June 12, 2024 – MassDEP is issuing **Draft Guidance Chapters 6 through 10 of the Risk Characterization Guidance in support of the Massachusetts Contingency Plan (MCP) 310 CMR 40.0000** for a 90-day public review period at the conclusion of which it intends to consider comments received and issue a final guidance. This Draft Risk Characterization Guidance supersedes the 1995 Risk Characterization Guidance (#WSC/ORS-95-141).

Additional chapters of the Risk Characterization Guidance will be released for external comment and review in additional phases to provide an opportunity for the public to provide feedback prior to finalizing the guidance.

This portion of the draft Risk Characterization Guidance incorporates the 2024 MCP amendments, incorporates current risk characterization practices and provides clarifications based on program experience and frequently asked questions.

Please send written comments on this portion of the draft Risk Characterization Guidance by September 12, 2024 to Greg Braun by email to Greg. Braun@mass.gov or by mail to Greg Braun, MassDEP/ORS, 100 Cambridge Street, Suite 900, Boston, MA 02114. You may also reach Greg Braun by telephone at (781) 697-4843.

MassDEP Guidance for Disposal Site Risk Characterization

Part 1 – General Site Characterization to Support Assessment (Contd.)

Chapter 6
Background

6.0 Background

6.1 Introduction

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 discussion in this section addresses the regulatory definition of "*background*" and the various uses of background information under the Massachusetts Contingency Plan (MCP). This section also provides specific guidance on the use of generic background levels published by MassDEP, 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 in the vicinity of the disposal site truly representative of background conditions for the site?
- Are the site concentrations reported (for one or more chemicals) consistent with background conditions for the disposal site?

Ideally, the risk assessor should be involved in the development of the site sampling plan and should have significant input on the number of samples collected as well as where and when to collect samples for the site risk characterization. There will, however, be situations where the site data have 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.

Many anthropogenic chemicals (particularly some chlorinated organic compounds) are expected to have non-detect background concentrations. These compounds, while common at c.21E disposal sites, are otherwise rare in the environment. In general, background levels are most important for naturally occurring metals found in the environment. It is also quite common to detect "background" levels of polycyclic aromatic hydrocarbons (PAHs) in soil, especially in urban areas. Except when MassDEP published background levels are used, background should be dealt with on a site-by-site basis and should be medium-specific.

6.2 MCP Background Provisions

6.2.1 Background Definitions

The regulatory definition of background levels and of two different categories of background are given at 310 CMR 40.0006. These definitions provide the foundation for using background data under the MCP:

> *Background means those levels of oil and hazardous material that would exist in the absence of the disposal site of concern, including both Natural Background and Anthropogenic Background.*
>
> *Natural Background means those levels of oil and hazardous material that would exist in the absence of the disposal site of concern, 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 ecological conditions.*
>
> *Anthropogenic Background means those levels of oil and hazardous material that would exist in the absence of the disposal site of concern and which are:*
> *(a) attributable to atmospheric deposition of industrial process or engine emissions and are ubiquitous and consistently present in the environment at and in the vicinity of the disposal site of concern;*
> *(b) attributable to Historic Fill;*
> *(c) attributable to coal, coal ash, or wood ash, excluding ash landfills or wood ash resulting from the combustion of lumber or wood products that have been treated with chemical preservatives;*
> *(d) associated with sources specifically exempt from the definitions of disposal site or release as those terms are defined in MGL c. 21E and 310 CMR 40.0006;*
> *(e) releases to groundwater from a public water supply system; or*
> *(f) petroleum residues that are incidental to the normal operation of motor vehicles.*

The definition of Anthropogenic Background also references an important subset of background: "*Historic Fill"*. "Historic Fill" is also defined in 310 CMR 40.0006:

> *Historic Fill means Fill Material that based on the weight of evidence and consistent with the Conceptual Site Model:*
> *(a) was emplaced before January 1, 1983;*
> *(b) may contain, but is not primarily composed of, construction and demolition debris, reworked soils, dredge spoils, coal ash, wood ash or other solid waste material;*
> *(c) was contaminated with metals, hydrocarbons, and/or polycyclic aromatic hydrocarbons prior to emplacement, at concentrations consistent with the pervasive use and release of such materials prior to 1983;*
> *(d) does not contain oil or hazardous materials originating from operations or activities at the location of emplacement;*
> *(e) is not and does not contain a generated hazardous waste, other than Oil or Waste Oil;*
> *(f) does not contain chemical production waste, manufacturing waste, or waste from processing of metal or mineral ores, residues, slag or tailings; and*
> *(g) does not contain waste material disposed in a municipal solid waste dump, burning dump, landfill, waste lagoon or other waste disposal location.*

Together, these definitions make it clear that the term "background" is not limited to pristine conditions (natural background). The Department recognizes that historic human activities have resulted in the widespread presence of certain chemicals in the environment (anthropogenic background). Under these definitions, however, OHM from one release ***cannot*** be considered background for another release.

6.2.2 Background in MCP Site Assessment

The determination of representative background levels for a disposal site is an explicit requirement of the MCP (310 CMR 40.0835(4)(f) and 40.0904(2)(b)):

> 40.0835
> *(4) The information and assessment findings outlined in 310 CMR 40.0835(4) shall be provided in the Phase II Report.. . .*
>
> > *(f) Nature and Extent of Contamination, including a characterization of the nature, and vertical and horizontal extent of oil and/or hazardous material in the environment, including any and all source(s), the presence, distribution, and stability of any NAPL, tabulation of analytical testing results, and, where appropriate, a characterization of background concentrations of oil and/or hazardous material at the disposal site*;
>
> 40.0904
>
> > *(2) Extent of Release. The documentation of the Risk Characterization shall contain a description of the source and extent of the release of the oil and/or hazardous material, including, where appropriate:…(b) background concentrations of oil and/or hazardous material in all evaluated media;*

Information relating to background conditions may be useful at any site. However, for most sites, information on background conditions is most appropriate where background conditions would be used for the determination of the nature and extent of the release of Oil or Hazardous Material (OHM), for the risk characterization process itself, and for making clean-up decisions.

6.2.3 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:

> *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 damage to health, safety, public welfare, or the environment during any foreseeable period of time.*

The regulations also require that, where feasible and to the extent possible, a Permanent Solution reduce the levels of OHM in the environment to background (310 CMR 40.0190(5) and 310 CMR 40.1020(1)):

> 301 CMR 40.0190
>
> > …
> > *(5) Where feasible, implementation of a Permanent Solution shall include a measure or measures designed to reduce to the extent possible the level of oil and/or hazardous materials in the environment to background.*

310 CMR 40.1020

> *(1) At any disposal site or portion of a disposal site where one or more remedial actions are undertaken to achieve a Permanent Solution, those remedial actions shall include, where feasible, one or more measures designed to reduce to the extent possible the concentrations of oil and hazardous material to levels that would exist in the absence of the disposal site of concern. Such measures shall, to the extent feasible, achieve or approach Background levels of oil and hazardous material in the environment as Background is defined in 310 CMR 40.0006.*

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 follows that the implementation of a permanent solution must be accompanied by an evaluation of the feasibility of reducing OHM levels to background. Accordingly, all Permanent Solution Statements must either document the extent to which site conditions have been reduced to background or demonstrate that the achievement of background is not feasible. This requirement is expressed at 310 CMR 40.1056(2)(g). In effect, 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 the levels to be used as cleanup criteria.

Note: The requirement to evaluate the feasibility of reaching background is not triggered at sites eligible for a Temporary Solution. At those sites, the requirement would only come into force when a Permanent Solution can be attained.

6.2.4 Feasibility of Achieving Background

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.

The background feasibility requirement is only triggered at sites if remediation is taking place. In planning the remediation activities, consideration should always be given, ideally early in the process, to approaching background conditions. If 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.

MassDEP has published guidance on conducting feasibility evaluations, including the feasibility of approaching or achieving background conditions. Readers are referred to Policy #WSC-04-160, ***Conducting Feasibility Evaluations Under the MCP*** for more details (https://www.mass.gov/doc/wsc-04-160-conducting-feasibility-evaluations-under-the-mcp-0/download).

Box 6.1

Achieving Background Levels is Considered Feasible Unless:

- The remedial alternative is not technologically feasible (technological feasibility criteria found in 310 CMR 40.0860(6)).
- 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(7)).
- Experienced individuals are not available to implement the remedial alternative.
- The alternative would necessitate off-site land disposal and no disposal facility is available.
- The elimination or control of the source is not achievable by the person conducting the response action.

Summarized from 310 CMR 40.0860(5): consult the regulations for exact wording and more detail.

6.2.5 Background and Downgradient Property Status

The MCP includes provisions to address situations in which a property is located downgradient of a property which is the source of the release of OHM. The owner or operator of that downgradient property may establish *Downgradient Property Status* pursuant to 310 CMR 40.0180. These provisions recognize 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.

6.2.6 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 Chapter 3.0 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 OHM have been reduced to background, and

(b) For the purposes of the requirements of achieving a Permanent Solution, the implementation of an AUL alone is not considered a "remedial action," 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 background.

6.2.7 Background in the Risk Characterization Process

The Department focuses assessment and remediation resources on contamination that is attributable to a release of OHM and that has the potential to pose significant risk of harm to health, safety, public welfare or the environment. While M.G.L Chapter 21E and the MCP may require remediation ***to*** background levels, there is no requirement to clean up ***beyond*** (lower than) background. To this end, chemicals that are present at levels consistent with background are removed from the risk characterization process (310 CMR 40.0902(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 (Chapter 7) for the risk characterization.

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 concentrations are consistent with background and document why it is appropriate to drop these contaminants from the process. An accurate determination of background conditions 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 will not be able to eliminate from further assessment chemicals that may actually be consistent with background, and ultimately these chemicals will be unnecessarily carried through the risk characterization. Conversely, 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 with an accurate determination of background conditions.

6.2.8 Background and Technical Justification

At many sites, particularly those resulting from sudden and discrete releases of OHM (i.e., "spills"), knowledge about the size and extent of the release may be sufficient to draw a conclusion about background levels with only limited analytical information. 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 MassDEP. The technical justification should be documented in sufficient detail to enable a reviewer/auditor to evaluate the decision to forego the requirements in question.

6.3 Approaches for comparing Background and Site Data

Background conditions should be considered when 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 subsections provide guidance to assist in the characterization of site background concentrations, including both the use of MassDEP published generic background levels and the establishment of site-specific background concentrations.

