12.5	0.076	20	20.0
14.47	2.35	17.376	17.376
+ 98.3	+ 1.954	+ 5.2	+ 5.2
125.3	4.38	40	42.6

Note the difference between the last two answers: the value of 20 in column 3 is taken to have 1 significant figure, while the 20.0 in column four has three significant figures. The value of 20 in column three could also read as having two significant figures and knowledge about the source of that number would determine whether one or two digits would be appropriate.

When multiplying or dividing numbers, the answer should be rounded off to contain only as many significant figures as are contained in the least exact factor. For example, 6.834 x 7.35 = 50.2, since 7.35 has only three significant digits. This is an approximation of a more exact rule that the fractional (or percentage) error of a product or quotient cannot be any less than the fractional or percentage error of any one factor. For this reason, numbers whose first significant figure is 1 (or occasionally 2) must contain an additional significant figure to have a given fractional error in comparison with a number beginning with 8 or 9.

> For example, 9.84 ÷ 9.3 = 1.06. By the simple rule stated above, the answer would be 1.1, but 1.1 (± 0.1) has a percent error of approximately 10%, much greater than the percent error contained in the value of 9.3 (9.3 ± 0.1 has a percent error of approximately 1 %).

Analytical results received from a laboratory will be reported in as many significant figures as is justified, given the accuracy and precision of the analysis. For example, the analyses of 3 rounds of groundwater samples could yield the following results for a drinking water supply well:

Benzene..... ....29 ppb..... ..... (2 significant figures)
Benzene..... ....5.5 ppb... ..... (2 significant figure)
Benzene..... ....347 ppb..... ..... (3 significant figures)

For the purpose of this example, assume that the Exposure Point Concentrations calculated from this data should be the arithmetic mean of the results from the three sampling rounds:

$$EPC = (29 + 5.5 + 347) \div 3 = 130$$

The value of 130 represents the results of the calculation (127.16667 by hand calculator) rounded to 2 significant figures. Note that the divisor, 3, is an exact number: the number of samples. Mathematical operations involving exact numbers do not reduce the accuracy and precision of the result and thus are not considered in determining the appropriate number of significant figures. (Another way of looking at this is that the value 3, being know exactly, could have been written as 3.000...or 3.0000000000 to denote the accuracy and precision of this value.)

Example 2.1

REFERENCES FOR CHAPTER 2

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3.0 SELECTION OF RISK CHARACTERIZATION METHOD

The Massachusetts Contingency Plan identifies three methods for the characterization of risk at a disposal site. In general, the selection of the method for a given disposal site is based upon the personal choice of the parties conducting the site assessment, in conjunction with the criteria set forth in the MCP at 310 CMR 40.0942. The most straight forward method is Method 1 which uses promulgated standards to characterize the risk posed by the disposal site. Method 2 builds on this approach by continuing to use promulgated standards, but adds some site specific information. Finally, Method 3 characterizes risk through the application of site specific methodologies. There are, however, some limitations on the use of the methods. This section will first discuss the general limitations applicable to all three methods, and then address each of the methods individually.

3.1 GENERAL LIMITATIONS

The method selected for the risk characterization should be clearly identified in the report. The site should be adequately characterized prior to assessing the risk posed by the site. In general, only one method should be used for a specific release, and the Response Action Outcome (RAO) Statement for each release should be based upon the one method selected. Risk Characterizations conducted to support an RAO Statement for a *portion* of a disposal site are discussed in Section 3.5. There are a few particular situations where methods may be combined. These situations will be addressed in each of the specific sections discussed below.

3.2 RESTRICTIONS ON THE USE OF METHOD 1

When determining whether Method 1 can be used to characterize the risk of harm to health, safety, public welfare and the environment, the risk assessor should scrutinize criteria found at 310 CMR 40.0942. It is expected that Method 1 will be an option at the majority of c.21E sites. At certain sites, however, the risk assessor will have to supplement the Method 1 risk characterization with some form of a Method 3 assessment, while at other sites Method 1 will not be an available option. This section describes the circumstances under which Method 1 may or may not be employed. Method 1 is <u>*never*</u> required for particular sites, however. It is up to the risk assessor to determine the appropriate risk characterization approach from among the methods identified as applicable to the site.

3.2.1 When Method 1 Alone May Be Used

Method 1 can be used as the sole form of risk characterization at sites where (a) the contamination is limited to the soil and groundwater, (b) there are no chemicals which bioaccumulate within the top two feet of soil, *and* (c) all the contaminants of concern present have Method 1 standards promulgated by MADEP in the Massachusetts Contingency Plan. It is expected that Method 1 will be an optional risk characterization approach at the majority of simple sites, as soil and groundwater are the environmental media most commonly contaminated and MADEP has developed standards for the most commonly reported chemicals.

3.2.2 When Method 1 Can Be Used In Combination With Method 3

For sites which do not meet the criteria for using Method 1 alone (listed above), a number of options are available, including the use of Method 1 in combination with risk characterization Method 3 *under limited circumstances*. (The Method 3 assessment in these mixed-Method cases is focused on the potential ecological risks associated with the site.) The risk assessor may also choose to employ Method 2 and/or Method 3, as described in Section 3.0 of this document and at 310 CMR 40.0942 of the MCP.

The combination Method 1/Method 3 risk characterization is an option at sites where *either* of the following conditions prevail:

- The contamination is not limited to soil or groundwater, but the exposure to humans comes predominantly from those media; or

- Chemicals which bioaccumulate are present in the top two feet of soil at a site which would otherwise meet the requirements for conducting a Method 1 risk characterization.

In the first set of conditions, Method 1 may be used to evaluate the soil and groundwater, and Method 3 would be used to evaluate the risk of harm to public welfare and the environment from the other contaminated media. This combination approach was written into the regulations in order that sites where there is minor sediment or surface water contamination could benefit from using the Method 1 standards while still adequately evaluating the potential environmental risks in a meaningful way (Method 3). Note that the human health risks associated with the sediment or surface water (or other media) must still be addressed to provide adequate demonstration to the Department that the soil and groundwater exposures are "*predominant*". In other words, the human exposures to the other media (not soil or groundwater) must be relatively minor, meaning that the cumulative risks associated with those exposures should be at least an order of magnitude below the MCP cumulative risk limits (i.e, a cumulative excess lifetime cancer risk no greater than one-in-one million, and a cumulative hazard index no greater than 0.1.) If the risks are greater than those levels, then the site as a whole must be addressed using the cumulative risk approach (Method 3.)

In the second set of circumstances, it is important to note that in developing the Method 1 standards, potential terrestrial ecological impacts were not considered. It is therefore not possible to conclude that a condition of no significant risk of harm to the environment exists when Method 1 is used to characterize risk at sites where contamination in the soil may pose ecological risk. Recognizing this limitation of the Method 1 soil standards, DEP requires additional site-specific ecological risk assessment at those sites most likely to pose a risk to terrestrial receptors. Rather than require ecological risk assessments at *all* sites with soil contamination, however, the need for additional assessment is triggered by the presence of bioaccumulating chemicals in surficial soil. The use of these two factors (a chemical's presence in surficial soil and that the chemical bioaccumulates) is considered by DEP to be adequate screening criteria for the purpose of streamlining the c.21E risk characterization process. The combination Method 1/Method 3 approach is used at these sites to insure that those potential terrestrial exposures are evaluated using an appropriate approach (a Method 3 environmental risk characterization) while Method 1 is used to otherwise characterize the potential human health risks.

Section 9.0 of this document, which provides guidance for conduction a Method 3 environmental risk characterization, should be consulted whenever a combined Method 1/Method 3 assessment is conducted.

When either of these combined approaches is used to support a Response Action Outcome Statement, *both* Method 1 and Method 3 should be checked off on the RAO Form (Form BWSC-004).

3.2.3 When Method 1 Is Not An Option

Method 1 is *not* an option and *cannot* be used at sites where: (a) the contamination present at the site is located in an environmental medium which is not soil or groundwater (unless human exposures to such contamination is minor as described above), in which case Method 3 is used to characterize potential risks, or (b) there are contaminants of concern present for which MADEP has not developed Method 1 standards, in which case either Method 2 or Method 3 may be used to characterize potential risks.

EXAMPLE

An underground storage tank has leaked heating fuel under a residential structure. The tank was removed, but residual contamination exists under the building. No soil gas studies were conducted and no indoor air sampling was done. Is it appropriate to use Method 1 and clean up to the appropriate soil and groundwater standard?

The MCP at 310 CMR 40.0942(1)(b) states that when oil or hazardous material is present in, or is likely to migrate at potentially significant concentrations to an environmental medium in addition to soil and groundwater, then Method 1 alone shall not be used. Therefore, in the situation described above it must be demonstrated that the indoor air at the residence is not being affected by the release. How this determination is best made will depend upon the particular site circumstances, but may include soil gas studies, indoor air sampling or fate and transport modeling.

3.3 RESTRICTIONS ON THE USE OF METHOD 2

Method 2 allows for consideration of limited site-specific information and may be used in two different ways. First, Method 2 may be used to fill data gaps by creating additional Method 1 Standards where they do not currently exist. Method 2 may also be used to incorporate site-specific fate and transport information to modify existing Method 1 Standards. It is also possible to combine the two approaches in one risk characterization. Since a Method 2 risk characterization builds upon the Method 1 risk characterization, all the limitations and options for Method 1 discussed above also apply to Method 2. Specifically, Method 2 may be used at sites where the contamination is limited to soil and groundwater and there are no chemicals which bioaccumulate within the top two feet of soil.

3.3.1 Development of Additional Method 1 Standards

The procedures for developing additional Method 1 Standards are set forth in the MCP at 310 CMR 40.0983 for groundwater standards and 40.0984 for soil standards. Section 6.3 of the guidance addresses the derivation of additional Method 1 Standards. Additional guidance is also available in the *Background Documentation for the development of the MCP Numerical Standards, April, 1994, Section 4.0 Groundwater and Section 5.0 Soil.*

3.3.2 Modification of Existing Method 1 Standards

The MCP allows for modification of existing Method 1 Standards. However, not all of the Method 1 standards may be modified. The Method 1 Standards which may be modified include:

- The Method 1 Soil Standards considering leaching potential (310 CMR 40.0985)
- The Method 1 GW-2 Standards considering volatilization potential (310 CMR 40.09886)
- The Method 1 GW-3 Standards considering the migration and discharge components (310 CMR 40.0987)

The Method 2 standards may be modified to incorporate site specific considerations. A more detailed discussion is presented in Section 6.4 of the guidance.

The Method 1 Standards which may not be modified include:

- The Method 1 Soil Standards based upon direct contact exposures (310 CMR 40.0985(6) Table 5)
- The Method 1 GW-1 Standards
- The Upper Concentration Limits (310 CMR 40. 0996(5) Table 6)

3.3.3 When Method 2 Alone May Be Used

Method 2 can be used as the sole form of risk characterization at sites where (a) the contamination is limited to the soil and groundwater and (b) there are no chemicals which bioaccumulate within the top two feet of soil.

3.3.4 When Method 2 May Be Used In Combination With Method 1

At sites with multiple chemicals and/or multiple exposures it is not necessary to modify the Method 1 standards for *all* the chemicals if only limited Method 2 modifications are appropriate. The risk assessor may use one or more Method 1 standards in combination with derived or modified Method 2 standards, as noted at 310 CMR 40.0982(5). For example, if Method 2 is used to derive a soil category S-1 standard for the chemical *methyl-ethyl-laccolith*, the Method 1 S-1 standards for the other chemicals at the site can be used without modification. Whenever some combination of Method 1 and Method 2 standards is used to characterize risk, the approach is described as a Method 2 risk characterization, and the appropriate box would be checked on the Response Action Outcome Statement.

3.3.5 When Method 2 Can Be Used In Combination With Method 3

For sites which do not meet the criteria for using Method 2 alone, Method 2 may be used in combination with risk characterization Method 3 *under the same limited circumstances that Method 1 can be used with Method 3* (See discussion, Section 5.0). The risk assessor could also choose to employ Method 3 alone to characterize the risk.

3.3.6 When Method 2 Is Not An Option

Method 2 is *not* an option and *cannot* be used at sites where all or some of the contamination present at the site is located in an environmental medium which is not soil or groundwater (unless human exposures to such contamination is minor as described in Section 5.0). In this case Method 3 *must* be used to characterize risk.

A Method 2 Risk Characterization should always be conducted in combination with a separate characterization of the risk of harm to safety posed by the contaminant conditions, as described in the MCP at 310 CMR 40.0960.

The detailed discussion in Section 5.0 of method applicability, soil and groundwater categorization, identification of exposure points, determination of exposure point concentrations, and risk characterization apply to Method 2 as well as Method 1, and will not be repeated in this section. The remainder of this section focuses on the differences between Method 1 and Method 2, which are related to the derivation and values of the standards used to characterize risk.