Site concentrations (both background and release-related) may vary over a wide concentration range due to the heterogeneity of the environmental medium, natural variation, the presence of "hot spots", or the vagaries of the analytical methods employed. 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 are sought, it is imperative that a well thought out sampling plan for each medium be developed. When MassDEP-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.

Two distinct approaches to evaluating whether site concentrations are consistent with background concentrations have been used at MCP sites:

- Comparison of site concentrations to MassDEP-Derived background Levels; and
- Comparison of site concentration to Site-Specific background Concentrations measured near the site.

These approaches are described in the Sections that follow.

6.4 MassDEP-Derived Background Levels

Published background concentrations are never site-specific. They may be based on samples collected from a wider geographic area or from a specific location that is not representative of the site in question. For this reason, comparison to site-specific background concentrations will generally provide a more reliable basis than published background levels for background evaluations. There are, however, cases where that is not possible. In some cases, it may not be possible to identify or access comparable sampling locations that have not been affected by the site in question. In others, the presence of other sites or sources of contamination in the vicinity may hinder efforts to identify suitable background locations. To provide an alternative in those cases, Mass DEP has published generic background levels for soil (MassDEP, 2002). The bases for these levels and guidance for their use are discussed in Section 6.4.1.

Table 6.1 provides the list of Massachusetts background soil concentrations of metals and polycyclic aromatic hydrocarbons (PAHs) for two types of soil: (1) “natural” soil found in locations where the soil is relatively undisturbed and has not been impacted by releases of hazardous materials, and (2) soil containing coal ash or wood ash associated with fill material. These values can be used as part of a c.21E assessment, when appropriate, in lieu of collecting site-specific background data. The data in Table 6.1 were obtained by DEP from analysis of several data sets, including:

- Data (30-140 samples) collected to represent background at c.21E sites located in non-urban areas, gathered from a review of DEP files,
- Site-specific background samples generated for locations in Worcester (68 samples) and Watertown (17 samples),
- Data (750-1,000 samples) collected by Mass Highway Department as part of the Central Artery/Tunnel (CA/T) project and presented in a draft document Background Soil Contaminant Assessment (CDM, April 1995),
- Data (590 natural soil samples from depths of 10 to 70 feet) collected by Haley & Aldrich, Inc. (2001) in the Boston Area,
- Preliminary data compiled by the Massachusetts Licensed Site Professional Association from background data submitted by its members (2001),
- Published data (62 samples) from ENSR, Inc. from 3 New England locations, and
- Generic background data published by the Agency for Toxic Substances and Disease Registry (ATSDR).

Box 6.2
Development of Mass DEP Soil Background Concentrations

In 2002, MassDEP published a Technical Update (MassDEP, 2002) with background values for metals and PAHs in natural soil and in soil with fill material containing coal ash or wood ash. The values in Table 6.1 are from that publication.

MassDEP initially published a list of Background concentrations of metals in natural soils in the 1995 *Guidance for Disposal Site Risk Characterization* and continues to recommend their use (first column of values in Table 6.1). The data sets used to identify these values are described in Table 6.2.

There is not one concentration of a chemical, of course, which can correctly be labeled the background level. Hundreds of years of human activities have only broadened the naturally occurring range of concentrations reported as "background", and this range is best thought of as a statistical distribution. In the evaluation of environmental contamination, we often select point values from the range of background levels and consider these to be representative of background. The use of such point-value "background" levels is essentially a short-cut method that allows consideration of background in the absence of site-specific information. The intent of MassDEP policy is to protect public health while minimizing the routine site-specific determinations at sites in the statewide cleanup program.

Generic background levels in soil published by MassDEP include:

“Natural” Soil

- Generally, the 90th percentile value from the MA DEP 1995 dataset was the point-value identified as background.
- In the absence of data in the MA DEP 1995 dataset, a lower percentile value from the CDM 1996 dataset was chosen as background.

Soil Containing Fill Material

- Generally, the 90th percentile value from the CDM 1996 dataset was point value identified as background.
- In the absence of data in the CDM 1996 dataset, the 90th percentile value from the “natural” soil (MA DEP 1995) dataset was chosen as background.

A high (e.g., 90th) percentile was chosen so that chemicals that are truly present at background levels would most likely be identified as such. It is inevitable that at some sites the use of the values listed in Table 6.1

will incorrectly require the assessment of some "true" background concentrations of OHM at the high end of the background range. Conversely, some chemicals that are related to the disposal practices at a site (and are not background) will be screened out of the risk assessment with the use of the Table 6.1 concentrations. The goal is to minimize both kinds of error.

Both metals and PAHs are ubiquitous and consistently present in the environment. Metals are present at relatively low levels in natural soil in locations that have not been affected by human activity, but the concentrations can be elevated in more developed areas due to non-site related anthropogenic inputs (anthropogenic background).

PAHs and are typically formed during the incomplete burning of organic material. including wood, coal, oil, gasoline and garbage. PAHs are also found in crude oil, coal tar, creosote and asphalt. Historically, PAHs have been associated with human activities such as cooking, heating homes and industries, and fuel for operating automobiles, although low levels of PAHs are also present in the environment from natural sources, such as forest fires. Their presence in the environment at higher concentrations is an artifact of habitation and is due to the widespread practice of emptying fireplaces, stoves, boilers, garbage, etc. in rural and urban areas over the past several hundred years. As a result, it is very common to detect background levels of PAHs in soils. Metals are both naturally occurring and found in man-made materials (such as paint, fuel, fertilizers and pesticides) and are widely distributed in the environment. Naturally occurring metals present in wood and coal are often found concentrated in ash residue.

The values in Table 6.1 are intended for use in determining whether levels of metals at are consistent with background when the collection of site-specific background data is not possible or practical. They are intended for use in c.21E risk characterization and are not necessarily appropriate for use in meeting the regulatory requirements of other programs (e.g., Solid Waste). Nothing in this guidance obviates the need to establish location-specific background conditions for other purposes, such as compliance with the soil management provisions of the MCP described at 310 CMR 40.0032(3)[1].

Table 6.1
Background Concentrations
in "Natural" Soil and in Soil Containing Coal Ash or Wood Ash Associated with Fill Material

OIL OR HAZARDOUS MATERIAL	"Natural" Soil mg/kg	Soil Containing Coal Ash or Wood Ash Associated With Fill Material mg/kg
ACENAPHTHENE[2]	0.5	2
ACENAPHTHYLENE[2]	0.5	1
ANTHRACENE[2]	1	4
ALUMINUM[1]	10,000	10,000
ANTIMONY	1	7
BARIUM[1]	50	50
BENZO(a)ANTHRACENE[2]	2	9

OIL OR HAZARDOUS MATERIAL	"Natural" Soil mg/kg	Soil Containing Coal Ash or Wood Ash Associated With Fill Material mg/kg
DIBENZO(a,h)ANTHRACENE[2]	0.5	1
FLUORANTHENE[2]	4	10
FLUORENE[2]	1	2
INDENO(1,2,3-cd)PYRENE[2]	1	3
IRON[1]	20,000	20,000
LEAD	100	600
MAGNESIUM[1]	5,000	5,000

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[1] More detailed guidance on the soil management provisions of 310 CMR 40.0032(3) is available in Policy WSC#-13-500: ***Similar Soils Provision Guidance*** (revised 2014), https://www.mass.gov/doc/wsc13-500-similar-soils-provision-guidance-0/download

BENZO(a)PYRENE[2]	2	7
BENZO(b)FLUORANTHENE[2]	2	8
BENZO(g,h,i)PERYLENE[2]	1	3
BENZO(k)FLUORANTHENE[2]	1	4
BERYLLIUM	0.4	0.9
CADMIUM	2	3
CHROMIUM (TOTAL)	30	40
CHROMIUM(III)	30	40
CHROMIUM(VI)	30	40
COBALT[1]	4	4
COPPER	40	200
MANGANESE[1]	300	300
MERCURY 0.3 1	0.3	1
METHYLNAPHTHALENE[2]	0.5	1
NAPHTHALENE[2]	0.5	1
NICKEL	20	30
PHENANTHRENE[2]	3	20
PYRENE[2]	4	20
SELENIUM	0.5	1
SILVER	0.6	5
THALLIUM	0.6	5

[1] In the absence of fill-specific data, the "natural" soil value has been adopted.
[2] In the absence of data specific to "natural" soil, a lower percentile value from the fill data set has been adopted.

Table 6.2
Details of the Data Set Used to Develop "Natural" Soil Background Levels Shown in Table 6.1

				Percentiles		
Chemical	**No. of Samples**	**Range** mg/kg	**Arith Mean** mg/kg	**50th** mg/kg	**90th** mg/kg	**95th** mg/kg
Aluminum	30	387 – 24,000	8,165	7,800	13,000	16,000
Antimony	90	< 0.22 – 22	0.9	0.34	1.4	4.8
Arsenic	139	<0.1 – 99	8.2	4.8	16.7	24.5
Barium	64	0.42 - 104	22.2	15.7	45.2	52.8
Beryllium	103	0.03 – 1.6	0.25	0.23	0.39	0.53
Cadmium	127	< 0.01 – 5.9	0.8	0.29	2.06	3.4
Chromium	147	0.02 - 105	15.2	10.6	28.6	38.8
Cobalt	10	< 0.5 – 4.7	1.7	NC	4.4	4.5
Copper	103	< 0.5 - 160	16.3	7.3	37.7	56.1
Iron	30	444 – 50 K	9,579	7,200	17,000	22,500
Lead	141	1 - 326	39.2	10.1	98.7	158
Magnesium	30	< 250 – 11K	2,141	1,300	4,900	6,700
Manganese	30	< 3 - 460	140	110	300	365
Mercury	107	<0.0002 – 1.4	0.13	0.066	0.28	0.43
Nickel	103	< 0.5 - 48	7.7	5.1	16.6	22.7
Selenium	93	< 0.0005 - 4.6	0.32	0.17	0.5	1
Silver	117	< 0.003 - 82	0.92	0.07	0.58	0.91
Thallium	71	< 0.005 - 5	0.41	NC	0.6	1.65
Vanadium	30	< 1 – 46.6	13.6	10.3	28.5	38.5
Zinc	112	3.52 - 190	42.6	27.7	116.4	131.2

6.4.1 Comparing Site Data to MassDEP-Derived Soil Background Concentrations

The list of background concentrations for natural soils may be compared to site soil concentrations with no site-specific justification. However, use of the list for soil containing fill material must be accompanied by documentation that the soil at the site does, in fact, contain coal ash or wood ash associated with fill material (or other material consistent with the regulatory definition of background). Such documentation may include information about the site history, soil strata, physical evidence or visual observations (including microscopic). Elevated chemical concentrations and/or urban settings are not, per se, sufficient evidence to justify the use of the background levels for soil containing fill. **If the site investigation indicates the presence of fill material in the soil,** then the values in Table 6.1 in the "Soil Containing Coal Ash or Wood Ash…" column may be used to evaluate whether site concentrations are consistent with background.