EXAMPLE

A risk assessor has proposed conducting a Method 2 risk characterization at a disposal site. The only data available is Total Petroleum Hydrocarbon (TPH) concentrations in soil. The proposal includes modification of the Method 1 Standards based upon fate and transport considerations. Is this acceptable?

There are several reasons why this approach may not be acceptable. Primarily the TPH values in Method 1 are based upon direct contact, not ability to leach and therefore can not be modified. Also, the TPH values do not assess BETX or PAH concentration, therefore it may not be appropriate to base the entire assessment on TPH data only.

3.4 RESTRICTIONS ON THE USE OF METHOD 3

There are no limitations on the Method 3 risk characterization. The MCP allows the use of site-specific risk assessment to evaluate ***any*** disposal site. It is important to note that when Method 3 is used to evaluate one or more human exposure pathways, it must be used for the entire risk assessment. More specifically, Method 1 and Method 2 cannot be used to evaluate risk from groundwater and soil at a site where Method 3 is applied to air exposures - the Method 1 (and thus Method 2) standards are not applicable and cannot be used in a method 3 assessment (310 CMR 40.0993(3)). This is not a "limitation" on the use of Method 3 because if contamination is present in media beyond soil and groundwater, Method 3 is the appropriate method to be used in the risk characterization.

EXAMPLE

An underground storage tank has leaked gasoline into soil and groundwater. The tank is located 100 feet upgradient of a pond. To date no environmental sampling has been conducted in the pond to test surface water and sediments for the possible presence of gasoline. The responsible party has proposed conducting a Method 1 risk characterization for the soil and groundwater contamination. Is this an appropriate approach?

No, not at this point. Given the proximity of the release to the pond the possibility of impacts on the pond should be addressed. If the surface water or sediments are contaminated, and soil and groundwater contamination does not "*predominate*", then it is best to use Method 3 to evaluate all the affected media at the site.

3.5 RISK CHARACTERIZATION FOR PORTIONS OF A DISPOSAL SITE

A Response Action Outcome may be achieved and a Response Action Outcome Statement submitted for an entire site, disposal site, or a portion of a disposal site (310 CMR 40.1003(3)). The ability to achieve separate RAOs for portions of a site allows the expedited cleanup of areas which are more readily addressed: problems which are more complex or difficult to assess/remediate can be dealt with on a different schedule. RAOs for a portion of a disposal site may also be an attractive option in situations where the disposal site includes more than one property.

The general provisions for Response Action Outcome are described at 310 CMR 40.1003. An Class A or Class B RAO submitted to DEP must be supported by documentation that a level of No Significant Risk exists or has been achieved for the site or disposal site (310 CMR 40.1004). RAO Statements submitted for a ***portion*** of a disposal site may be problematic, as the fundamental risk management criteria of the MCP are expressed as limits on cumulative risk (i.e., the risk to a receptor received from all applicable exposure pathways and all chemicals).

Therefore, by breaking up a site into discrete areas and assessing them separately, the *cumulative* impact of the contamination may not be adequately addressed.

Several questions have been raised about how to conduct risk characterizations for *portions* of a disposal site:

- *Must the same risk characterization Method be used for each portion of the site?*
- *Must the last RAO submitted for a site include a risk characterization for the entire site?*
- *How is the concept of Cumulative Risk considered for a site achieving multiple RAOs?*

In order to answer these questions, the Department recommends the following approach:

The method of risk characterization used to support a Response Action Outcome for a portion of a disposal site should be selected using the criteria set forth in 310 CMR 40.0942 and may be different from the risk characterization method used for other portions of the same disposal site.

- If Methods 1 or 2 are used to characterize risk for that portion of a disposal site no further consideration of cumulative risk is needed. Note that the Method 1 standards were set at levels which would be generally protective of multi-chemical, multi-pathway exposures.

- If Method 3 is used to characterize risk at one or more portions of the disposal site particular attention must be paid to how the Method 3 assessment is conducted and how the results are interpreted in order to insure that the Cumulative Receptor Risk Limits are met for the entire site or disposal site. In other words, Method 3 risk characterizations conducted in support of an RAO for a portion of a disposal site must still address the issue of Cumulative Receptor Risk. Specifically, each Method 3 risk characterization should either:

  - evaluate all potential exposure pathways for each identified receptor of concern, even those exposures occurring at points beyond the portion of the site considered in the RAO, or

  - demonstrate that the risks from the exposure pathways evaluated are sufficiently below the Cumulative Receptor Risk Limits that the exposures associated with *this* portion of the disposal site would not be significant *even if* the same receptor were exposed to contamination at other portions of the same site.

  In the first Method 3 option above, the risk assessor must identify all potential exposure points for each receptor (310 CMR 40.0924). If all the receptors' exposure points happen to be located within the portion of the disposal site addressed in the RAO, then the Method 3 assessment would not differ from a standard assessment. If one or more exposure points are located outside the portion of the disposal site

addressed in the RAO then the risk assessor must consider the exposures occurring at those locations. Some coordination of site assessment is needed since this approach would likely require access to analytical data describing contaminant concentrations at those locations.

Under the second Method 3 option above, the approach is similar to screening of exposure pathways described in Section 3.2.2 of this guidance: the exposures from this portion of the disposal site must be relatively minor, meaning that the cumulative risks associated with those exposures should be at least an order of magnitude below the MCP cumulative risk limits (i.e, a cumulative excess lifetime cancer risk no greater than one-in-one million, and a cumulative hazard index no greater than 0.1.) If the risks associated with this portion of the disposal site are greater than those levels, then the additional exposures experienced by that receptor must be evaluated (the first Method 3 option) using the cumulative risk approach.

This approach for characterizing risk to support a Response Action Outcome for a portion of a disposal site allows different risk characterization methods to be used for the different RAOs, it eliminates the need for a final "comprehensive" risk characterization of the site after all the RAOs for the different portions have been submitted, and this approach addresses the regulatory requirement to meet the Cumulative Receptor Risk Limit.

3.6 NOTATION ON THE RAO FORM

The Response Action Outcome (RAO) Statement & Downgradient Property Status Transmittal Form (BWSC-104) requires the person submitting the form to identify the risk characterization method used. Section F of the form provides a simple check list to identify the Risk Characterization Method(s) used and the applicable soil and groundwater categories at the site. The appropriate boxes should be checked.

Remember that there are only limited circumstances under which more than one Risk Characterization Method will be used to support a single RAO - most RAO Statements will have just one box checked. It would be appropriate to mark two boxes, Methods 1 and 3, for example, if Method 1 was used to conduct the human health risk characterization and Method 3 was used to address the environmental risk characterization.

It is not necessary to check a Risk Characterization Method box **if** the concentrations of all the oil or hazardous material at the site are consistent with background, since no risk characterization is required at such sites (310 CMR 40.0901(3)). These sites are eligible for a Class A-1 or Class B-1 RAO.

Since more than one soil category and more than one groundwater category may apply at a given site, *all* the applicable soil and groundwater categories within the area covered by the RAO should be checked. Note that the ***applicable*** categories are checked, not the category of the standards actually achieved. For example, additional remediation may be conducted to achieve S-1 standards at sites where soil is actually categorized as S-2 in order to avoid having to record an Activity and Use Limitation. The S-2 box should be checked on the RAO form because that is the actual applicable category, even though the S-1 standards were achieved.

4.0 CHARACTERIZATION OF RISK OF HARM TO SAFETY

This section describes the evaluation of the risk of harm to safety, including a discussion of the definition of "risk to safety", criteria to be used to evaluate safety risks, and some descriptions of situations that are presumed to constitute safety hazards. It is anticipated that most evaluations of risk to safety will use qualitative rather than quantitative criteria.

A characterization of risk to safety is required at all sites at which a Subpart I risk characterization is performed (310 CMR 40.0941(2)). The risk to safety must be looked at separate from, and in addition to the Method 1, 2, or 3 evaluation of risk of harm to health, public welfare, and the environment. Typically, the assessment of safety issues should be presented as a separate chapter in the risk characterization report.

The scope and level of detail of a safety evaluation is expected to vary from site to site, and should be sufficiently detailed to conclude whether a safety problem related to the release or threat of release of oil or hazardous material exists at the site. The individual or individuals performing the evaluation of risk of harm to safety should follow the "Response Action Performance Standards" (RAPS), which are discussed in 310 CMR 40.0191, in determining the appropriate level of effort.

The Massachusetts Contingency Plan (310 CMR 40.0960) requires the characterization of the risk of harm to safety at a disposal site when using *any* of the risk assessment methods. Any identified safety risks must be considered when determining the need for remediation. Remediation may be required based upon the risk of harm to safety, even if no further remedial response actions are necessary based upon human health considerations. It must also be stressed that in characterizing the risk of harm to safety one must look not only at releases which have occurred, but also at the "threat of a release".

The purpose of evaluating the risk of harm to safety is to identify conditions which have resulted or may result in a release of oil and/or hazardous material currently or in the foreseeable future that will pose a threat of physical harm or bodily injury to people. The general definition of harm to safety in the Massachusetts Contingency Plan states that a level of no significant risk to safety exists or has been achieved if the conditions at the disposal site which are related to a release of oil and/or hazardous material do not currently and will not in the foreseeable future pose a threat of physical harm or bodily injury to people.

4.1 CONDITIONS CONSTITUTING A RISK OF HARM TO SAFETY

Some common examples of conditions that constitute a risk of harm to safety are as follows: rusted or corroded drums or containers; weakened berms; the threat of fire or explosion, including the presence of explosive vapors resulting from the release of oil and/or hazardous material; reactive chemical(s) stored or disposed of in a way that does not reasonably preclude uncontrolled reactions; unsecured pits, ponds, lagoons or other dangerous structures; any uncontained materials which exhibit the characteristics of corrosivity, reactivity, flammability, or are considered infectious materials as described in 310 CMR 40.0347; and the presence of ionizing or nonionizing radiation.

There may be conditions present at a site that are not related to the release of hazardous material and would, therefore, not be considered a risk to public safety under M.G.L. Ch.21E in most instances. Such site conditions may include the presence of metal shards or other sharp objects or the presence of a structurally unsound building at a site. It should be noted that there may be uncommon circumstances which could be considered to pose a risk to safety under c.21E. An example is the presence of sharp objects or syringes at a disposal site which have the potential to increase the exposure of a receptor to the oil or hazardous material (including infectious material pursuant to 310 CMR 40.0347(5)) present at the site through a puncture wound or similar injury.

4.2 DEFINITIONS OF CHARACTERISTICS OF HAZARDOUS MATERIALS WHICH MAY POSE A RISK OR HARM TO SAFETY

In this section particular characteristics of hazardous materials, those which pose a risk of harm to safety, will be discussed more in depth. How one determines if a material is flammable/ignitable, corrosive, reactive, or infectious is outlined in section 40.0347 of the Massachusetts Contingency Plan.

The definition of ***flammability/ignitability*** is discussed in section 310 CMR 40.0347(1) of the MCP. A material is considered flammable/ignitable if a representative sample exhibits any of the following characteristics: liquid with a flash point of less than 60 degrees Celsius/140 degrees Fahrenheit; a non-liquid which is capable under standard temperature and pressure of catching fire through friction, absorption of moisture or spontaneous chemical changes and, when ignited burns so vigorously and persistently that it creates a hazard; a compressed gas that is ignitable or an oxidizing agent. Methods for testing for determining flash point of liquids and the ignitability of compressed are outlined in section 310 CMR 40.0347(1)(b) and (c).

Corrosivity is discussed in section 310 CMR 40.0347(2) of the MCP. A material is considered corrosive if a representative sample exhibits any of the following properties: it is aqueous and has a pH equal to or less than 2.0 or equal to or greater than 12.5; it is a liquid and corrodes steel (type SAE 1020) at a rate greater that 6.35 mm per year at a test temperature of 55 degrees Celsius; or it is a liquid that causes visible destruction or irreversible alterations in mammalian skin tissue at the site of contact. Methods for testing pH and determining the rate of corrosion are outlined in section 310 CMR 40.0347(2)(b) and (c).

Reactivity is discussed in section 310 CMR 40.0347(3) of the MCP. A material is considered reactive if a representative sample exhibits any of the following properties: it is normally unstable and readily undergoes violent changes without detonating; it reacts violently with water; it forms potentially explosive mixtures with water; when mixed with water it generates toxic gases, vapors, or fumes in a sufficient quantity to pose a risk to safety; it is capable of detonation or explosive reaction if it is subjected to a strong initiating source or if heated under confinement; it is readily capable of detonation or explosive decomposition or reaction at a standard temperature and pressure; or is defined as a forbidden explosive, or a Class A or Class B explosive.