When comparing the generic background levels to site data, the risk assessor may conclude that the concentrations of an OHM are consistent with background conditions if and only if all the detected site concentrations are equal to or less than the MassDEP Background Level for that chemical. In other words, the 90th percentile values published by MassDEP are intended for use as "not to exceed" values. Therefore, **only concentrations detected in discrete soil samples from the site are fit for the purpose of background evaluations using the MassDEP Background Levels**. The results of composite samples or samples collected using an incremental sampling method are estimates of the mean and are not suitable for comparison to these "not to exceed" values.

Even though comparing site concentrations to published values is straightforward and does not involve statistical analysis, the comparison should be done using a representative site data set. The 90th percentile values listed by MassDEP are high-end from medium- to large-size data sets. Applying those values to a small data set can easily lead to the conclusion that site conditions are consistent with background when in fact they are not. See Chapter 4 (Sampling for Risk Assessment) for information on sample size and data representativeness.

If the analytical results from **one or more** site samples are greater than the established MassDEP 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 MassDEP-Derived 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.**

6.5 Background Evaluations Using Site-Specific Background Data

Site-specific background determinations are necessary for chemicals not included in the list(s) of generic MassDEP Background Levels. Site specific background determinations would also be appropriate where background values are higher than concentrations that would pose a significant risk.

When a site-specific background evaluation is undertaken, the collection of adequate data to define background conditions requires consideration of the number of samples to collect, the sample location, the sample collection methodology, the analytical 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.

The validity of all background evaluations described in this section depends upon using adequate quality data. While cost is a consideration when designing sampling plans 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.

Collection and analysis methods for background samples must be consistent with those for the site samples in order for the data sets to be comparable. 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.

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 or background 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.

Note that for many chemicals, including chlorinated organic compounds, expected background levels would be non-detect (ND), and the risk assessor should assume a background concentration of zero (or ND) without further analysis.

6.5.1 Background Data Set Size

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 (see Box 6-3) 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.

Several U.S. EPA guidance documents describe approaches to determining what is an adequate number of samples. One useful publication is the *Guidance for Data Useability in Risk Assessment* (U.S. EPA, 1992). The Guidance for Data Useability contains equations (in Appendix IV) that can be used to calculate the minimum number of samples required to achieve specific statistical goals. An understanding of basic statistics is helpful in determining background sample size.

6.5.2 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 CMR 40.0006). Background samples should be collected in locations that are relatively undisturbed, unstained, and unlikely to have been used for handling or storing OHM or to have been affected by OHM 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 must <u>not</u> 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 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 (U.S. EPA), 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 OHM. 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.

6.5.3 Media Specific Background Sampling 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 Chapter on Exposure Point Concentrations (Chapter 11). 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

Sampling depth must be considered 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 where 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, shoreline development, and 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 shoreline and 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. 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 is also recommended to collect the background samples at water depths similar to those selected for site sampling.

Sediment

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 airborne particulate matter, for chemical constituents in air, or both. The choice of target contaminants and sampling methods will depend upon the nature of potential air emissions that are being assessed. When potential exposure to site-related particulate matter is of concern, a sampling method that targets the respirable fraction of particulate matter is recommended.

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 site-specific indoor air background samples is not possible because environmental sources of contamination are only one factor in determining indoor air concentrations. Differences in building construction and use mean that concentrations in one building cannot be interpreted as background concentrations for another. However, ambient air concentrations are important factors to consider when evaluating indoor air data. Therefore, indoor air sampling plans should generally include the collection and analysis of ambient air samples to ensure that indoor air contamination from ambient air is not identified as site-related contamination.

6.5.4 Approaches for Comparing Site-Specific Background Concentrations to Site Data

Comparing a site-specific background data set to a data set collected from the site (or a portion of the site) can provide a strong technical basis for a decision as to whether site conditions are consistent with background conditions or not. As noted in Section 6.2.2, several key decisions made during the assessment and remediation of c.21E disposal sites depend upon a comparison of site conditions to background concentrations, so the bases of the comparisons must be reliable and defensible.

A key determinant of the reliability of a background evaluation is the representativeness and comparability of the background and site data sets. The sampling design and number of samples necessary to compare the site contaminants to background chemical levels depend mainly on the distribution of contaminants, the analytical variability, and the variation in contaminant levels at the study and background sites. Data quality and quantity is important regardless of the method used to compare site and background data sets.

This guidance provides three optional approaches for comparing site data to site-specific background data:

- **Comparison of Summary Statistics**
- **Inferential Statistical Analysis**
- **Graphic Comparisons (Box and Whisker Plots)**

These methods of comparing data sets are in essence different ways of comparing both the central tendency and the variability in the values. In contrast, the use of MassDEP-Derived Background Levels (as discussed above) is essentially a comparison of the maximum site concentration to the 90th percentile concentration of the background data set.

6.5.4.1 Summary Statistics

Summary, or descriptive statistics for both site and background samples should be provided in a table in the risk assessment report (even when another comparison method is being used for background evaluation). 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, and standard deviation.* It is useful to include in this table the frequency and limits of detection as well. Definitions of summary statistics that may be used to compare site and background data sets are given in Box 6.3.

The median and arithmetic mean are measures of the central tendency of the data set. The range (minimum to maximum) and standard deviation measure the spread and variability in the contaminant levels among the samples.

Descriptive statistics may be used to compare the background data set with the samples from the disposal site when the number of background samples is insufficient to achieve the specified power for an inferential procedure (see discussion below). Nevertheless, reasonably representative data sets are needed to avoid significant errors in background determination. 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, data set sizes of **less than 10 samples should never be used** to compare data sets.

Generally speaking, the data sets should be comparable in size to provide meaningful comparisons. Environmental data generally fall into a right-skewed distribution (ITRC, 2013). This being the case, high values that fall into the tail of the distribution are less likely to be picked up in small data sets. **If the background data set is much smaller than the site data set, the site may appear to be inconsistent with background even when there is no real difference.**

Box 6.3
Descriptive Statistics

Measures of Central Tendency for the Data Set

<u>Mean:</u> the arithmetic average, calculated by summing the values and dividing by the total sample size.

<u>Median:</u> the 50th percentile value; half the values in the data set are above the median.

Measures of Variability or Spread in the Data Set

<u>Range:</u> A single value which represents the difference between the minimum and maximum values in a data set.

<u>Extremes:</u> The minimum and maximum values in a data set.

<u>Percentiles:</u> The percent of individual values below a particular value.

<u>Variance:</u> A measure of variation among individual values in a data set. It is calculated as the average squared deviation from the mean.

<u>Standard Deviation:</u> The square root of the variance.

<u>Standard Error of the Mean:</u> The uncertainty or variability around a mean; or the standard deviation around a mean.

<u>Coefficient of Variation:</u> The standard deviation expressed as a percent of the mean:

SD/mean x 100 = CV

<u>Recommended Summary Statistics for Comparison:</u>

When comparing summary statistics, a measure of central tendency and a measure of spread should be compared and interpreted. MassDEP recommends comparing the <u>*median*</u> and <u>*maximum*</u> 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, as 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, MassDEP is concerned only if the site concentrations are <u>above</u> background levels, the high end of the observed concentration range (i.e., the <u>*maximum value)*</u> is recommended as an indicator of the spread in the data.

<u>Recommended Rules of Thumb for Background Determination:</u>

- 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 (the median and the maximum values) 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.

The appropriate determination becomes less clear 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*, MassDEP has historically recommended a tolerance factor 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.

This tolerance factor is not intended to imply that slight exceedances of background levels are acceptable, but that, given the uncertainty prevalent in soil sampling and analysis, slightly higher site concentrations may be due to variability rather than contamination. There may be cases where this tolerance factor could erroneously lead to a conclusion that site concentrations are consistent with background when in fact they are not. Such an error would be of greatest concern where the contamination poses a significant risk. Risk assessors should exercise judgement when applying this tolerance factor to ensure that clearly elevated concentrations that pose a significant risk are not deemed to be background and left in place.

If the site median and maximum values both exceed the corresponding background levels (regardless of the magnitude of the differences), that is sufficient evidence to conclude that the site data are greater than background levels.

This approach is offered because it is simple to implement. Relative to comparisons that use MassDEP-derived background concentrations, this method has the advantage of considering the central tendency of the data sets in addition to the maximum values.

6.5.4.2 Inferential Statistical Tests

Formal statistical tests are often considered the "gold standard" for comparisons of data sets. Typically, to determine whether site conditions are consistent with background, the hypothesis that there is no difference between the site and background would be tested. If the test has sufficient power, the likelihood of correctly concluding that site concentrations are elevated is high. Box 6.4 defines some of the terms relevant to such a test.

Statistical tests utilizing a sample size large enough to provide appropriate power, confidence, and minimal detectable relative difference can provide definitive determinations about the relationship between site concentrations and background concentrations.

In many cases, however, it is impractical to obtain data sets large enough to achieve an acceptable level of power. In such cases, there is a high probability of incorrectly concluding that a site with elevated concentrations is consistent with background, and the statistical test will not provide a basis for a defensible conclusion. **Analyses performed with low statistical power could make incorrect conclusions about exposure risk and inadvertently jeopardize public health.**

There are several statistical tests that could be used for comparing site and background contamination levels. These tests can be generally divided into two categories: parametric and nonparametric, and selection of the appropriate test depends on the distribution of the contaminant data. Nonparametric tests do not assume that the data follow a particular (i.e. normal) distribution, but they tend to have less statistical power than parametric tests. Parametric tests, in contrast, do assume that the data are normally distributed. As discussed in Section 6.5.4.1 above, most environmental data are not normally distributed, and instead tend to be right-skewed (ITRC, 2013). The use of parametric statistical tests for non-normally distributed data, especially for small sample sizes, may be inappropriate and lead to erroneous project management decisions. A detailed discussion of specific tests is beyond the scope of this document, but numerous references are available, including U.S. EPA guidance (U.S. EPA, 2002).