Infectious materials, which pose a risk of harm to safety, are defined in section 310 CMR 40.0347(5) of the MCP. Infections material are those materials, that, because of their infectious characteristics may: cause, or significantly contribute to an increase in mortality or an increase in serious irreversible or incapacitating reversible illness; or pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of or otherwise managed. Infectious materials are hazardous materials subject to the provisions of the MCP, unless specifically excluded from regulation.

4.3 APPLICABLE OR SUITABLY ANALOGOUS STANDARDS, GUIDELINES, AND POLICIES

At a minimum, current and reasonably foreseeable disposal site conditions and conditions in the surrounding environment must be compared to applicable or suitably analogous safety standards, guidelines, and policies when characterizing the risk of harm to safety. When assessing the flammability/ignitability of an oil or hazardous material, ORS recommends applying National Institute for Occupational Safety and Health (NIOSH) standards for determining the Lower Explosive Limits (LELs) of compounds in air.

5.0 METHOD 1

The specific regulations concerning the Method 1 risk characterization procedure are found at 310 CMR 40.0970 of the Massachusetts Contingency Plan. Readers are reminded that general requirements applicable or potentially applicable to all risk characterizations are found in 310 CMR 40.0900 through 40.0960, collectively referred to as Subpart I. Readers are urged to refer to the MCP if there are questions about the specific regulatory requirements.

The Method 1 approach was developed to provide a straightforward comparison of site conditions to promulgated standards to evaluate the risk of harm to health, public welfare and the environment[1]. The use of promulgated standards in the risk characterization has many benefits:

- The assessment process is simplified. The risk assessor does not need to quantitatively evaluate receptor exposures, nor explicitly estimate risk.

- There is greater certainty that the requirements of the regulations have been achieved. The "No Significant Risk" levels are stated explicitly and in terms that are familiar to the lay public and site assessment specialists alike: concentrations of the contaminant in soil and groundwater.

- There is greater consistency in remedial decisions. Because the No Significant Risk requirements are explicit, there is little opportunity for varied interpretation from site-to-site.

- The cost and time required for the risk characterization is reduced, freeing resources to be used for remediation.

> Promulgated standards are generic by nature, and use of the MCP Method 1 standards provides very limited site-specific flexibility. *By choosing to use the Method 1 risk characterization approach the risk assessor is implicitly accepting the assumptions identified by MADEP for the development and use of the standards.*

[1] - The risk of harm to *safety* must be evaluated separately, as described in Section 4.0 of this guidance document.

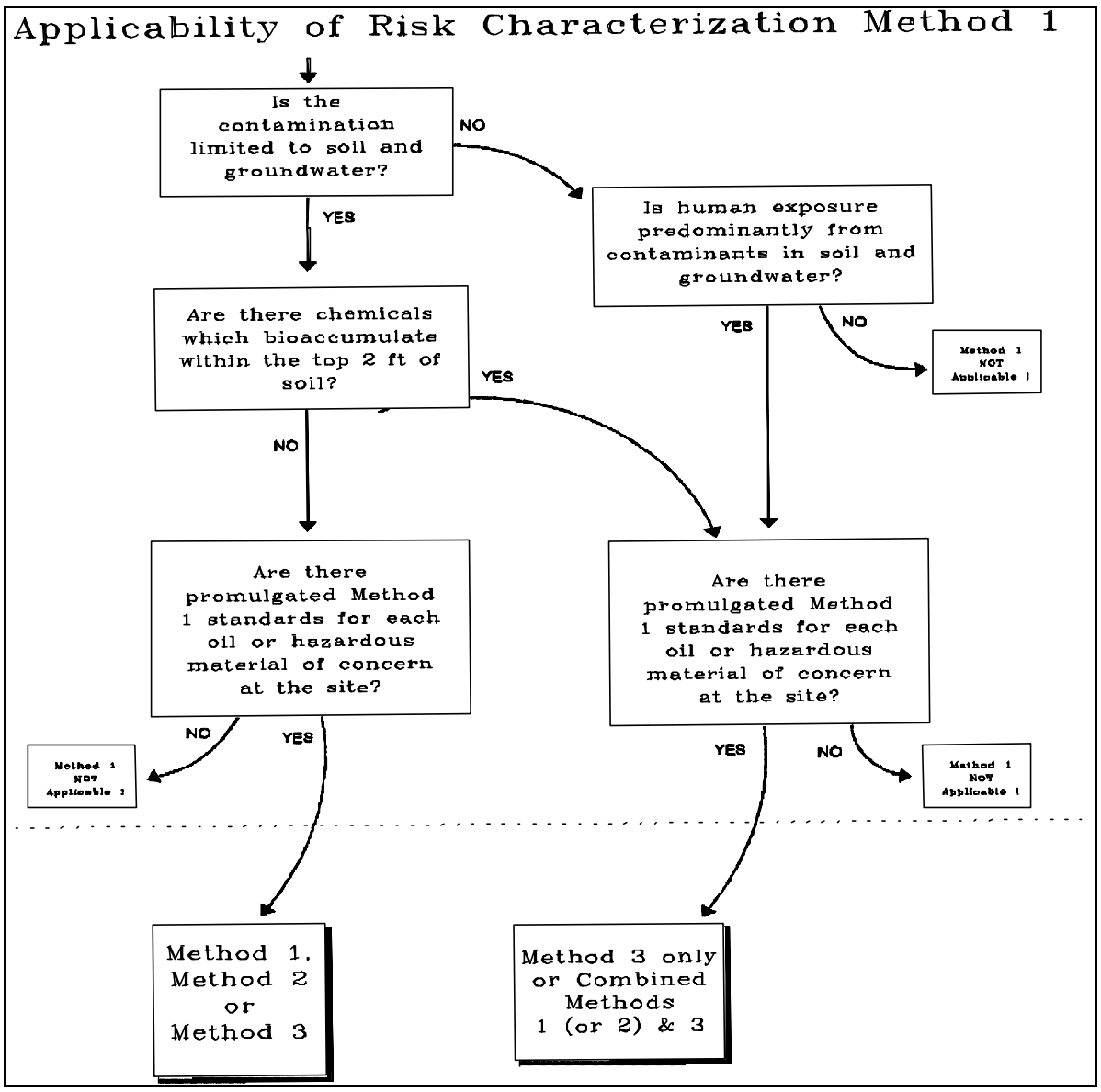

Applicability of Risk Characterization Method 1
Is the contamination limited to soil and groundwater?
NO
YES
Is human exposure predominantly from contaminants in soil and groundwater?
YES
NO
Method 1 NOT Applicable !
Are there chemicals which bioaccumulate within the top 2 ft of soil?
YES
NO
Are there promulgated Method 1 standards for each oil or hazardous material of concern at the site?
NO
YES
Method 1 NOT Applicable !
Are there promulgated Method 1 standards for each oil or hazardous material of concern at the site?
YES
NO
Method 1 NOT Applicable !
Method 1, Method 2 or Method 3
Method 3 only or Combined Methods 1 (or 2) & 3

Figure 5.1

Because of the generic nature of the Method 1 standards, this approach is not available to all sites. Method 1 is also not *required* at sites where it is an available option as the risk assessor may chose to conduct either a Method 2 or Method 3 risk characterization in lieu of Method 1 if he/she believes that the benefits of such a site-specific approach outweigh those described above.

5.1 APPLICABILITY

When determining whether Method 1 can be used to characterize the risk of harm to health, public welfare and the environment, the risk assessor should scrutinize criteria found at 310 CMR 40.0942. It is expected that Method 1 will be an option at the majority of c.21E sites. At certain sites, however, the risk assessor will have to supplement the Method 1 risk characterization with some form of a Method 3 assessment, while at other sites Method 1 will not be an available option. This section describes the circumstances under which Method 1 may or may not be employed. Method 1 is *never* required for particular sites. It is up to the risk assessor to determine the appropriate risk characterization approach from among the methods identified as applicable to the site.

5.2 GENERAL APPROACH

A Method 1 risk characterization always includes the following steps, although the scope and level of effort of the risk characterization will depend upon the complexity of the disposal site and the response action being taken.

- Information gathered as part of the site investigation is used to determine the nature and extent of oil or hazardous material present and the extent of contamination.
- Information gathered as part of the site investigation is used to identify background concentrations and to determine the contaminants of concern for the risk characterization.
- The applicability of Method 1 is affirmed.
- Knowledge about the disposal site and the surrounding area is used to categorize the soil and the groundwater.
- The soil and groundwater categories are used to identify the Method 1 standards which are applicable to the disposal site.
- Chemical concentrations and their spatial distribution are used to identify exposure points (including hot spots) and exposure point concentrations.
- The exposure point concentrations are compared to the applicable Method 1 standards.
- The risk of harm to safety is characterized.

- A conclusion is drawn as to whether a condition of no significant risk of harm to health, safety, public welfare or the environment exists or has been achieved at the disposal site, with or without Activity and Use Limitations.

- Activity and Use Limitations (if necessary) to limit future use of the site are described.

Note that Method 1 represents a streamlined approach to the risk characterization process, *not* to the site assessment process; an adequate knowledge of the site and the contamination present is still necessary to employ this approach. Of course, the resources required for the site assessment will vary from site-to-site, depending upon the nature and complexity of the release under investigation: the scope and level of effort required for the site investigation and the risk characterization will be determined using the professional judgement of the investigator considering site-specific circumstances.

The risk assessor should keep in mind that the Method 1 approach does not evaluate potential Imminent Hazards which may be present at the disposal site. If site conditions suggest that a quantitative Imminent Hazard Evaluation be conducted for the disposal site, the regulations found at 310 CMR 40.0950 and the guidance provided in Section 10.0 of this document must be considered. Such evaluations are *not* routinely required at all disposal sites.

Information concerning the site, nature and extent of contamination, soil and groundwater categories, exposure point concentrations, applicable Method 1 standards and conclusions of the risk characterization must be provided to MADEP in the documentation which supports the risk characterization. The documentation of the risk characterization may be one or more chapters of another submittal to the Department or it may be presented as a separate document.

The remaining sections of this chapter will describe in more detail the general steps outlined above.

5.3 DETERMINING THE NATURE AND EXTENT OF CONTAMINATION

Section 2.2 of this document presents general guidance on determining the nature, extent, distribution and magnitude of contamination at disposal sites for the purpose of risk characterization. The MCP (310 CMR 40.0904) directs the investigator to collect sufficient site and contaminant information to support the risk characterization. Knowledge about the nature and extent of contamination is used to determine whether a Method 1 risk characterization is appropriate for the disposal site, and whether, pursuant to Method 1, the contamination at the site poses No Significant Risk.

At the start of the risk characterization process the investigator should know what chemicals are present, the environmental media in which the chemicals are located, the concentrations of each chemical in each medium and the spatial distribution of the contaminants. In addition, the migration potential of each chemical should be considered to determine the likelihood of the oil or hazardous material spreading within existing contaminated media (e.g., growing plumes of chlorinated hydrocarbons) or being transferred to an environmental medium which is currently unaffected by the site (e.g., future discharge of groundwater to a surface water body). If contaminant concentrations are likely to increase at a current or foreseeable exposure point then the risks associated with those estimated future concentrations must also be characterized. Chemical-specific information which may be relevant to the risk characterization includes the factors listed at 310 CMR 40.0904(3), including environmental fate and transport characteristics, mobility, persistence, volatility and potential for bioaccumulation.

Overall confidence in the assessment and remediation process is directly related to the site characterization: if the investigator fails to analyze a medium likely to be contaminated by the chemicals at the site, if the focus of the evaluation is the source area to the exclusion of contamination which has migrated off the property, or if too few samples were taken (or taken in dubious locations, or analyzed following the wrong methodology) to sufficiently describe the nature and extent of contamination, then conclusions drawn from the risk characterization will be meaningless.

METHOD 1 ASSESSMENTS AT CYANIDE SITES

When cyanide is present in accessible soil at a site, an imminent hazard evaluation of the potential risk from a one-time dose should be done automatically, regardless of which risk assessment method is being used. Of all of the chemicals commonly detected at disposal sites, cyanide is the only one which could pose a significant health risk from a one-time exposure to concentrations that are often found in the environment. Although acute exposures to some other hazardous materials could pose a health risk at some level, the concentrations at which acute exposures are of concern are much higher than levels typically found in the environment.

With cyanide, the risk estimate for a one time exposure may exceed the risks from long term exposures. There are two reasons for this paradox. First, one-time risk estimates are based on the highest concentration detected, while long-term risk estimates and comparisons to Method 1 Standards use average soil concentrations. Second, because cyanide is metabolized and cleared from the body relatively quickly, exposures which occur in a short period of time will have a greater effect than exposure to the same total amount received over a longer period of time - even if the time difference is a matter of hours. The Method 1 Standard for cyanide is the same as the concentration above which a one-time dose could pose a significant risk. Therefore, comparing an average soil concentration to the Method 1 Standard does not protect against potential health risks from a one-time dose.