Box 6.4
Inferential Statistical Test Terminology

For a hypothesis test where the null hypothesis is that there is no difference between the site background conditions:

The **power** is the probability of correctly concluding that site concentrations are elevated above background when that is actually the case.

The **confidence** is the probability of correctly concluding that site concentrations are consistent with background levels when that is actually the case.

The **minimum detectable difference (MDD)** is the minimum difference between the site and background means that must exist to detect a statistically significant difference between the means.

The **sample size (n)** is the number of samples in a data set.

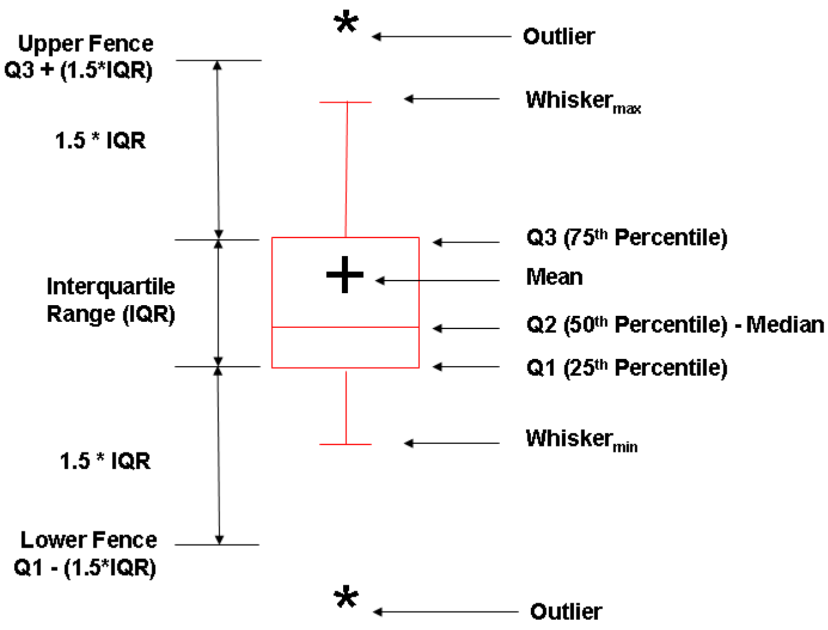
Power is dependent on several other factors, including the size of the data set and the minimum detectable difference. If the investigator opts to use a statistical test to evaluate background, the risk characterization report should include the calculations of power and confidence for the statistical test conducted and a discussion of the implications of the results of those calculations. The minimum detectable 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.

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.

6.5.4.3 Summarize and Report Data Using Box Plots

Graphical depictions of data are under-rated and underused. For the purpose of comparing site and background data, side by side box plots can be extremely helpful. A depiction of a boxplot is shown in Figure 6.1.

Figure 6.1
Boxplot Depiction



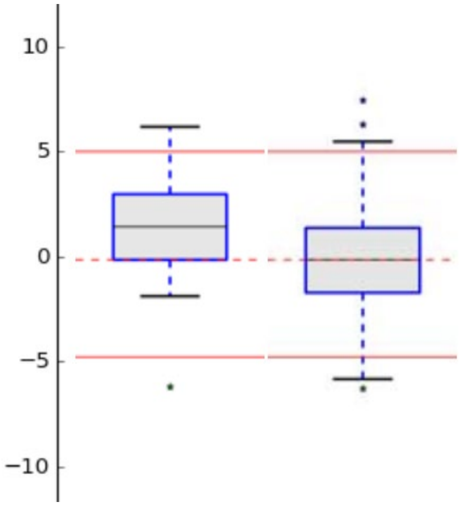
(U.S. EPA, 2014)

Figure 6.1 shows how the following statistics are displayed in a box plot (U.S. EPA, 2014):

- Q3 (75th Percentile)
- Q2 (50th Percentile) - Median
- Q1 (25th Percentile)
- Arithmetic Mean
- $\text{Whisker}_{\text{min}}$ & $\text{Whisker}_{\text{max}}$ - The lowest and highest values respectively that are found within the upper and lower fence. The upper and lower fences are defined as values between Q1 - (1.5*IQR) and Q3 + (1.5 * IQR), where “IQR” = the difference between Q3 and Q1.
- Outliers: All values that fall outside (above or below) the upper and lower fences.

An example of what side-by-side boxplots for comparing site and background data could look like is shown in Figure 6.2:

Figure 6.2
Side-by-Side Boxplots



(U.S. EPA, 2014)

In some cases, a simple graphical comparison may provide sufficient evidence to judge without question whether or not site concentrations are consistent with background conditions. In others, graphical representation of the data may simply provide support for conclusions based on a different method of comparison.

The main advantage of box plots is that they display the relationship between the two data sets in a transparent way. The main disadvantage is that decisions based on box plots are inherently subjective. MassDEP believes that, in many cases, the advantages will outweigh the disadvantages. Regardless of whether decisions about background are based on box plots, MassDEP strongly recommends including boxplot displays for all site and background data comparisons that are performed for MCP risk assessment purposes.

References for Chapter 6:

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Chapter 7
Identifying Contaminants of Concern

7.0 Identifying Contaminants of Concern (COCs) for the Risk Assessment

7.1 Introduction

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

- A chemical is present at a very **low frequency** of detection and in **low concentration**;
- A chemical is a **field or laboratory contaminant**; or
- A chemical is present at levels which are **consistent with "background"** concentrations for the area and does not appear to be elevated in any site locations due to use or disposal.

The risk assessment report should document the process of identifying the contaminants of concern (COCs), and it should discuss the specific basis for eliminating a chemical detected at the site from the list of COCs. The report should list the chemicals that are identified for both the human health risk assessment and the ecological risk assessment.

The three criteria listed above for eliminating a contaminant as a COC are discussed in the sub-sections that follow.

7.2 Low Concentration and Frequency of Detection

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 consistently present in the medium of concern and does not contribute appreciably to exposure.

In the context of identifying COCs, the term "low concentration" refers to the concentration of the chemical relative to the method detection limit. The intent is to allow elimination of a chemical that may not actually be present. In other words, when a positive analytical result is likely to be an artifact of the method and does not demonstrate with certainty that the chemical is present.

As a general rule of thumb, detecting a chemical in only five percent of samples at an exposure point (i.e., in an exposure area) may be considered low frequency of detection. 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 1 out of 20 total samples, but that sample might be located in a particular portion of the site and may represent a localized area of contamination. The MCP 40.0924 (11) 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 4.8 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.

Box 7.1
Terminology Note:

MassDEP generally uses the term "contaminants of ***potential*** concern" for all chemicals that ***may*** be present based on the site history and Conceptual Site Model. In this sense, target analytes discussed in the previous section could be considered chemicals of potential concern.

The term "contaminants of concern" refers to chemicals that are carried through the risk assessment. OHM that do not pose a significant risk by themselves are carried through the risk assessment unless they meet the criteria for elimination.

The intent of the "low concentration and detection frequency" criterion is to eliminate chemicals that are not contributing to exposure and not likely to be site related.

This criterion is not meant to screen out contaminants that pose a low health risk. While some regulatory agencies include a more aggressive screening step to reduce the number of COCs (e.g., USEPA), MassDEP does not. The MCP requires assessment of cumulative risk from all COCs, so even contaminants that pose a low risk are included in the assessment.

7.3 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 site or a release. A careful review of quality assurance and quality control data is necessary to avoid including sampling or laboratory contaminants as COCs but ensure that site-related chemicals 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
- the available 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 blank samples, the chemicals should either be considered COCs, 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.

7.4 Background

If the concentration of an oil or hazardous material (OHM) at a disposal site is at or below background levels, then that OHM need not be included in the disposal site risk characterization (310 CMR 40.0902(3)). In other words, when levels of an OHM detected at a site are consistent with background conditions, it may be eliminated as a contaminant of concern. Evaluation of background conditions is detailed in Chapter 6.0.

7.5 Risk-Based Screening

In general, site-related contaminants of potential concern (COPCs) should not be screened out of the risk assessment based on comparison to reportable concentrations, standards, guidelines, or other risk-based concentrations. The risk assessment process itself considers toxicity in estimating risks and it is premature to eliminate contaminants before the assessment is done. Further, some chemicals that might be considered unimportant in the assessment of human health risk may still present a risk to the environment (e.g., mineral oil) or to public welfare (e.g., odors).

In some cases, however, it may be appropriate to eliminate from the human health assessment chemicals known to be essential nutrients (e.g., iron) that are present at levels that would not result in doses higher than the minimum daily requirement. The risk assessor should be cautious in exercising such judgments, though, because 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 analysis and discussion of the technical justification for taking such a step. Alternatively, the chemicals should be carried through the risk assessment process.

MassDEP Guidance for Disposal Site Risk Characterization

Part 2 - Human Health Risk Assessment

Chapter 8
Risk Characterization Method Selection

8.0 Method Selection

The Massachusetts Contingency Plan (MCP) 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.

8.1 General Limitations

The method selected for the risk characterization should be clearly identified in the risk characterization 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 Permanent or Temporary Solution Statement for each release should be based upon the one method selected. Risk Characterizations conducted to support a Permanent or Temporary Solution Statement for a *portion* of a disposal site are discussed in Section 8.5. There are a few particular situations where methods may be combined. These situations will be addressed in each of the specific sections discussed below.

8.2 When Method 1 is Allowed

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. 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. The risk assessor must determine the appropriate risk characterization approach from among the methods identified as applicable to the site.

8.2.1 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 (listed in Section 8.2.2 below) within the top two feet of soil, *and* (c) all the contaminants of concern present have Method 1 standards promulgated by MassDEP in the MCP. It is expected that Method 1 will be the most commonly used risk characterization approach at the majority of simple sites, as soil and groundwater are the environmental media most commonly contaminated and MassDEP has developed standards for the most commonly reported chemicals.

8.2.2 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, while human health risks are considered adequately addressed by Method 1.

Method 1 and Method 3 may be combined to characterize human health and environmental risk respectively 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 that 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 this case, Method 1 could be used to assess the risk of harm to human health, while Method 3 is used to assess the risk of harm to environmental receptors. Substances known to bioaccumulate include, but are not necessarily limited to mercury, cadmium, PCBs, dioxin and pesticides (MassDEP, 1995).

In the first set of conditions described above, 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 included in the regulations to allow sites where there is minor sediment or surface water contamination to 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 MassDEP 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, MassDEP 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 MassDEP to be adequate screening criteria for the purpose of streamlining the c.21E risk characterization process. The combined Method 1/Method 3 approach is used at these sites to ensure 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.

Chapter 11 of this document, which provides guidance for conducting 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 Permanent or Temporary Solution Statement, *both* Method 1 and Method 3 should be checked off on the form (form BWSC-104).

8.2.3 When Method 1 Alone 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 that is not soil or groundwater (unless human exposure 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 MassDEP has not developed Method 1 standards, in which case either a combined Method1/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 OHM 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.

8.3 When Method 2 May Be Used

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.

8.3.1 Development of Additional Standards under Method 2

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. Chapter 10 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.*

8.3.2 Modification of Existing Standards under Method 2

In a Method 2 Risk Assessment, 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 under Method 2 include:

- The Method 1 Soil Standards considering leaching potential (310 CMR 40.0985)
- The Method 1 GW-2 Standards considering volatilization potential (310 CMR 40.0986)
- The Method 1 GW-3 Standards considering the migration and discharge components (310 CMR 40.0987)

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 Method 3 Ceiling Limits (310 CMR 40. 0996(5) Table 6)

8.3.3 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.

8.3.4 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 an unlisted chemical, 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 Permanent or Temporary Solution Statement.

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

For sites that 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, Chapter 9). The risk assessor could also choose to employ Method 3 alone to characterize the risk.

8.3.6 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 Chapter 9). 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 Chapter 9 of Method 1 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.

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 cannot be modified. Also, the TPH values do not assess benzene, toluene, ethylbenzene, xylene (BTEX) or PAH concentrations, therefore it may not be appropriate to base the entire assessment on TPH data only.

8.4 Restrictions on the Use of Method 3

There are no limitations on the use of 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 affected media at the site.

8.5 Risk Characterization for Portions of a Disposal Site

A Permanent or Temporary Solution may be achieved and a Permanent or Temporary Solution 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 Permanent or Temporary Solutions for portions of a site allows the expedited cleanup of areas which are more readily addressed: exposure risks that are more complex or difficult to assess/remediate can be dealt with on a different schedule. A Permanent or Temporary Solution 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 Permanent and Temporary Solutions are described at 310 CMR 40.1003. A Permanent Solution Statement 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. A Permanent Solution Statement 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 Permanent or Temporary Solution Statement 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 Permanent or Temporary Solutions?*

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

The method of risk characterization used to support a Permanent or Temporary Solution 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 ensure 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 a Permanent or Temporary Solution 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 Solution Statement, 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 Permanent or Temporary Solution Statement, then the Method 3 assessment would be focused on the portion of the disposal site addressed in the Permanent or Temporary Solution Statement. However, if one or more exposure points are located outside the portion of the disposal site addressed in the

Permanent or Temporary Solution, then the risk assessor must consider the exposures occurring at locations beyond the portion of the site addressed in the Permanent or Temporary Solution Statement. 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 8.2.2 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 second approach for characterizing risk to support a Permanent or Temporary Solution for a portion of a disposal site allows different risk characterization methods to be used for the different portions of the site. It eliminates the need for a final "comprehensive" risk characterization of the site after all the Permanent or Temporary Solution Statements for the different portions have been submitted, and this approach addresses the regulatory requirement to meet the Cumulative Receptor Risk Limit.

8.6 Risk Characterization Notation on the Permanent/Temporary Solution Form

The Permanent or Temporary Solution 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 checklist 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 Permanent or Temporary Solution Statement - most 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 OHM at the site are consistent with background, since no risk characterization is required at such sites (310 CMR 40.0902(3)). These sites are eligible for a Permanent Solution.

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 Permanent or Temporary Solution 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 the need to record an Activity and Use Limitation. The S-2 box should be checked on the Permanent or Temporary Solution form because that is the actual applicable category, even though the S-1 standards were achieved.

References for Chapter 8:

MassDEP (1995). Q&A Special Edition #4, published within Master MCP Q&A: 1993-2016, published in 2017. https://www.mass.gov/files/documents/2017/12/27/Master%20MCP%20QA.pdf.

Chapter 9 - Method 1

9.0 Method 1

9.1 Introduction

The specific regulations concerning the Method 1 risk characterization procedure are found at 310 CMR 40.0970 of the Massachusetts Contingency Plan (MCP). Readers are reminded that general requirements applicable or potentially applicable to all risk characterizations are found in 310 CMR 40.0900 through 40.0998, 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 provides a straightforward comparison of site conditions to promulgated standards to evaluate the risk of harm to health, public welfare and the environment[2]. 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 confidence 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.

9.2 Applicability

The selection of Risk Characterization Method is discussed in detail in Chapter 8 of this Guidance. Method 1 risk characterization may be used at disposal sites where assessments have determined the presence of OHM is limited to soil and/or groundwater. 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 any site. It is an available option as the risk assessor may choose to conduct either a Method 2 or Method 3 risk characterization in lieu of Method 1 if they believe that the benefits of such a site-specific approach outweigh the benefits of a Method 1 risk characterization. The decision to *not* use Method 1 does not require justification.

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[2] The risk of harm to *safety* must be evaluated separately, as described in Chapter 13 of this guidance document.

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)). MassDEP 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 risk assessor (and/or LSP) is compelled to think through the applicability criteria at every site. Figure 9-1 and Section 8.2 provide guidance for when of Method 1 is allowed at c.21E disposal sites.

9.3 Development of Method 1 Standards

The processes and values used to develop the Method 1 standards are documented in several different places. The general procedures used to develop the standards are outlined in "*MCP Numerical Standards"* (MassDEP, 2017). The current exposure factors and toxicity values used to calculate the standards are presented in the spreadsheets used to compute the standards. This material is available online on the Department's website[3].

In addition to the factors used to consider direct contact exposure in the Method 1 standards, fate and transport models are also used to evaluate potential indirect impacts to groundwater, indoor air and surface water. The computational models used for the leaching component of the soil standards and the vapor intrusion component of the groundwater standards are described in Appendices 9-A and 9-B respectively. Brief descriptions of the computational models follow:

Leaching Component of Method 1 Standards

The Method 1 Soil Standards listed in Tables 2, 3 and 4 (310 CMR 40.0975(6)(a), (b) and (c)) 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 ground water categories under consideration (e.g., S-1/GW-3, S-3/GW-1).

In setting these leaching- and health-based standards, MassDEP 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 concentrations from zero to 100 feet downgradient from the site (See Appendix 9-A).

The parameters selected for input into the models were based upon assumptions about a "typical disposal site". 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, alternative methods may be used to demonstrate that the concentrations of oil and/or hazardous material (OHM) 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 (See Chapter 10).

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[3] As of April 2024, the URL for this material is:
https://www.mass.gov/lists/risk-assessment-information#site-cleanup-&-facility-assessment---regulations-

Vapor Intrusion Component of Method 1 Standards

The MCP Method 1 GW-2 Standards (Table 1, 310 CMR 40.0974(2)) 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 used to develop the Method 1 Standards was the Heuristic Model developed by Johnson and Ettinger (1991) (See Appendix 9-B).

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.

Surface Water Discharge Component of Method 1 Standards

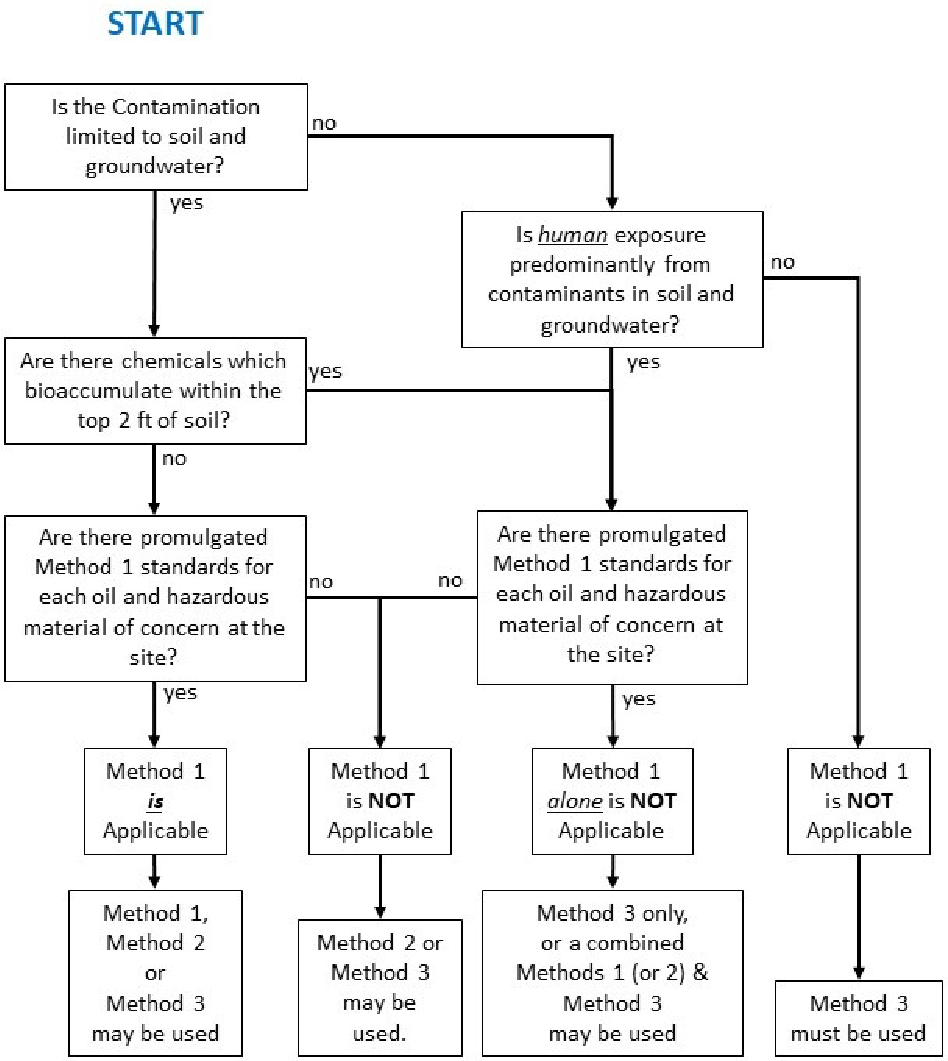
The MCP GW-3 standards (Table 1, 310 CMR 40.0974(2)) consider potential impacts from the discharge of contaminated groundwater into a surface water body. The standards incorporate a chemical-specific dispersion factor and a simple dilution factor of ten (10)

- The groundwater attenuation factor is a value based on the organic carbon portioning coefficient (Koc) and professional judgement.
    - Chemicals with a Koc less than 1,000 were assigned an attenuation factor of 2.5.
    - Chemicals with a Koc between 1,000 and 100,000 were assigned an attenuation factor of 25.
    - Chemicals with a Koc greater than 100,000 were assigned an attenuation factor of 100.