5.4 IDENTIFICATION OF CONTAMINANTS OF CONCERN (COC)

Once the oil or hazardous material present at the site have been identified for each contaminated environmental medium, the process of selecting the contaminants of concern may proceed. The contaminants of concern are those chemicals which are carried through the risk characterization process. General guidance on the selection of contaminants of concern is provided in Section 2.4 of this document. At some sites there may be a single contaminant of concern, while the list of COCs may be lengthy at others.

The discussion in Section 2.4 identifies three basic criteria used to eliminate a chemical from further consideration in the risk assessment: (1) the chemical is present at a very low frequency of detection and at very low concentration, or (2) the chemical is present at a level consistent with "background", or (3) the chemical is a field or laboratory contaminant. The reader is also referred to the "background" discussion presented in Section 2.3, including the identification of background levels at a site and the comparison of site concentrations to background conditions. The process of identifying contaminants of concern is the same for Method 1 as for a site-specific risk assessment.

5.5 AFFIRMATION OF METHOD 1 APPLICABILITY

The risk characterization report should demonstrate that the use of Method 1 to characterize risk at the site is appropriate (310 CMR 40.0971(4)). The Department understands that there is a bias towards the use of Method 1 due to its simplicity and ease of use which could result in the use of Method 1 standards to situations where they do not apply. By requiring that the method selection process be documented in the risk characterization report, the regulations compel the risk assessor (and/or LSP) to think through the applicability criteria at every site. Section 5.1 of this document reviews the applicability of Method 1 at c.21E disposal sites.

5.6 SOIL AND GROUNDWATER CATEGORIZATION

General guidance on the categorization of soil and groundwater is provided in Section 2.1.5 of this document, and the regulations pertinent to categorization are found in the MCP at 310 CMR 40.0930. The current and foreseeable use of the soil and groundwater determine the categories (S-1, S-2 and/or S-3 for soil, GW-1, GW-2 and/or GW-3 for groundwater) which apply at the site.

Soil is categorized based upon its accessibility (depth), the age of potential receptors (child or adult) at the site, the frequency at which the receptors visit the location and the nature (intensity) of the activities that occur at the location. These factors allow the soil to be described as having high, medium or low exposure potential: the soil categories represent an exposure gradient, where accessibility, the presence of children, frequent use and intense activity indicate a higher exposure potential, while soil at depth, limitations on access for children, infrequent and passive use all indicate lower potential for exposure. Often the use of properties in the surrounding area (e.g., adjacent land) may give an indication of potential

exposures on the property under investigation, and thus they should also be considered (e.g., a property located next to an elementary school is likely to be routinely visited by school-age children. Due to the various factors which go into the categorization of soil, it will be common to find more than one soil category present at the site: the surficial soil may be considered S-1, for example, while the soil located more than three feet below the surface could be S-2. A property supporting multiple uses (a light manufacturing facility with an in-house day care center, for example) could have the surficial soil categorized as S-1 in the area of the day care while the surficial soil in other areas may be S-3. [It should be obvious, however, that a specific area cannot be in two soil categories at the same time.]

Groundwater is categorized based upon its current and/or future use as drinking water (GW-1), its potential to act as a source of volatile material to indoor air (GW-2), and its potential to discharge material to surface water (GW-3). Groundwater may be, at the same time, GW-1, GW-2 and GW-3 as these exposures are not mutually exclusive. In fact, *all* groundwater is categorized as GW-3. The groundwater at the site may also be GW-2 and/or GW-1, depending upon site-specific factors. Thus, the potential combinations of groundwater categories are:

- GW-3 only,
- GW-1 and GW-3,
- GW-2 and GW-3, or
- GW-1 and GW-2 and GW-3.

It is not possible for groundwater to be GW-1 alone or GW-2 alone.

One additional factor to consider when evaluating groundwater is the potential migration of the contaminated water into an area with a different groundwater category.

Note that both the current and future use of the land and groundwater must be considered in the categorization process. Thus, in categorizing soil as S-2 or S-3, it is implied that the potential future exposures to that soil are restricted in some manner (by depth to the soil, access to the site, etc.). Under Method 1 only S-1 soils can be described as "unrestricted" for any use. For groundwater, the consideration of the future use of the groundwater as a drinking water source (GW-1) and as a future source of discharge to surface water (GW-3) are built into the categorization criteria. It is only for the GW-2 category that future changes in the use of the property could effect the groundwater category (i.e., constructing a building where there is presently no structure.)

All soil and groundwater must be categorized. There is no soil or groundwater which does not fit into one of the established categories.

5.7 IDENTIFICATION OF APPLICABLE METHOD 1 SOIL AND GROUNDWATER STANDARDS

The categorization process summarized above is the basis for selecting the applicable soil and groundwater standards under Method 1. The regulations pertinent to the applicability of those standards are found at 310 CMR 40.0974 and 310 CMR 40.0975, for groundwater and soil, respectively.

The Department has published (MADEP, 1994) a detailed description of the development of the MCP Method 1 Standards.

The documentation which supports the risk characterization should include a list of the MCP Method 1 groundwater and soil standards determined to be applicable for the site (310 CMR 40.0973(5).

5.7.1 Groundwater

The Method 1 groundwater standards are listed at 310 CMR 40.0974(2), in Table 1 of Subpart I. A portion of that table is presented as Figure 5-2 for illustration purposes. The table of groundwater standards consists of five columns:

- the name of the oil or hazardous material,
- the CAS number of the oil or hazardous material,
- the GW-1 standard for the oil or hazardous material,
- the GW-2 standard for the oil or hazardous material, and
- the GW-3 standard for the oil or hazardous material.

As previously described, more than one groundwater category can apply to the groundwater at a site, and *all* groundwater is considered to be GW-3. Thus the standards listed in the last column (GW-3 Standard) of Table 1 (Figure 5-2) apply to the groundwater at all sites. In addition, the standards listed in column three (GW-1 Standard) and column four (GW-2 Standard) may also be applicable, depending upon site-specific factors. In the case when more than one category applies, for example, if the groundwater at a site is GW-1, GW-2 and GW-3, then *all* the applicable standards must be considered, and the lowest applicable value would drive the risk characterization.

It is *not* true that GW-1 standards are always the lowest groundwater standards.

Because the groundwater categories look at markedly different exposure routes, any of the three categories may be the most sensitive, depending upon the chemical. In general, GW-3 is the most stringent category for pesticides and some metals, while the GW-2 standards may be lowest for some halogenated volatile chemicals.

FIGURE 5-2

310 CMR 40.0974(2)

TABLE 1

MCP Method 1 GROUNDWATER STANDARDS APPLICABLE IN AREAS WHERE THE GROUNDWATER IS CONSIDERED TO BE ONE OR MORE OF THE FOLLOWING CATEGORIES PER 310 CMR 40.0932

Oil and/or hazardous Material	CAS Number	GW-1 Standard µg/liter (ppb)	GW-2 Standard µg/liter (ppb)	GW-3 Standard µg/liter (ppb)
ACENAPHTHENE	83329	20	NA	2,000
ACENAPHTHYLENE	208968	300	NA	2,000
ACETONE	67641	3,000	50,000	50,000
ALDRIN	309002	0.5	0.5	9
ANTHRACENE	120127	600	NA	600

This table is presented as an example of the *format* in the regulations. Consult the actual table in the regulations for current standards.

5.7.2. Soil

The Method 1 soil standards are listed at 310 CMR 40.0975(6) in the MCP. The soil standards are organized in three tables (Subpart I Tables 2, 3 and 4), and a portion of each is presented for illustration purposes in Figures 5-3, 5-4 and 5-5, respectively. Each table is specific to a single soil category: Table 2 contains all the MCP Method 1 Category S-1 standards, Table 3 contains all the Method 1 Category S-2 standards, and Table 4 contains all the Method 1 Category S-3 standards. Each table is made up of 5 columns:

- the name of the oil or hazardous material,
- the CAS number of the oil or hazardous material,
- the soil standard for soil overlying a GW-1 aquifer,
- the soil standard for soil overlying a GW-2 aquifer,
- the soil standard for soil overlying a GW-3 aquifer.

Figure 5-3

310 CMR 40.0975(6)(a)

TABLE 2

MCP Method 1: SOIL CATEGORY S-1 STANDARDS

APPLICABLE TO SOIL WHERE THE COMBINATION OF SOIL & GROUNDWATER CATEGORIES ARE:

Oil and/or hazardous Material	CAS Number	S-1 SOIL & GW-1 µg/g (ppm)	S-1 SOIL & GW-2 µg/g (ppm)	S-1 SOIL & GW-3 µg/g (ppm)
ACENAPHTHENE	83329	20	1,000	1,000
ACENAPHTHYLENE	208968	100	100	100
ACETONE	67641	3	60	60
ALDRIN	309002	0.03	0.03	0.03
ANTHRACENE	120127	1,000	1,000	1,000

This table is presented as an example of the *format* in the regulations. Consult the actual table in the regulations for current standards.

The soil standards were derived in consideration of potential direct contact exposures (incidental soil ingestion and dermal contact) and considering the potential for the oil or hazardous material to leach from the soil and contaminate the underlying groundwater. Thus the allowable level of a chemical in soil depends, in part, upon the allowable level of the chemical in the groundwater. If the groundwater at the site is determined to be in more than one groundwater category (e.g., both GW-2 and GW-3) then more than one soil standard will apply (e.g., both S-1/GW-2 and S-1/GW-3) and the lowest of the applicable standards will drive the risk characterization.

Figure 5-4

310 CMR 40.0975(6)(b)

TABLE 3

MCP Method 1: SOIL CATEGORY S-2 STANDARDS

APPLICABLE TO SOIL WHERE THE COMBINATION OF SOIL & GROUNDWATER CATEGORIES ARE:

Oil and/or hazardous Material	CAS Number	S-2 SOIL & GW-1 µg/g (ppm)	S-2 SOIL & GW-2 µg/g (ppm)	S-2 SOIL & GW-3 µg/g (ppm)
ACENAPHTHENE	83329	20	2,500	2,000
ACENAPHTHYLENE	208968	100	2,500	800
ACETONE	67641	3	60	60
ALDRIN	309002	0.04	0.04	0.04
ANTHRACENE	120127	1,000	2,500	1,000

This table is presented as an example of the *format* in the regulations. Consult the actual table in the regulations for current standards.

Figure 5-5

310 CMR 40.0975(6)(c)

TABLE 4

MCP Method 1: SOIL CATEGORY S-3 STANDARDS

APPLICABLE TO SOIL WHERE THE COMBINATION OF SOIL & GROUNDWATER CATEGORIES ARE:

Oil and/or hazardous Material	CAS Number	S-3 SOIL & GW-1 µg/g (ppm)	S-3 SOIL & GW-2 µg/g (ppm)	S-3 SOIL & GW-3 µg/g (ppm)
ACENAPHTHENE	83329	20	5,000	2,000
ACENAPHTHYLENE	208968	100	2,500	800
ACETONE	67641	3	60	60
ALDRIN	309002	0.1	0.1	0.1
ANTHRACENE	120127	1,000	5,000	1,000

This table is presented as an example of the *format* in the regulations. Consult the actual table in the regulations for current standards.

Interestingly, the leaching-to-groundwater pathway is often more sensitive (produces a lower allowable soil concentration) than the direct contact exposure pathway. As a result, many of the standards for S-1, S-2 and S-3 soil overlying a particular groundwater category

will be the same value: for example the S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards for acetone in the tables above are all 3 µg/g. Thus, while one would expect the allowable acetone soil concentration to increase as the soil category increases (S-1 soil to S-3 soil, or high to low exposure potential), this does not occur.

5.8 IDENTIFICATION OF EXPOSURE POINTS AND EXPOSURE POINT CONCENTRATIONS (Including Hot Spots)

The regulations which address the identification of exposure points and the development of exposure point concentrations for Method 1 risk characterizations are found at 310 CMR 40.0973(3) and (4). More general discussion of these terms appears at 310 CMR 40.0924 and 40.0926.

5.8.1. Groundwater

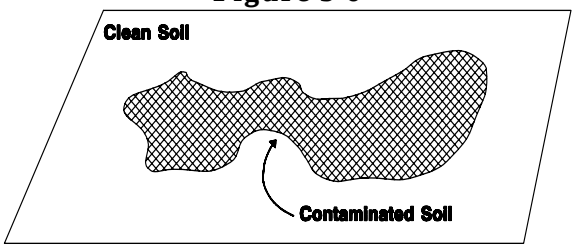
For groundwater, the MCP defines the exposure point to be used for a Method 1 risk characterization as "*...the wellhead and/or nearest tap of a well screened within the horizontal and vertical distribution of the oil or hazardous material in the groundwater. Existing water supply wells and monitoring wells shall be considered current or potential Exposure Points...*" (310 CMR 40.0973(3)(a)). Thus each well located within the contaminated area is considered either a current or future exposure point.

The exposure point concentrations for groundwater are thus easily identified as the concentrations reported from each water supply or monitoring well, as described in 310 CMR 40.0973(4)(b). Limited averaging over time of these reported concentrations would be consistent with the statement at 310 CMR 40.0926 that exposure point concentrations shall be arithmetic averages providing a conservative estimate of the concentration at the exposure point, although averaging of data across wells (across exposure points) is not acceptable for Method 1. The quality of data collected in the past and trends in the data should be assessed to determine whether a temporal average is appropriate to yield a *conservative* estimate. There are, of course, situations when the maximum concentration reported (or an upper percentile) is appropriate, including the evaluation of acute exposures, the evaluation of chemicals associated with lethal or severe health effects, evaluations performed with insufficient data, or conservative screening assessments.

5.8.2 Soil

In the MCP the exposure points for soil are defined by "*the vertical and horizontal distribution of the material in soil in combination with the soil category(ies) determined to be applicable*" (310 CMR 40.0973(3)(b)). Thus, in order to identify the soil exposure points for a Method 1 risk characterization the investigator must know the extent of contamination and how the soil would be categorized at the site. Figures 5-5 through 5-10 describe situations which may arise when identifying soil exposure points.

Figure 5-6



The Exposure Point Would Include Only The Contaminated Soil

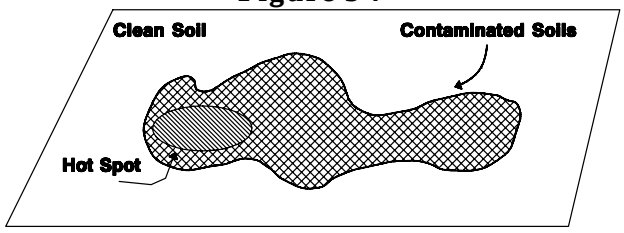
First, Method 1 soil Exposure Points encompass only continuous areas of contaminated soil and do not include clean soil. Thus, the boundary of an Exposure Point is no larger than the extent of the soil contamination at the site. Figure 5-6 illustrates that only the area of contamination would be considered the soil Exposure Point.

Second, hot spots are specifically identified (310 CMR 40.0924(2)) as distinct exposure points. The identification of a "*hot spot*" is discussed in more detail in Section 2.2.3 of this document, but is defined within the MCP as a discrete area with substantially higher contamination relative to the surrounding area. Thus, if a hot spot exists with a larger area of contamination, there would be at least two Exposure Points identified: the hot spot and the area of more generalized contamination. Figure 5-7 illustrates a hot spot as a distinct exposure point.

Third, if the area of contaminated soil is not contiguous, then the discrete areas of contaminated soil which exist at the site are treated as a separate Exposure Point. Figure 5-8 illustrates this point.

Finally, if the boundary of a soil category bisects the contaminated area, then the soil which falls within each soil category is treated as separate Exposure Points. Figure 5-9 Illustrates how this may occur.

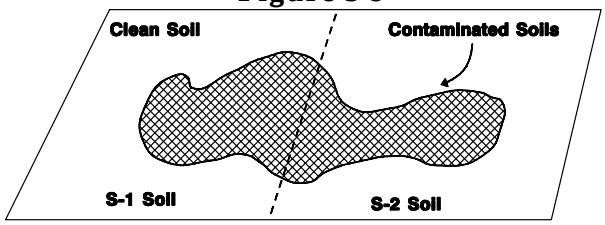
Figure 5-7



A Hot Spot Within An Area Of Contaminated Soil Is Treated As A Distinct Exposure Point

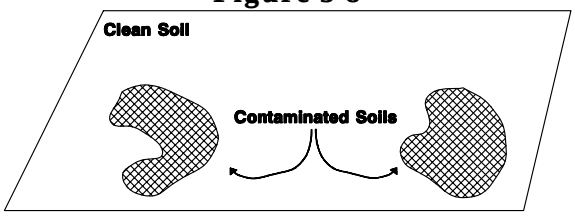
It is also important to remember that the exposure points exist in three dimensions. Figures 5-6 through 5-9 present exposure points in two dimensions for clarity, but there is a depth component as well, which is why the term "*volume*" is used in the MCP in the discussion of Method 1 exposure points (310 CMR 40.0973(3)(b)). Thus, a volume of contaminated soil five feet below ground would be considered a Method 1 Exposure Point, and that Exposure Point would not include the uncontaminated soil on the surface (See Figure 5-10). Multiple soil categories, hot spots and disconnected contamination would be considered in the same manner in three dimensions as they were described above.

Figure 5-9



A Contiguous Volume Of Contaminated Soil Which Spans Two Soil Categories Is Treated As Two Distinct Exposure Points

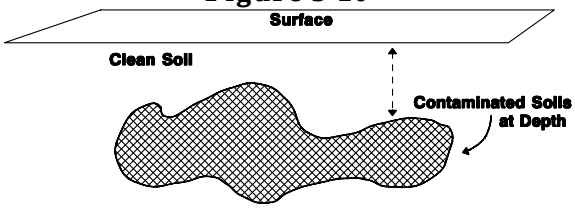
Figure 5-8



Two Areas of Contaminated Soil Would Be Treated As Two Separate Exposure Points

Soil at depth is considered an Exposure Point under Method 1 due to the potential for future excavation and contact. Since such potential future exposures are part of the basic premise of Method 1 (310 CMR 40.0972), the risk assessor cannot eliminate this exposure pathway (determine that such exposure would never occur, and that the soil at depth does not constitute an Exposure Point) when using Method 1 to characterize risk, although such site-specific risk assessment may be appropriate under a Method 3 assessment.

Figure 5-10



A Volume of Soil Below the Surface Is Also Considered a Method 1 Exposure Point

The exposure point concentrations for soil are representative concentrations for the oil or hazardous material within each exposure point. Typically the Exposure Point Concentration would be the arithmetic average of the contaminant concentration, although consideration should be given to using the maximum concentration reported or an upper percentile of the range of concentrations reported when the site data may not be adequate, when evaluating acute exposures, when evaluating chemicals associated with lethal or severe health effects or when performing screening assessments (310 CMR 40.0926(3)). Since the Method 1 exposure point is defined such that it excludes uncontaminated soil, analytical results from "clean" areas of the site should not be incorporated into the exposure point concentration.

5.9 CHARACTERIZING RISK UNDER METHOD 1

Having identified the Method 1 standards applicable to the site (Section 5.7) and the site Exposure Points and Exposure Point Concentrations (Section 5.8), the risk characterization is simply the comparison of the exposure point concentrations to the applicable Method 1 standards. As described in the MCP (310 CMR 40.0973(7)), "*a condition of no significant risk of harm to health, public welfare or the environment exists if no Exposure Point Concentration is greater than the applicable MCP Method 1 Soil or Groundwater Standard*". The report which documents the risk characterization should include tables ordered by environmental medium and exposure point comparing the exposure point concentrations to the applicable MCP Method 1 standards. An example of such a table is presented in Figure 5-11.

5.9.1 Characterizing Risks Using TPH Data

Using the Method 1 Standard for Total Petroleum Hydrocarbon

Total Petroleum Hydrocarbon, or TPH, is one of the one hundred and seven chemicals (or groups of chemicals) for which MADEP has developed Method 1 Standards. TPH is a loosely defined parameter which provides an estimate of the total concentration of petroleum hydrocarbons in a sample. MADEP receives many questions from risk assessors and site managers regarding appropriate use of the Method 1 TPH Standard. This section is written to provide additional guidance on using the Method 1 Standard to evaluate releases of petroleum hydrocarbons.

What is the meaning of the footnote associated with the Method 1 TPH Standard?

The Method 1 Standards for TPH (contained in Tables 1-5 of Subpart I in the MCP) are marked with a footnote which reads:

> Total Petroleum Hydrocarbon as measured using standard analytical methods or methods which provide toxicity-weighted concentrations, such as the MADEP TPH approach. This standard does <u>not</u> address and is <u>not</u> sufficient to evaluate specific chemicals which may be present in some petroleum products and which have promulgated MCP standards (such as benzene, toluene, ethylbenzene, xylenes and polycyclic aromatic hydrocarbons (PAHs).

The Department has promulgated Method 1 standards for TPH to make it possible to more easily address, in a quantitative manner, the bulk of compounds in petroleum products which are difficult to identify and evaluate and which in the past, were largely ignored in risk assessments. In deciding to develop a TPH standard, the Department recognized that there are difficulties associated with quantitatively evaluating the many chemicals present in petroleum products. The Department also recognized that there are risks associated with exposure to these compounds and they should not be ignored in the risk assessment. Thus, the TPH standard was developed to allow evaluation of the mass of compounds in petroleum products which typical analytical methods cannot quantify and for which good toxicity information does not exist.

Contrary to what its name suggests, the Method 1 TPH standard was developed without considering all of the compounds that may be present in petroleum products. In other words, the Method 1 TPH Standard is not, by itself, sufficient to evaluate the total number of compounds which may be present in a petroleum product. The TPH standard does not address and is not sufficient to evaluate all of the compounds which may be present in a petroleum product because in developing the TPH standard, the Department intentionally did not consider the toxicity of a number of compounds which are often present in petroleum products. Specifically, the TPH standard does not incorporate common constituents of TPH which can be identified and quantified easily and constituents for which good toxicity information exists. In addition, the Department did not include additives that may be present in some petroleum products. Examples of compounds which are commonly present in petroleum products whose toxicities were not considered in developing the TPH standard are provided in the accompanying box. It should be clear that since the toxicity of these compounds was not considered in developing the TPH standard, these compounds must be evaluated separately from TPH in the risk assessment. In other words, comparison of site levels of TPH with the Method 1 standard for TPH does not eliminate the need to compare concentrations of other petroleum product constituents with their respective Method 1 standards.

EXAMPLES OF COMPOUNDS NOT COVERED BY THE TPH STANDARD

Benzene
Toluene
Ethylbenzene
MTBE
Xylenes
Polycyclic Aromatic Hydrocarbons

I want to be able to use the TPH standard, what analytical method(s) should I use to investigate the site?

The MCP does not recommend specific analytical methods to be used for TPH (or for any other oil or hazardous material). Rather, the MCP relies on the use of professional judgement in selecting the analytical method most appropriate for a specific purpose. The first step is to determine the petroleum product(s) which may have been released at the site. MADEP recognizes that is often difficult, especially when the release occurred in the past. The site manager should use available historical records, site observations, screening analyses, and any other relevant information in combination with professional judgement to identify the petroleum product(s) which may have been released at a site. Once the likely petroleum product(s) have been identified, the site manager can then select appropriate analytical methods.

It should be stressed that if one wants to use the Method 1 TPH standard, one will likely need more than just a TPH analysis to evaluate the petroleum hydrocarbons. Selecting an analytical method and selecting petroleum hydrocarbon compounds to analyze for should be done considering type of petroleum product that was released. If the site manager suspects that the petroleum product contained benzene, toluene, ethylbenzene, xylenes

(BTEX) or PAHs, such compounds must be specifically analyzed for. For example, if the release of interest is gasoline from an old underground storage tank, the analyses should certainly include BTEX and TPH. The site manager should also consider analyzing for gasoline additives such as lead and MTBE. Site managers should refer to the MADEP *Policy for the Investigation, Assessment, and Remediation of Petroleum Releases* (1991) and the MADEP *Interim Final Petroleum Report: Development of Health-Based Alternative to the TPH Parameter* (1994) for information which may be helpful in identifying the chemicals which are may be associated with various petroleum products.

When is development of a Method 2 standard needed?

MADEP receives many questions regarding whether it is necessary to develop Method 2 Standards for specific petroleum hydrocarbons that a laboratory may report along with the TPH results. When performing TPH analyses, many laboratories also identify and quantify chemicals such as trimethylbenzenes, trichloropropane, 4-isopropyltoluene and isopropyl benzene. MADEP receives many questions regarding whether it is necessary to develop Method 2 standards for such chemicals or whether it is appropriate to simply compare site concentrations of TPH with the TPH standard. It is MADEP's view that if the mass of a chemical reported by a laboratory is included in the mass being reported in the TPH value, then the TPH standard is applicable and a separate Method 2 standard need not be developed.

However, recall that concentrations of BTEX and PAHs must be compared with their respective Method 1 standards, regardless of whether their mass is included in the mass being reported in the TPH analysis. This is because the toxicities of BTEX and PAHs were not considered by MADEP in the development of the TPH standard.

If I have only TPH results, is that enough?