- The dilution factor is based upon the experience of MassDEP Bureau of Water Resources (BWR) (formerly the Division of Water Pollution Control) in writing groundwater and surface water discharge permits.

Figure 9-1

Applicability of Risk Characterization Method 1



9.3.1 Method 1 Risk Limits

In contrast to Method 3, where cumulative risks from exposure to multiple chemicals are assessed, Method 1 standards just assess risks from individual chemicals. To ensure that “No Significant Risk” determinations for Method 1 are comparable to those for Method 3, the allowable risk limits used to calculate the standards are lower than the cumulative risk limits applied in a Method 3 risk assessment. The cancer risk limit associated with a Method 1 standard is 1-in-one million, whereas the cancer risk limit for Method 3 is a cumulative receptor risk of one-in-one hundred thousand. The non-cancer risk limit for a Method 1 standard is a Hazard Index of 0.2, while a cumulative receptor Hazard Index of 1 is the risk limit for Method 3.

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 MassDEP for the development and use of the standards.***

9.4 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 are established (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; 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 who is 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 should be conducted for the disposal site, the regulations found at 310 CMR 40.0950 and the guidance provided in Chapter 12 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 MassDEP in the documentation that supports the risk characterization. The documentation of the risk characterization may be one or more chapters of another submittal to MassDEP 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.

9.5 Determining the Nature and Extent of Contamination (for Method 1)

Chapters 4 through 6 of this document present 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., expanding 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. Conclusions drawn from the risk characterization will be meaningless if (1) the investigator fails to analyze a medium that is likely to be contaminated by the chemicals at the site, (2) the focus of the evaluation is only on the source area and does not include and evaluation of that contamination which has migrated away from the source, including migration off the property, or (3) 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.

9.6 Identification of Contaminants of Concern

Once the OHM 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 Chapter 7 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 process of identifying contaminants of concern is the same for Method 1 as for a site-specific risk assessment. The discussion in Chapter 7 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, (2) the chemical is present at a level consistent with "background", or (3) the chemical is a field or laboratory contaminant (see Chapter 5). Please refer to the "background" discussion presented in Chapter 6, including the identification of background levels at a site and the comparison of site concentrations to background conditions.

9.7 Soil and Groundwater Categorization

General guidance on the categorization of soil and groundwater is provided in Section 3.2 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 is 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.]

Box 9-1
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 exposure.

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 affect 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.

9.8 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 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).

9.8.1 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 Table 9-1 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 in the Commonwealth is considered to be GW-3. Thus, the standards listed in the last column (GW-3 Standard) of Table 1 are always applicable in a Method 1 groundwater risk characterization. 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 (e.g., 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.

310 CMR 40.0974(2): Table 9-1 (*a portion of the full table)*

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

		GW-1 Standard	**GW-2 Standard**	**GW-3 Standard**
Oil and/or hazardous Material	**CAS Number**	**µg/liter (ppb)**	**µg/liter (ppb)**	**µg/liter (ppb)**
ACENAPHTHENE	83-32-9	20	NA	10,000
ACENAPHTHYLENE	208-96-8	406,300	10,000	40
ACETONE	67-64-1	0.5	50,000	50,000
ALDRIN	309-00-2	100	2	30
ANTHRACENE	120-12-7		NA	30

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

9.8.2 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 this document in Tables 9-2, 9-3 and 9-4, 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:

- 9-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.

310 CMR 40.0975(6)(a): TABLE 9-2 *(a portion of the full 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	83-32-9	4	1,000	1,000
ACENAPHTHYLENE	208-96-8	2	600	10
ACETONE	67-64-1	6	50	400
ALDRIN	309-00-2	0.09	0.09	0.09
ANTHRACENE	120-12-7	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.

310 CMR 40.0975(6)(b): TABLE 9-3 *(a portion of the full 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	83-32-9	4	3,000	3,000
ACENAPHTHYLENE	208-96-8	2	600	10
ACETONE	67-64-1	6	50	400
ALDRIN	309-00-2	0.5	0.5	0.5
ANTHRACENE	120-12-7	3,000	3,000	3,000

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

310 CMR 40.0975(6)(c): TABLE 9-4 *(a portion of the full 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	83-32-9	4	5,000	5,000
ACENAPHTHYLENE	208-96-8	2	600	10
ACETONE	67-64-1	6	50	400
ALDRIN	309-00-2	4	4	4
ANTHRACENE	120-12-7	5,000	5,000	5,000

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 6 µg/g. Thus, while one might 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.

9.9 Identification of Exposure Points and Exposure Point Concentrations (Including Hot Spots) under Method 1

The regulations that address the identification of exposure points and the development of exposure point concentrations for Method 1 risk characterizations are found at 310 CMR 40.0924 and 40.0926. These are discussed further at 310 CMR 40.0973(3) and (4).

9.9.1 Groundwater

For groundwater, the MCP defines the exposure point to be used for a Method 1 risk characterization as "…*the groundwater resource itself, as measured at each wellhead and/or nearest tap of a well screened within the horizontal and vertical distribution of the oil and/or hazardous material in the groundwater. Existing water supply wells and monitoring wells shall be used to represent current or potential groundwater Exposure Points*." (310 CMR 40.0924(6)(a)). Thus, each well located within the contaminated area is considered either a current and/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(5) that "*the objective shall be to identify a conservative estimate of the mean concentration contacted by a receptor at each Exposure Point over the relevant exposure period*," 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, or as part of conservative screening assessments.

9.9.2 Soil

In the MCP, for Methods 1 and 2, the exposure point(s) for soil are defined by "*the horizontal and vertical extent and distribution of the contamination in combination with the soil category(ies) determined to be applicable"* (310 CMR 40.0924(7)(a)). In that section, the MCP further specifies:

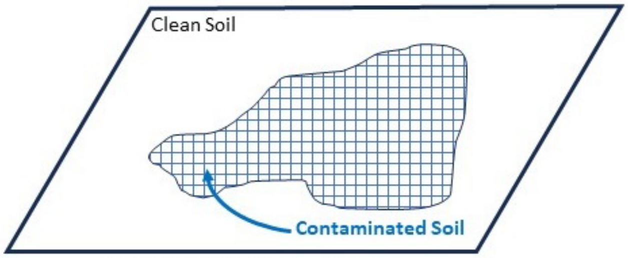
1. Where a contiguous volume of contaminated soil includes more than one soil category, the soil in different categories will represent separate exposure points, and
2. The top 3 feet of surface soil must be evaluated as a separate exposure point for current use scenarios.

To identify the soil exposure points for a Method 1 risk characterization the investigator must know <u>both the vertical and horizontal extent of contamination</u> and how the soil would be categorized at the site.

<u>Horizontal Distribution of Contaminants</u>

Figures 9-2 through 9-5 describe how different horizontal patterns of contamination should be considered when identifying soil exposure points.

Figure 9-2

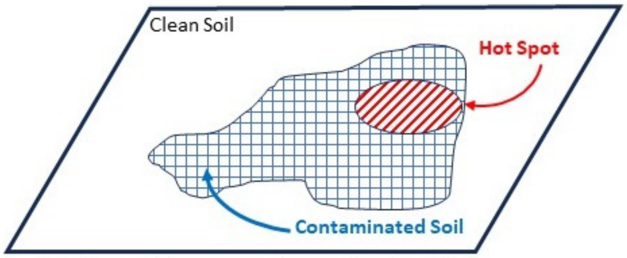


The Exposure Point would include *only* the contaminated soil.

For Methods 1 and 2 Risk Characterization, the Exposure Point(s) shall be defined by the horizontal and vertical extent and distribution of the contamination (310 CMR 40.0924(7)(a)) and do not include clean soil (As shown in Figure 9-2). Thus, the boundary of an Exposure Point is no larger than the extent of the soil contamination at the site. Figure 9-2 illustrates that only the area of contamination would be considered the soil Exposure Point.

Second, hot spots are specifically identified (310 CMR 40.0924(11)) as distinct exposure points. The identification of a "*hot spot*" is discussed in more detail in Section 4.3.2.1 of this document and is defined within the MCP as a discrete area with substantially higher contamination relative to the surrounding area. Thus, if a hot spot exists within a larger area of contamination, there would be at least two Exposure Points identified: the hot spot and the entire area of more generalized contamination including the hotspot. Figure 9-3 illustrates a hot spot as a distinct exposure point.

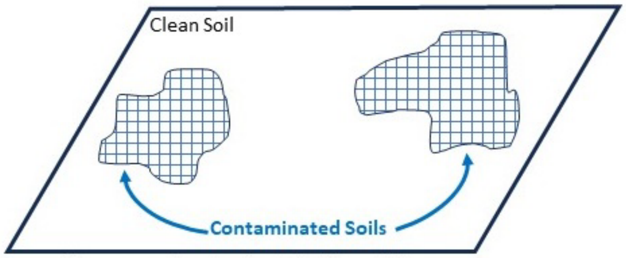
Figure 9-3



A Hot Spot within an area of contaminated soil is treated 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 separate Exposure Points. Figure 9-4 illustrates this point.

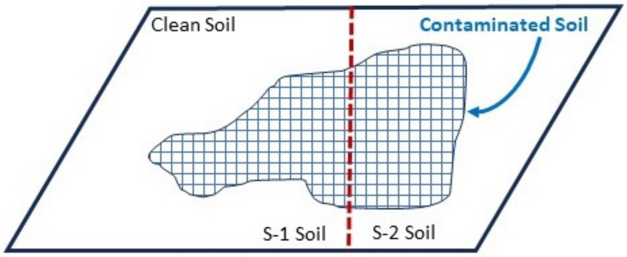
Figure 9-4



Two areas of contaminated soil would be treated as two separate Exposure Points.

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 9-5 Illustrates how this may occur.

Figure 9-5



A contiguous volume of contaminated soil which spans two soil categories is treated as two distinct Exposure Points.

Vertical Distribution of Contaminants

It is important to remember that the exposure points exist in three dimensions. While Figures 9-2 through 9-5 present exposure points in two dimensions (horizontal extent of contamination) for clarity, the depth component (vertical extent of contamination) is equally important to consider, as specified in the MCP at 310 CMR 40.0924(7)(a).