In general, TPH alone will often not provide sufficient information to evaluate risks from petroleum hydrocarbons. Depending on the type of petroleum product released, it may be necessary to analyze for the additional constituents whose toxicities were not considered in developing the Method 1 Standard for TPH (i.e. BTEX and PAHs).

5.10 CHARACTERIZING SAFETY RISKS

The Method 1 risk characterization process does not specifically look at potential safety risks posed by the site, as safety is a concept which is difficult to distill down to a set of generic standards. As a result, the MCP requires that the risk of harm to safety be evaluated separately at all disposal sites: the same safety evaluation will occur whether a Method 1, Method 2 or Method 3 risk characterization is being performed. Section 4.0 of this guidance document discusses the MCP requirements (310 CMR 40.0960) for the evaluation of safety concerns. The characterization of site safety risk would be included as part of the overall documentation of the risk characterization.

5.11 DRAWING CONCLUSIONS FROM A METHOD 1 RISK CHARACTERIZATION

The overall purpose of the risk characterization is to determine whether or not the site poses no significant risk of harm to health, safety, public welfare or the environment, and a clear statement of the results is required (310 CMR 40.0973(8)) in the documentation of the Method 1 risk characterization.

Sites where all exposure point concentrations fall below the applicable Method 1 standards (and where there is no risk to safety) require no further remedial response action to achieve a condition of No Significant Risk, and those sites may be eligible for a Class A or Class B Response Action Outcome (RAO) pursuant to Subpart J of the MCP. It is important to remember that achieving a condition of No Significant Risk is not the only requirement for an RAO: the regulations apropos Response Action Outcomes contain additional requirements for the elimination of continuing sources of oil or hazardous material (310 CMR 40.1003(5)), for implementing Activity and Use Limitations (310 CMR 40.1012) and for achieving background conditions (310 CMR 40.1020). The No Significant Risk standard should be thought of a *minimum* requirement, but it is not the only requirement governing site cleanup.

Figure 5-11

COMPARISON TO APPLICABLE MCP METHOD 1 SOIL STANDARDS

EXPOSURE POINT	Oil or Hazardous Material	Exposure Point Concentration mg/kg	MCP Method 1 Soil Category and Applicable Standard: Soil Category(ies)	Standard mg/kg	Check if Standard Exceeded
#1 - Surface soil in yard at 10 Downing Street (see attached map)	Acenaphthene	50	S-1/GW-1 S-1/GW-3	20 1,000	✔
	Acetone	0.5	S-1 GW-1 S-1 GW-3	3 60	
	Aldrin	10	S-1/GW-1 S-1/GW-3	0.03 0.03	✔ ✔
#2 - Soil from 4' to 10', beneath pavement at 10 Downing Street (See attached map)	Acenaphthene	10	S-2/GW-1 S-2/GW-3	20 2,000	
	Acetone	ND	S-2/GW-1 S-2/GW-3	3 60	
	Aldrin	0.02	S-2/GW-1 S-2/GW-3	0.04 0.04	

COMPARISON TO APPLICABLE MCP METHOD 1 GROUNDWATER STANDARDS

Exposure Point	Oil or Hazardous Material	Exposure Point Concentration µg/L	MCP Method 1 Groundwater Category and Applicable Standard: Groundwater Category(ies)	Standard µg/L	Check if Standard Exceeded
#1 - Private drinking water well at 10 Downing Street	Acenaphthene	35	GW-1 GW-3	20 2,000	✔
	Acetone	700	GW-1 GW-3	3,000 50,000	
	Aldrin	10	GW-1 GW-3	0.5 9	✔ ✔
#2 - Monitoring Well at downgradient property line at 10 Downing Street	Acenaphthene	10	GW-1 GW-3	20 2,000	
	Acetone	150	GW-1 GW-3	3,000 50,000	
	Aldrin	ND	GW-1	0.5	

One important aspect of the MCP is that a distinction is made between *current* use, exposure and risk and *future* use, exposure and risk. One possible outcome of a Method 1 risk characterization is a demonstration that a condition of No Significant Risk has been achieved for current (but not future) conditions. A Class C Response Action Outcome is possible for such sites, as a demonstration that all substantial hazards have been eliminated (310 CMR 40.1050) is sufficient.

If one or more Exposure Point Concentrations exceed an applicable Method 1 standard, then a condition of No Significant Risk has not been achieved, and further response actions are required, although implementing a remedial response action is not the only course of action available. A more site-specific risk characterization approach (Method 2 or Method 3) may be employed to evaluate the site. For some sites where a Method 1 risk characterization has indicated that a condition of No Significant Risk has not been achieved, the site-specific approach might demonstrate that, in fact, a level of No Significant Risk does exist. (Of course the more detailed evaluation could also reach the same conclusions as the Method 1 assessment, but at significantly greater cost.) Guidance for conducting such risk characterization methods is contained in this document. Another option available is to conduct a remedial response action designed to reduce the concentrations of oil or hazardous material to levels below the Method 1 standards. A third approach would be to restrict future site use to those activities which would be consistent with a level of No Significant Risk. Under Method 1, the changes in site activities would have to be sufficient to change the soil or groundwater category and thus the applicable standards. Such limitation on site use would also require the application of Activity and Use Limitations (AULs). The response action chosen for a site may also be a combination of the options described above, as long as the result of the combined efforts is a site which poses no significant risk of harm to health, safety, public welfare and the environment.

5.12 ACTIVITY AND USE LIMITATIONS

The MCP requires the application of Activity and Use Limitations (AULs) whenever it is assumed that the future use of the property is not unrestricted. The AULs are used to inform future owners of the property of residual contamination and of potential uses of the property which could be inconsistent with the Response Action Outcome achieved for the site.

AULs are specifically not required at sites where the exposure point concentrations meet the soil category S-1 standards (310 CMR 40.0923(3)(b)2) or where the levels of oil or hazardous material are consistent with background. Such conditions are considered consistent with a level of No significant Risk for any use of a property.

Activity and Use Limitations are required whenever the condition of No Significant Risk has been achieved through implicit or explicit assumptions that the use of the property is such that exposure to the contaminated soil or groundwater is limited. For example, if the soil is categorized as S-2 because there is currently asphalt paving which prevents contact with the

soil, then there is an implicit assumption that the asphalt covering will be maintained into the future. If soil is categorized as S-3 due to its depth (greater than 15 feet), then there is an implicit assumption that no excavation will take place on the property which will disturb those soils. If groundwater is not categorized as GW-2 because the land is currently vacant, there is an implicit assumption that no building will be constructed on the site which would result in reclassification of the groundwater. Such land use decisions may also be explicitly a part of a comprehensive remedial response action designed to eliminate or minimize potential exposures. All of these land use decisions must be conveyed to future owners of the property through Activity and Use Limitations. The regulations specific to AULs may be found in the MCP at 310 CMR 40.1012 and 40.1070.

Note that soils which are categorized as S-2 or S-3 based upon the current use of the property but which meet the S-1 standards for all the oil or hazardous material present do not require AULs as that property would be acceptable for unrestricted use.

The documentation which supports the risk characterization must clearly state the nature of the land or groundwater use restrictions which are incorporated into the risk characterization and describe the Activity and Use Limitations. The risk characterization results are not considered to be final until the all required Activity and Use Limitations are in place.

5.13 UNCERTAINTY ANALYSIS

The documentation of the Method 1 risk characterization should contain a discussion of the possible sources of uncertainty present in the site assessment and risk characterization process which could have an affect on the conclusions of the assessment. To the extent that it is known, the uncertainty discussion should describe whether the uncertainty is due to an incomplete knowledge of the site (e.g., the e.g., composite soil samples could mask the presence of a hot spot), incomplete data from the scientific literature or other information source (e.g., the GW-1 designation for a site may be based upon an Interim Wellhead Protection Area rather than a mapped Zone II, so the true impact on the public water supply well is unknown) or from the effects of natural, unquantified variability (e.g., natural fluctuation of the water table could result in a different depth to groundwater). The discussion should also indicate whether or not the uncertainty has a biased impact on the risk characterization results and, if possible, the magnitude of the effect.

6.0 METHOD 2 MODIFICATIONS

The Massachusetts Contingency Plan (MCP) describes three different methods for characterizing risk of harm to public health, public welfare and the environment at a disposal site. This chapter provides guidance on conducting a **Method 2** Risk Characterization per 310 CMR 40.0980.

As described in Section 5.0 of this document, risk characterization Method 1 relies upon the use of promulgated, generic numerical standards for chemicals in groundwater and soil to characterize potential risk. The Method 1 Standards were developed by the Department using relatively conservative (health-protective) exposure assumptions to describe potential exposures which could occur to soil and groundwater. These defined sets of such assumptions (or "*exposure scenarios*") are considered to be conservative estimates of potential exposures at most sites. The details of the development of the Method 1 Standards are described in the *Background Documentation for the Development of the MCP Numerical Standards* (April 1994).

As described in Section 7.0 of this document, a Method 3 risk characterization employs site-specific exposure assumptions to characterize potential risks posed by contamination at a disposal site.

Thus, Method 1 and Method 3 represent the extremes on the generic/site-specific continuum.

Risk characterization Method 2 is a mixture of those two methods. Method 2 allows for *limited* modification of the generic Method 1 standards based upon site-specific information. The Method 2 approach provides some flexibility over the strict use of Method 1 Standards, but since the modifications allowed under Method 2 are focused on certain aspects of the standards, Method 2 results are not as site-specific as those obtained using Method 3. The Method 2 approach can be used to either supplement and/or modify the Method 1 standards in the following ways:

- Method 2 can be used to fill in data gaps by creating a Method 1 Standard where one does not presently exist. Method 1 standards were developed for 107 chemicals or groups of chemicals commonly reported at c.21E disposal sites. It is inevitable that many sites will have chemicals in the soil and groundwater for which Method 1 standards were not promulgated. Method 2 may be used to generate standards which are the equivalent of the MCP Method 1 values.

- Method 2 can also be used to incorporate site-specific *fate and transport* information to modify the existing Method 1 Standard. The Method 1 standards consider the potential for chemicals to leach from the soil to groundwater, the potential for chemicals in groundwater to migrate to indoor air, and the potential for chemicals to discharge from the groundwater to surface water. These migration pathways may be examined under Method 2 using site-specific measurements and/or models to identify site-specific cleanup goals.

Note that the risk assessor may both develop a new standard for a chemical lacking a Method 1 standard ***and*** adjust the fate and transport aspects of that new standard to address site-specific conditions.

Whether the Method 2 standards are created *de novo* or represent modifications of existing Method 1 values, the process of risk characterization under Method 2 is similar to that of Method 1: site Exposure Point Concentrations are compared to the identified standards. If the site concentrations are equal to or less than the Method 2 standards then the risk assessor may conclude that a condition of No Significant Risk of harm to public health, welfare and the environment exists or has been achieved.

6.1 APPLICABILITY OF METHOD 2

The applicability of Method 2 is similar to that of Method 1, as noted at 310 CMR 40.0942(2), as both approaches rely upon the use of chemical-specific standards in soil and groundwater. The reader is referred to Sections 5.1 and 3.3 of this document which describe the applicability of Method 1 and the restrictions on the use of Method 2, respectively.

When determining whether Method 2 can be used to characterize the risk of harm to public health, welfare and the environment, the risk assessor should scrutinize both the inclusive and the exclusive criteria found at 310 CMR 40.0942. At certain sites the risk assessor will use a combination of Method 1 standards and standards derived using Method 2, at some sites the risk assessor may have to supplement the Method 2 risk characterization with some form of a Method 3 assessment, while at other sites Method 2 will not be an available option. The documentation of the risk characterization should affirm and document the applicability of Method 2 to the disposal site.

A Method 2 Risk Characterization should always be conducted in combination with a separate characterization of the risk of harm to safety posed by the contaminant conditions, as described in the MCP at 310 CMR 40.0960.

The detailed discussion in Section 5.0 of soil and groundwater categorization, identification of exposure points, determination of exposure point concentrations, and risk characterization apply to Method 2 as well as Method 1, and will not be repeated in this section. The remainder of this section focuses on the differences between Method 1 and Method 2, which are related to the derivation and values of the standards used to characterize risk.

6.2 DERIVATION OF ADDITIONAL METHOD 1 STANDARDS

Method 1 Standards have been developed by MADEP for one hundred and six chemicals or groups of chemicals. These chemicals were targeted as being those most commonly encountered at disposal sites. When other chemicals are encountered at a disposal site, which are not included in this group, standards may be developed using Method 2. The procedures to be followed in developing groundwater standards are described in the MCP at 310 CMR 40.0983 (for groundwater) and 40.0984 (for soil).