Delineation of each exposure point takes into account the extent and distribution of contamination along with the vertical extent of each soil category. **In all cases where there is contamination in the top 3 feet of soil,**

separate exposure points are required for the intervals from the zero to three foot depth interval and for the zero to fifteen foot interval (310 CMR 40.0924(7)(a)2.). This provision guards against underestimating ongoing exposures to surface soil under the current use.

The soil categories for different types of exposures are shown in the MCP Soil Category Selection Matrix (310 CMR 40.0933(9)). The matrix specifies different soil categories (S-1, S-2 or S-3) for high and low frequency and intensity of exposure for situations where children are present and situations where only adults are present.

In most cases shown in the matrix, the zero to three foot depth interval and the three to fifteen foot interval fall into different categories. In those cases, it is clear from the matrix alone that soil in the zero to three foot interval represents a separate exposure point because soil from different categories cannot be combined in a single exposure point and also because soil categories are applicable to specific volumes of soil (310 CMR 40.0933(1)). However, in two cases, soil in the zero to three foot interval falls into the same category as the deeper soil. These are:

- Areas where children are present and exposures are characterized as high frequency and high intensity (S-1), and
- Areas where only adults are present and exposures are characterized as low frequency and low intensity (S-3).

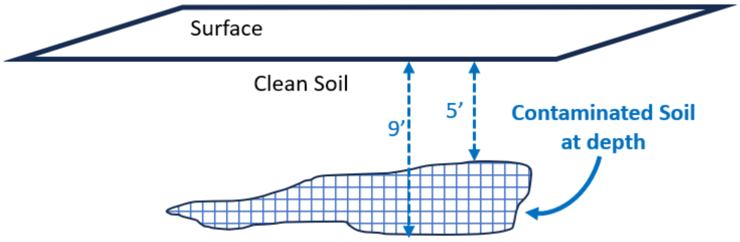
In these cases, the soils from zero to three feet and those from zero to fifteen feet must be assessed as separate Exposure Points. If either of the two exposure point concentrations exceeds the applicable Method 1 Standard, a condition of No Significant Risk cannot be achieved using Method 1.

In places where the soil column from the soil surface to 15 feet falls into a single category, the interval from 0 to 3 feet and the interval from 0 to 15 feet must be assessed as a separate Exposure Points.

Three additional points related to soil contamination at depth are important to keep in mind:

- Where contamination is present only at depth and does not extend upward to within three feet of the soil surface, it is not necessary to identify the top three feet as a separate exposure point, because it is outside of the volume of soils that is contaminated. For example, a volume of contaminated soil five feet to nine 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 9-6).

Figure 9-6



A volume of soil below the surface is also considered a Method 1 Exposure Point

- When considering the vertical distribution of contaminants, multiple soil categories, hot spots and isolated contamination would be considered in the same manner in three dimensions as they were described above. This means that an exposure point cannot extend beyond the vertical extent of contamination and cannot include soil that falls into different categories based on depth.

- With a Method 1 or Method 2 risk characterization, an Activity and Use Limitation may not be used to justify a conclusion that a condition of No Significant Risk exists or has been achieved (See Section 3.3.6 of this guidance document).

Under Method 1, exposure to soil at depth cannot be eliminated from the risk assessment due to an opinion that future contact has been or will be eliminated. Future soil exposure can only be eliminated under Method 3 or with the use of an AUL under Method 3.

9.9.3 Soil Exposure Point Concentrations

Exposure point concentrations are representative concentrations for the OHM within each exposure point and should be a conservative estimate of the mean (310 CMR 40.0926(5)). In some limited circumstances the maximum concentration must be used, such as when evaluating acute exposures, evaluating chemicals associated with lethal or severe health effects or when performing screening assessments (310 CMR 40.0926(6)). 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.

9.10 Characterizing Risk Under Method 1

Having identified the Method 1 standards applicable to the site (Section 9.7) and the site Exposure Points and Exposure Point Concentrations (Section 4.2.5, Section 11.3.3 and 11.3.4), 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 organized by environmental medium and exposure point comparing the exposure point concentrations to the applicable MCP Method 1 standards.

9.11 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. Chapter 13 of this guidance document discusses the MCP requirements for the evaluation of safety concerns (310 CMR 40.0960). The characterization of site safety risk would be included as part of the overall documentation of the risk characterization.

9.12 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 in the documentation of the Method 1 risk characterization (310 CMR 40.0973(8)) .

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 Permanent Solution pursuant to 310 CMR 40.1000 of the MCP. Achieving a condition of No Significant Risk is not the only requirement for a Permanent Solution: the regulations pertaining to Permanent and Temporary Solutions contain additional requirements, such as the elimination or control of continuing sources of OHM (310 CMR 40.1003(5)), implementing Activity and Use Limitations (310 CMR 40.1012) when required and achieving background conditions (310 CMR 40.1020) where feasible. The No Significant Risk standard should be thought of a *minimum* requirement. One important aspect of the MCP is that a distinction is made between *current* use, exposure and risk and *future* use, exposure and risk. As is the case for other methods, a 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 Temporary Solution is a possible outcome for such sites, as a demonstration that all substantial hazards have been eliminated is the applicable risk goal for Temporary Solutions (310 CMR 40.1050(1)(a)).

If one or more Exposure Point Concentrations exceed an applicable Method 1 standard, then a condition of No Significant Risk has *not* been achieved. One option to address this scenario is to employ a more site-specific risk characterization approach (Method 2 or Method 3) to evaluate the site risk. 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 Method 2 and Method 3 risk assessments is contained in Chapter 10 and Chapter 11, respectively, of this document.

Another option available is to conduct a remedial response action designed to reduce the concentrations of OHM 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.

9.13 Activity and Use Limitations (AULs)

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. AULs are used to inform future interests of the property of residual contamination and of potential uses of the property which could be inconsistent with the Permanent Solution 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 40.1012(3)(d) or where the levels of OHM are consistent with background (310 CMR 40.1012(3)(a) and 40.1020(2)). 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 assumption(s) that the activities and/or uses of the property have been restricted to reduce or eliminate exposure to the contaminated soil or groundwater. 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. There are, however, exceptions to this general rule. One exception is for soil at a depth greater than 15 feet that is categorized as S-3, but contaminants do not exceed the Method 3 Ceiling Limits. In such a case, an AUL is not required. The regulations specific to AULs may be found in the MCP at 310 CMR 40.1012 and 40.1070. Additional guidance on AULs can be found in Chapter 3 of this document and the Department's AUL Guidance.

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 OHM 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 required Activity and Use Limitations are in place.

9.14 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(s) (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 the uncertainty has a biased impact on the risk characterization results and, if possible, the magnitude of the effect.

References for Chapter 9:

MassDEP (2017). MCP Numerical Standards. Document reformatted in 2017 from original web age content.
https://www.mass.gov/files/documents/2017/12/27/MCP%20Numerical%20Standards%20-%20Derivation.pdf

MassDEP Guidance for Disposal Site Risk Characterization

Part 2 - Human Health Risk Assessment

Chapter 10
Method 2 Modifications

10.0 Method 2 Modifications

10.1 Introduction

The Massachusetts Contingency Plan (MCP) describes three different methods for characterizing the 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 Chapter 9 of this document, Method 1 Risk Characterization relies upon the use of promulgated, generic numerical standards for chemicals in groundwater and soil to assess potential risk. The Method 1 Standards were developed by the Department using relatively conservative (health-protective) assumptions to estimate potential exposures which could occur to contaminated soil and groundwater. These defined sets of assumptions (or "*exposure scenarios*") are considered to be conservative estimates of potential exposures at most sites.

In contrast to a Method 1 Risk Characterization, Method 3 employs site-specific exposure assumptions to characterize risks posed by contamination at a disposal site. Thus, Method 1 and Method 3 represent the extremes on the generic/site-specific continuum.

A Method 2 Risk Characterization is a blend of Method 1 and Method 3 Risk Characterizations. The Method 2 approach can be used to 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 have been developed for 123 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 modify existing Method 1 Standards by **incorporating site-specific fate and transport information**. The Method 1 standards consider the potential for chemicals to leach from the soil to groundwater or the potential for chemicals to discharge from the groundwater to surface water. These migration pathways may be examined under Method 2 either by using site-specific measurements and/or by employing computational models to identify site-specific cleanup goals.

A fate and transport model cannot be used under Method 2 to rule out risk from the vapor intrusion pathway because under 310 CMR 40.0981, Method 2 shall not be used if contamination is present in environmental media other than soil and/or groundwater. The evaluation of vapor intrusion exposures requires direct measurement of indoor air contaminant levels. Thus, only Method 1 or Method 3 can be used to assess risks from vapor intrusion.

The risk assessor may develop a new standard for a chemical lacking a Method 1 standard, adjust the fate and transport aspects of that new standard to address site-specific conditions, or *<u>both at the same time</u>*.

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.

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 all applicable Method 1 and/or 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.

When Method 2 is used to develop new standards or to modify selected Method 1 standards, the result is a risk assessment that incorporates Method 2 standards for some chemicals and/or pathways but retains the existing Method 1 standards for others. These assessments are designated as Method 2 risk assessments, despite being a blend of Method 1 and Method 2.

Any risk assessment that includes a new standard for a chemical not listed in the MCP and/or adjusted standards based on site-specific information is referred to as a Method 2 Risk Characterization.

10.2 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 Chapters 8 and 9 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 may use a combination of Method 1 standards and standards derived using Method 2, while at other sites Method 2 will not be an available option. 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 risk characterization report should affirm and document the applicability of Method 2 to the disposal site. Risk characterizations that do not document the applicability of the method selected will be considered incomplete by the Department.

The site characterization steps that are necessary to determine the nature and extent of contamination and to identify the exposure pathways that apply to Method 2 are addressed in Chapters 2 through 5. The remainder of this section focuses on the differences between Method 1 and Method 2 related to the derivation and values of the standards used to characterize risk.

10.3 Derivation of Additional Method 1 Standards

Method 1 Standards have been developed by MassDEP for one hundred and twenty-three chemicals or groups of chemicals. These chemicals were identified as those most commonly encountered at disposal sites. When chemicals not included in this group are encountered at a disposal site, standards may be developed using Method 2. The procedures to be followed in developing Method 2 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 to ensure that the numbers generated under Method 2 are consistent and comparable to those developed by MassDEP. 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 process for developing Method 1 Standards is described in MCP Numerical Standards (MCP, 2017).