The process and equations described under Method 2 mirror the methodology used to develop the MCP Method 1 standards in order that the numbers generated by the risk assessor in Method 2 be consistent and comparable to those developed by MADEP. In other words, the goal of this Method 2 approach is to develop a standard identical to what the Department would have derived if it had chosen to develop standards for that chemical. The *Background Documentation for the Development of the MCP Numerical Standards* (April 1994) provides additional detail and discussion of the methodology for developing groundwater and soil standards (Sections 4.0 and 5.0, respectively, in that document).

Note that the equations and exposure assumptions to be used in deriving additional standards under Method 2 are contained in promulgated regulations (310 CMR 40.0983 and 310 CMR 40.0984) and cannot be changed by the risk assessor.

When additional standards are developed by the risk assessor under Method 2 each step taken should be clearly identified and described. All sources utilized for the development of the standard should be referenced.

6.3 MODIFICATION OF EXISTING METHOD 1 STANDARDS

In developing the Method 1 soil and groundwater standards, MADEP made many health-protective assumptions about potential exposures and the movement of contaminants to ensure that the standards represent a level of No Significant Risk at virtually all disposal sites to which they are applicable. For any given disposal site, however, investigations may reveal

that the fate and transport models employed to develop the Method 1 standards overestimate (or underestimate) potential risks. Under Method 2, site-specific information may be used to demonstrate and document that a concentration of oil or hazardous material which is different than an applicable Method 1 standard poses No Significant Risk. Such a concentration would be used in the risk characterization process as the Method 2 standard.

Examples of such Method 2 demonstrations include:

- The use of site-specific leaching models to document that residual soil levels will not result in an exceedance of an applicable groundwater standard;
- The use of site-specific volatilization models to document that groundwater contaminants will not result in unacceptable indoor air concentrations;
- The use of site-specific migration models to demonstrate that the groundwater will not pose a significant risk when it discharges to surface water.

Note that there are some Method 1 standards which *cannot* be modified under Method 2 (see 310 CMR 40.0982(1) and (2)). For example, groundwater protected as a current or potential source of drinking water must meet the promulgated GW-1 standards listed in MCP Table 1 (310 CMR 40.0974(2)). Similarly, while some site-specific information may be used to adjust the leaching-component of the soil standards, the results cannot exceed soil standards based upon direct contact exposures. These soil standards are listed in MCP Table 5 (310 CMR 40.0985(6)).

The fate and transport modifications to the Method 1 standards which are allowed under a Method 2 risk characterization rely heavily upon models used to predict environmental concentrations of oil or hazardous material, although direct environmental monitoring may also be employed.

6.3.1 General Considerations When Using Predictive Models

Predictive modeling used in Method 2 to modify Method 1 standards is one prominent example of how such models may be used under the MCP. The discussion which follows is applicable to all uses of fate and transport models[1].

While direct measurements of environmental concentrations are preferred, Predictive Modeling is often a necessary or desirable component of the risk characterization process, providing a means to:

- adjust the promulgated Method 1 standards based upon site-specific fate and transport information; and/or

[1] The use of predictive models is not permissible under Method 1, except to evaluate future site conditions. Predictive models may be used under Method 3 as needed and appropriate to obtain estimates of current and/or future Exposure Point Concentrations, as discussed in Section 7.3.4.5 of this document.

- characterize risks at a site that may be manifested at a future point in time or space, due to the migration, partitioning, or transformation of oil and hazardous material; and/or

- interpret, characterize, or confirm current risks at a site, from migration and/or exposure pathways that are difficult or impossible to accurately measure or quantify.

Although Predictive Modeling has become an integral part of the site assessment and risk characterization process, there has been little standardization, or indeed validation, of modeling procedures and techniques. This situation has been further exacerbated by the explosive growth in commercially available software, capable of executing increasingly more complex modeling applications, on increasingly more powerful computers.

For this reason, risk assessors should exercise appropriate caution in the evaluation, utilization, and interpretation of modeling results. Further, the risk assessor must justify and document the use of a predictive model as part of a Method 2 Risk Characterization.

6.3.1.1 Types of Predictive Models

Predictive Models are mathematical approximations of processes that occur at a disposal site. These models attempt to evaluate the migration of oil and hazardous material released at a site by the mathematical simulation of physical, chemical, and/or biological processes.

Most models used for this purpose are classified as either "analytical" or "numerical" models:

- **Analytical Models** are relatively simple mathematical relationships or algorithms, with solutions obtained through hand calculation or on a personal computer. Generally, the use of analytical models requires a series of simplifying assumptions and conditions.

- **Numerical Models** are more complex mathematical relationships, with solutions obtained through a numerical analysis using a computer program. Numerical models allow for the evaluation of more complex and heterogeneous systems, and provide a more "customized" characterization of site conditions.

There is considerable variability in the scope, complexity, and degree of validation of available analytical and numerical models.

The majority of commercially available models address the leaching of contaminants from soil and/or movement of aqueous-phase contaminants in the unsaturated (vadose) or saturated (groundwater) zone. Newer models have also been developed to simulate multiphase transport, including vapor-phase transport in the unsaturated zone. Most models are deterministic; some are probabilistic.

6.3.1.2 Selection of Models

The key steps in the consideration, selection, and application of Predictive Models are summarized in Figure 6.1.

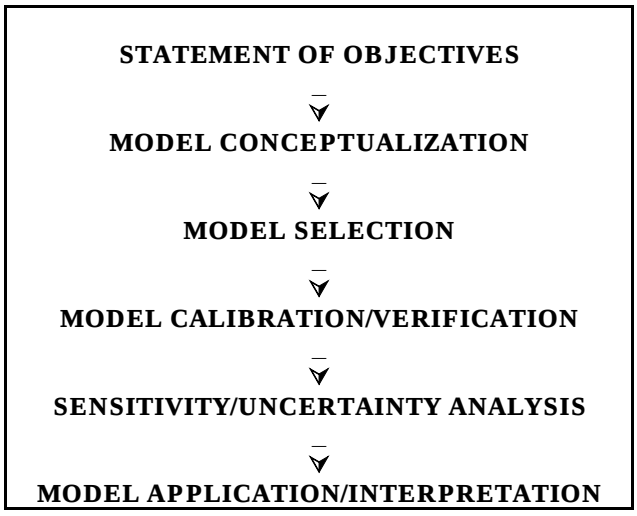


Figure 6.1

All models are premised on certain assumptions and conditions, and all are subject to certain limitations. At the present time, there are no universally accepted or even universally recommended models for all applications.

In evaluating and selecting a Predictive Model, the following factors should be considered:

(1) **Characterization and modeling objectives**. Study objective should be clearly defined early in the site evaluation process. Of prime consideration is whether a "screening" or a "detailed" evaluation is required, as this decision will affect not only the selection of a model, but also the nature, extent, and costs of necessary site investigation/data gathering activities. In many cases, a "screening" evaluation may be the most appropriate option, given study objectives, site conditions, and/or modeling and characterization uncertainties.

(2) **Model Conceptualization/Selection**. It is important to ensure that selected models address those transport processes and domains that are of interest or importance at the site under evaluation. For example, some groundwater transport models can address multi-phase transport, which may be desirable at sites with Non Aqueous Phase Liquids and/or Volatile Organic Compounds. Similarly, some models incorporate a biological degradation component; this may be important when evaluating readily degradable contaminants like petroleum, but not important or necessary for sites with heavy metal contamination.

(3) **Extent and quality of site/input data**. A detailed site evaluation using a numerical model generally requires a significant amount of site-specific data, for calibration/ validation purposes, and/or to otherwise yield meaningful modeling results. In the absence of such data, a "screening" analysis by an analytical model may be more appropriate.

(4) **Model accuracy, validation, and verification**. These terms are used and defined differently by different parties, but concern the same central issue: the degree of certainty and documentation that exists or that needs to be obtained to demonstrate that a given model will accurately predict and characterize conditions *at the site under evaluation*.

Some models, particularly complex numerical models, will need to undergo a series of iterative calibration/validation processes. In other cases, a vendor or distributor may assert that a model has been "validated" or "verified"; such claims should be closely scrutinized to ensure that sufficient documentation exists to support such an assertion, and that all model validation assumptions,

conditions, and limitations are applicable *at the site under evaluation*, consistent with defined characterization and modeling objectives.

(5) **Budget and resource availability**. The costs to obtain and use a Predictive Model, including ancillary costs associated with obtaining site assessment data needed for model calibration, validation, and/or model input, can be considerable, especially for detailed studies using numerical models. Moreover, it is very important that persons using a model be experienced and proficient in its use and interpretation; for complex numerical models, proficiency and experience is essential.

Ideally, the designation of study objectives, identification of risk characterization needs, and selection of a Predictive Model should be accomplished prior to the initiation or completion of comprehensive site assessment activities, in order to ensure/optimize data collection for modeling/risk characterization purposes.

6.3.1.3 Use, Application, and Interpretation of Predictive Models

The selection of an appropriate model is only the first step in obtaining meaningful results: the second, and perhaps more important step, relates to the use and application of the selected model.

In many cases, a number of models will exist that will satisfy study objectives. Assuming that all models are sufficiently accurate, the input of identical data sets should yield similar results. In practice, however, significant differences in computed results arise, due to differences in how a modeler interprets and extrapolates available "raw data", and conceptualizes the modeled system.

In this regard, the following recommendations and considerations are offered:

- Given the uncertainties that exist using any model, conservative input values should be used wherever appropriate and reasonable. In some cases, it may be prudent or even cost-effective to use "worst case" values during a screening analysis, to rule out a pathway or exposures believed to be insignificant.

- A sensitivity or uncertainty analysis should be considered in cases where a "worst case" analysis is not performed. In such an analysis, input parameters are varied in order to determine variations in the predicted results. This information can then be used to determine which input parameters require accurate determination and which input parameters may be approximated with little loss in model accuracy. In situations where an accurate determination of sensitive input parameters cannot be obtained, such an analysis can be used to define the range of possible modeled outputs.

- A conceptualization of the modeled system and understanding of the transport processes being simulated is necessary to avoid making mistakes related to the "blind faith" acceptance of predicted results. Although it is difficult in some cases to relate abstract mathematical relationships and solutions to real-world situations, predicted results that are inconsistent with technical insight or intuition should be a cause for concern and re-evaluation.

6.3.1.4 Performance Standards for Predictive Modeling

The use of Predictive Models in characterizing risk at disposal sites under the Massachusetts Contingency Plan are subject to the following standards and practices:

- Selected models must be scientifically valid and sufficiently documented.
- Predictive Models shall be selected, used, and applied in a manner that leads to a reasonably conservative and protective estimate of Exposure Point Concentrations.
- Data that is input to Predictive Models shall be of sufficient extent and quality to allow for the meaningful use, interpretation, and/or confirmation of modeling outputs, considering the sensitivity and uncertainty of modeling parameters, and the intended application of model outputs.
- All modeling and site-specific assumptions and conditions must be clearly articulated.
- All results must be clearly documented.

6.3.1.5 Predictive Modeling & the MCP Method 1 Standards

The Method 1 Standards were developed by DEP using certain predictive models and a number of conditions and assumptions. Parties contemplating the use of Predictive Models to modify these standards using a Method 2 analysis, or to develop alternative standards using a Method 3 analysis, may wish to review the specifics of this development process. Key Method 1 predictive modeling procedures and assumptions are summarized in Table 6.1. Complete details are provided in Background Documentation for the Development of the MCP Numerical Standards (April 1994).

Table 6.1
Development of MCP Method 1 Standards

Leaching of Contaminants from Soil

MODEL(S): SESOIL coupled with AT123D, as available through the USEPA Graphical Exposure Modeling System (GEMS) package, suitable for use on IBM-compatible personal computers (PCGEMS).

APPROACH: SESOIL was used to estimate seasonal leaching of contaminants from the vadose zone. This value was then input to AT123D to model flow through the saturated zone to a designated "point of compliance". Dilution and Attenuation Factors (DAF) were developed in this manner for 8 indicator chemicals, which were then used to develop a multiple linear regression model to relate the DAFs with partition coefficients (K_{oc}) and Henry's Law Constants (H). This relationship was then used to estimate DAFs for other chemicals.

KEY ASSUMPTIONS:

- Contamination in vadose zone is 10 meters X 10 meters, 1 meter in depth (i.e. 100 m^3), and is located 1 meter below the ground surface and 1 meter above the ground-water table.
- Groundwater "Point of Compliance" was surface of water table located 10 meters downgradient of contaminated soil.
- Sandy, pervious soils
- Moderate biodegradation rate for benzene; zero degradation rate for all other contaminants.

Volatilization/Infiltration of Contaminants into Buildings

MODEL(S): Based upon Heuristic Model developed by Johnson and Ettinger (1991)

APPROACH: Assumed partitioning at groundwater table = 10% of equilibrium condition predicted using Henry's Law. Assumed attenuation factor between inside and outside of building = 5 X 10^{-4} (Johnson and Ettinger).

KEY ASSUMPTIONS:

- Dissolved contaminants within 30 feet of building structure.
- Depth to groundwater 15 feet or less.
- Sandy, pervious soils.

Discharge of Contaminated Groundwater to Surface Waters

MODEL(S): None

APPROACH: Simple 10 fold dilution factor.

Risk assessors are not limited to using the models employed by MADEP in setting the Method 1 standards, as long as the chosen model meets the performance criteria discussed above.

The following references are provided for risk assessors desiring a more detailed discussion of modeling and the selection of appropriate fate and transport models.

Mass DEP *Standard References for Monitoring Wells,* DEP Publication #WSC-310-91, Section 7.0 Groundwater Modeling.

US EPA, 1991 *Ground-Water Issue, Characterizing Soils for Hazardous Waste Site Assessments.* EPA/504/4-91/003. U.S. Environmental Protection Agency. Office of Solid Waste and Emergency Response, Washington, D.C.

US EPA, 1992 *Ground-Water Issue, Fundamentals of Ground-Water Modeling.* EPA/540/S-92/005. U.S. Environmental Protection Agency. Office of Solid Waste and Emergency Response, Washington, D.C.

US EPA, 1989 *Predicting Subsurface Contaminant transport and Transformation: Consideration for Model Selection and Field Validation.* EPA/600/2-89/045. U.S. Environmental Protection Agency. Robert S. Kerr Environmental Research Laboratory, Ada, Oklahoma.

US EPA, 1992 *Quality Assurance and Quality Control in the Development and Application of Ground-Water Models.* EPA/600/R-93/011. U.S.Environmental Protection Agency. Robert S. Kerr Environmental Research Laboratory, Ada, OK.

US EPA, 1993 *Compilation of Ground-Water Models.* EPA/600/R-93/118. U.S.Environmental Protection Agency. Robert S. Kerr Environmental Research Laboratory, Ada, OK.
US EPA, 1994 *Identification and Compilation of Unsaturated/Vadose Zone Models.* EPA/600/R-94/028. U.S. Environmental Protection Agency. Robert S. Kerr Environmental Research Laboratory, Ada, OK.

US EPA, 1994 *Evaluation of Unsaturated/Vadose Zone Models for Superfund Sites.* EPA/600/R-3/184. U.S. Environmental Protection Agency. Robert S. Kerr Environmental Research Laboratory, Ada, OK.

6.3.2 Leaching of Contaminants from Soil

The Method 1 Soil Standards (Tables 2, 3 and 4 of the MCP) consider the potential for contamination in soil leaching into the groundwater and resulting in adverse impacts on the aquifer. Remember that the underlying aquifer could be category GW-1, GW-2 and/or GW-3, so the soil standards are specific to the *combination* of soil and groundwater categories under consideration (e.g., S-1/GW-3, S-3/GW-1).

In setting these leaching- and health-based standards, the Department made certain assumptions about the characteristics of the soil and the properties of the aquifer. Two models were then used to develop the Method 1 Standards. The SESOIL (Seasonal Soil Compartment) Model was used to estimate seasonal leaching of site contaminants from the vadose zone. The value calculated from the SESOIL model was then input to the groundwater transport model (AT123D), to estimate the flow through the saturated zone and the contaminant concentration at a specified point of compliance ten meters downgradient from the site (Figure 6.2).

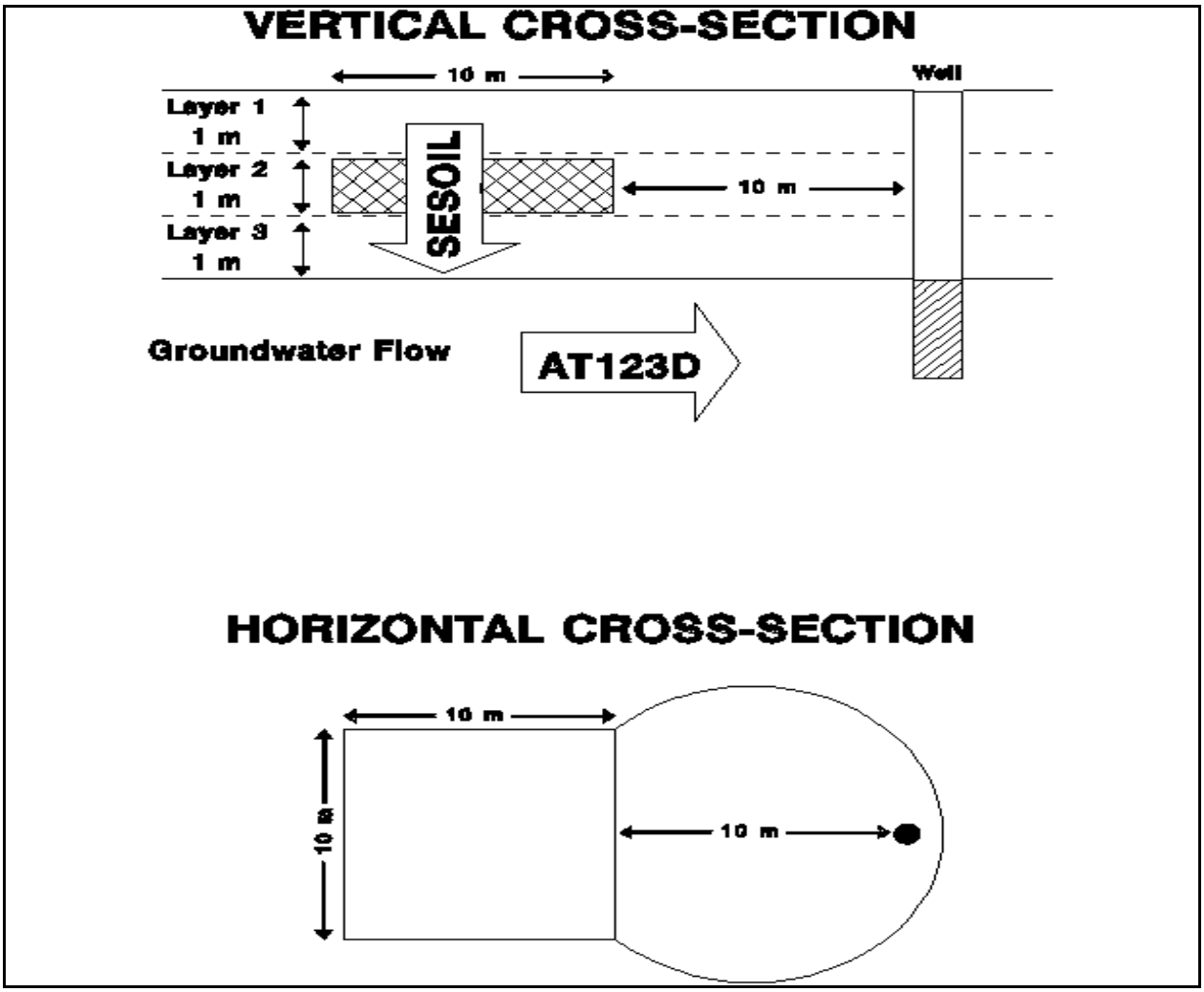


Figure 6.2

The parameters selected for input into the models were based upon assumptions about a "typical disposal site". (A brief summary of these parameters is given in Table 6.1 and a detailed description is given in *Background Documentation for the Development of the MCP Numerical Standards* (April 1994). This was done to make the approach as generalizable as possible to sites across the state. In so doing it was recognized that depending upon the individual characteristics of a particular site, the input parameters may be more or less applicable to any one location. In light of this, the following methods are identified in the MCP at 310 CMR 40.0985 (3) to demonstrate that the concentrations of oil and/or hazardous material in soil at the disposal site currently and in the foreseeable future will result in compliance with all MCP Method 1 or 2 Groundwater Standards:

(a) fate and transport modeling that incorporates site-specific information on source mass and subsurface hydrogeological conditions; and/or

(b) laboratory tests that demonstrate, under site conditions, the oil and/or hazardous material in the soil will not leach to groundwater at levels which exceed the applicable MCP Method 1 or 2 Groundwater Standards.

The result of a Method 2 modification of the Method 1 soil standards is one or more alternative soil standards which are both ***demonstrably*** protective of the site groundwater ***and*** equal to or less than the Direct Contact Exposure-Based Soil Concentrations listed in Table 5 of the MCP (310 CMR 40.0985(6)). If the calculated site-specific leaching-based concentration is greater than the Direct Contact Concentrations (or if the site-specific information indicates that material is not leaching to groundwater, and will not leach to groundwater, at significant levels), then the Direct Contact concentrations in Table 5 are adopted as the Method 2 soil standards (310 CMR 40.0982(2)).

6.3.3 Volatilization of Contaminants

The MCP Method 1 GW-2 Standards are based upon the potential for volatilization of contamination in groundwater into indoor air. As with the soil leaching modeling, certain assumptions were made to attempt to represent conditions at a "typical disposal site". The particular model utilized to develop the Method 1 Standards was the Heuristic Model developed by Johnson and Ettinger (1991). The development of GW-2 standards based upon this approach is described in Section 4.2 of the *Background Documentation for the Development of the MCP Numerical Standards* (April 1994).

Site-specific factors such as building conditions, soil type, depth to groundwater and depth to contamination may influence the degree to which vapors infiltrate a structure. The risk assessor may want to consider these factors, as well as any soil gas or indoor air measurements in determining whether the groundwater contamination is affecting the indoor air and when establishing groundwater concentrations of a chemical which would represent a condition of No Significant Risk for this exposure pathway.

The result of a Method 2 modification of the Method 1 GW-2 standards is one or more alternative groundwater standards which are both ***demonstrably*** protective of potential indoor air exposures ***and*** equal to or less than the groundwater Upper Concentration Limits listed in Table 6 of the MCP (310 CMR 40.0996(5)). If the calculated site-specific volatilization-based concentration is greater than the groundwater Upper Concentration Limit (or if the site-specific information indicates that material is not volatilizing, and will not volatilize, to indoor air at significant levels), then the Upper Concentration Limits in Table 6 are adopted as the Method 2 GW-2 standards (310 CMR 40.0982(4)).

6.3.4 Discharge to Surface Water

The MCP GW-3 standards consider potential impacts from the discharge of contaminated groundwater into a surface water body. The standards incorporate a simple dilution factor of ten (10) based upon the experience of MADEP Division of Water Pollution Control in writing groundwater and surface water discharge permits. The development of GW-3 standards based upon this approach is described in Section 4.3 of the *Background*

Documentation for the Development of the MCP Numerical Standards (April 1994).

Site-specific factors, such as the soil type, volume of contaminated groundwater and distance to the point of discharge to surface water may influence the concentration of oil or hazardous material in the groundwater at the point of discharge. The risk assessor may want to consider these factors in determining whether the groundwater concentration at the site will significantly affect surface water and when establishing a groundwater concentration (i.e., a Method 2 standard) that would represent a condition of No Significant Risk for this pathway.

The result of a Method 2 modification of the Method 1 GW-3 standards is one or more alternative groundwater standards which are both ***demonstrably*** protective of receiving surface water bodies ***and*** equal to or less than the groundwater Upper Concentration Limits listed in Table 6 of the MCP (310 CMR 40.0996(5)). If the calculated site-specific surface water risk-based concentration is greater than the groundwater Upper Concentration Limit (or if the site-specific information indicates that material is (and will) not discharge to a surface water body at significant levels), then the Upper Concentration Limits in Table 6 are adopted as the Method 2 GW-3 standards (310 CMR 40.0982(4)).

6.4 RISK CHARACTERIZATION

The process for a Method 2 Risk Characterization will follow the same methodology as a Method 1 Risk Characterization (310 CMR 40.0988(1)), with the exception that at least some of the applicable standards will have been developed or modified using Method 2 procedures. Thus the documentation for a Method 2 risk characterization must:

- Identify the Human Receptors (310 CMR 40.0921)
- Identify the Environmental Receptors (310 CMR 40.0922)
- Identify the Site Activities and Uses (310 CMR 40.0923)
- Identify Exposure Points (310 CMR 40.0924 and 40.0973)
- Identify Exposure Pathways (310 CMR 40.0925)
- Identify Exposure Point Concentrations (310 CMR 40.0926 and 40.0973)
- Identify Site Groundwater and Soil Categories (310 CMR 40.0930)
- Identify Applicable Groundwater and Soil Standards (310 CMR 40.0973)

- Compare the Exposure Point Concentrations to Applicable Method 1 and Method 2 Standards (310 CMR 40.0988)

- Clearly State Conclusions of the Risk Characterization (40.0988).

These risk characterization steps are discussed in detail for Method 1 in Section 5.0 of this document, and the reader is referred there for specific requirements.

REFERENCES FOR CHAPTER 6

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