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 in the risk assessment report. All sources used for the development of the standard should be referenced to support the Method 2 derivation.

10.4 Modification of Existing Method 1 Standards

In developing the Method 1 soil and groundwater standards, MassDEP made health-protective assumptions about the movement of contaminants through exposure pathways to ensure that the standards represent a level of No Significant Risk at virtually all disposal sites to which they are applicable. Computational fate and transport models are used to simulate leaching of contaminants from soil to groundwater and to estimate migration of contaminants from groundwater to indoor air (i.e., vapor intrusion).

Computational models have been defined as:
". . . ***models that use measurable variables, numerical inputs, and mathematical relationships to produce quantitative outputs***" (NAS 2007, U.S. EPA 2009).

The models employed to develop the Method 1 standards use generally conservative assumptions about site characteristics and input variables to obtain generic standards that are protective for most situations. As a consequence, these models will overestimate contaminant transport and Exposure Point Concentrations for some sites. Therefore, Method 2 allows three alternative approaches to account for site-specific conditions:

1. Collecting **site specific concentration data** on which to base the Method 2 Standard(s). This approach is preferred to the use of computational models. Absent unusual conditions, current exposure pathways must always be evaluated, in whole or in part, with actual site data. This approach is further described in Section 10.4.1.
2. Using **site-specific inputs** to the computational models used to derive the Method 1 standards. This approach is described in Section 10.4.2.
3. Using **different computational models** altogether to compute the Method 2 Standard(s). As described in Section 10.4.2, this approach requires substantially more justification and documentation than the first two approaches.

Where possible, direct measurement of environmental concentrations should be used rather than modeled concentrations.

Any of the three procedures listed above will result in a value that may be designated as a Method 2 Standard. Further, application of any of these should be sufficiently supported by follow-up monitoring to confirm that the Method 2 Standards protects against the risk of harm to human health and the environment.

It is important for risk assessors to be aware that there are some limitations on modifications to Method 1 standards. 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)).
- While some site-specific information may be used to adjust the leaching-component of the soil standards, Method 2 standards cannot exceed the soil standards based upon direct contact exposures listed in MCP Table 5 (310 CMR 40.0985(6)).
- A Method 2 GW-3 standard cannot override the requirements for surface water sampling detailed at 310 CMR 40.0904(2)(c).

10.4.1 Using Site-Specific Measurements to Identify Method 2 Standards

Direct measurements of concentrations may be used to develop Method 2 Standards for the site in question. There are three conditions under which this Method 2 approach may be appropriate.

1. Groundwater concentrations may be measured to judge whether site soil concentrations have resulted in groundwater concentrations that pose a risk of harm due to leaching. If not, the Method 2 soil standards may be set equal to the Method 2 Direct Contact Exposure-Based Soil Standards listed in Table 5 (310 CMR 40.0985(6)). However, if leaching is only being prevented by the presence of a building or overlying pavement, GW-2 standards cannot be developed in this way.

2. Sub-slab soil gas and indoor air may be analyzed to determine whether site groundwater contaminants pose a risk of harm via vapor intrusion. If not, the Method 2 GW-2 groundwater standard may be set

equal to the site groundwater concentration or the applicable Method 3 Ceiling Limit in Groundwater listed in 310 CMR 40.0996(7), whichever is lower, as described (per 310 CMR 40.0982(4)).

3. Groundwater concentrations at the leading edge of a stable plume[4] may be analyzed to determine whether site groundwater poses a risk of harm to surface water. If not, the Method 2 GW-3 groundwater standard may be set equal to the groundwater concentration in the source area or the applicable Method 3 Ceiling Limit in Groundwater listed in 310 CMR 40.0996(7), whichever is lower, as described (per 310 CMR 40.0982(4)).

In principle, these methods are straightforward to apply and involves the following steps:

1. Measure the contaminant concentrations in the source medium:
    - Where the leaching potential from contaminated soil is being evaluated, soil is the source medium.
    - Where the transfer of contaminants from groundwater through sub-slab soil gas to indoor air is being evaluated, groundwater is the source medium.
    - Where the transfer of contaminants from groundwater into surface water is being evaluated, groundwater is the source medium.

2. Measure the contaminant concentrations in the receiving medium:
    - Where the leaching potential from contaminated soil is being evaluated, groundwater is the receiving medium.
    - Where the transfer of contaminants from groundwater through sub-slab soil gas to indoor air is being evaluated, both sub-slab soil gas and indoor air should be analyzed as receiving media.
    - Where lateral groundwater transport is being evaluated, groundwater at the edge of a stable plume should be analyzed as the receiving medium.

3. Compare the concentrations in the receiving medium to the risk-based target concentrations on which the Method 1 target risk-based concentrations are based. (See column 3 in Table 10.1.)

4. If the concentration in the receiving medium is below the target concentration, the source medium concentration may be identified as the relevant Method 2 Standard unless one of the following applies:
    - If a Method 2 soil standard is above the direct contact value listed in MCP Table 5 of 310 CMR 40.0985(6), then the Method 2 standard is set at the direct contact-based concentration.
    - If a Method 2 GW-2 or GW-3 groundwater standard is above the Method 3 Ceiling Limit listed in Table 6 at 310 CMR 40.0996(7), then the Method 2 groundwater standard is set at the Method 3 Ceiling Limit.

Since this procedure is intended to consider fate and transport adjustments only, the receiving medium concentrations on which the Method 1 Standards are based are used as the target concentrations for Method 2 standards. These are shown in the third column of Table 10.1.

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[4] A stable plume is one where the extent of groundwater contamination is not expanding and the contaminant concentrations within the plume are not increasing.

Table 10-1
Applying Site-Specific Measurements to Identify Method 2 Standards

Assessment Objective	Receiving Medium (in which site concentrations are measured)		Conclude that the source medium concentration will not pose a significant risk by the transport pathway if the receiving medium concentration is below the target concentration:
To demonstrate that the Method 1 leaching model overestimates the groundwater concentration.	Groundwater		For each groundwater category applicable at the site: • the measured site groundwater concentrations are less than or equal to all applicable GW-1, GW-2 and/or GW-3 Standards; and • the measured site groundwater concentrations are less than or equal to all applicable Method 3 Ceiling Limits.
To Demonstrate that the Method 1 vapor intrusion model overestimates concentrations in indoor air.	Indoor Air		For each Contaminant of Concern: • The measured indoor air concentration is equal to or less than the "Target Indoor Air Level" listed in the MCP GW.xlsx workbook, tab "GW-2", column J; and • the measured site groundwater concentrations are less than or equal to all applicable Method 3 Ceiling Limits.
To demonstrate that the assumptions used to set the Method 1 GW-3 standards overestimate the concentrations at the leading edge of the plume.	Leading edge of a stable plume		For each Contaminant of Concern: • The measured site groundwater concentration at the leading edge of the plume is equal to or less than the 10 x "Lowest Ecological Criterion" listed in the MCP GW.xlsx workbook, tab "GW-3", column B; and • the measured site groundwater concentrations are less than or equal to all applicable Method 3 Ceiling Limits. (The factor of 10x accounts for groundwater to surface water dilution.)

As is always the case, the quality and quantity of data used in site assessment are key considerations for risk assessment. Reliable data is crucial because it provides the basis for making informed decisions about whether a condition of no significant risk exists or does not exist at the site.

10.4.2 Using Computational Models to Develop Method 2 Standards

This section addresses the use of computational models to approximate the migration of oil and hazardous material by simulating physical processes.

Possible computational model modifications of Method 1 Standards include:

- The use of a site-specific model and/or model inputs to demonstrate that residual soil levels will not result in an exceedance of an applicable groundwater standard; and
- The use of site-specific migration models to demonstrate that the groundwater will not pose a significant risk when it discharges to surface water.

Except as described under Method 1 (See Section 9.3), a computational model alone cannot be used to rule out impacts on indoor air via vapor intrusion. Direct measurements must be used for this purpose.

The main objective of this section is to outline the steps for developing, applying and evaluating computational models in Method 2 Risk Characterizations. The applicable steps must be documented whenever a model is used in the risk assessment. Section 10.4.2.1 describes modeling terminology with the aim of facilitating clear and constructive communications about models and their use. Note that the requirements and recommendation in this section apply equally to the use of computational models in Method 3 Risk Characterizations (Chapter 11).

This section draws heavily from two publications: U.S. EPA's *Guidance on the Development, Evaluation and Application of Environmental Models* (U.S.EPA, 2009) and the National Academy of Sciences' *Models in Environmental Regulatory Decision Making* (NAS, 2007). The reader is referred to these publications for detailed and complete guidance on developing and evaluating computational models. Comprehensive guidance is beyond the scope of this document.

10.4.2.1 Terminology and Procedural Updates for Using Models in Method 2

Computational modeling guidance and the terminology are continually evolving. MassDEP's 1994 Guidance referred to computational models as *predictive* models and recommended *model validation* to demonstrate a model's reliability. However, models employed in environmental regulation represent complex environmental systems. Scientists and practitioners have long challenged the portrayal of such models as predictive and disputed the idea that predictive power can be *validated* by comparing measured result to modeled results at a given point in time (Oreskes 1998).

"It is not possible to demonstrate the predictive reliability of any model of a complex natural system in advance of its use".
(Oreskes 1998)

It has become conventional to refer to models used in environmental regulation as *computational models*, and to use the term *model evaluation* (as opposed to validation) to assess whether the results of a model are of sufficient quality and reliability to serve as the bases for decisions (See Box 10-1).

The National Academy of Sciences and the U.S. Environmental Protection Agency have published extensive, detailed guidance on developing, selecting and evaluating models (NAS 2007, U.S. EPA 2009). Within these frameworks, model evaluation is a continuing process from development of the conceptual site model through application of a model, as depicted in Figure 10-1.

The recommendations offered in the EPA guidance are drawn from Agency white papers, EPA Science Advisory Board reports, the National Research Council's Models in Environmental Regulatory Decision Making, and peer-reviewed literature. For organizational simplicity, the recommendations are categorized into three sections: model development, model evaluation, and model application, as follows:

Model development can be viewed as a process with three main steps: (a) specify the environmental problem (or set of issues) the model is intended to address and develop the conceptual model, (b) evaluate or develop the model framework (develop the mathematical model), and (c) parameterize the model to develop the application tool.

Model evaluation is the process for generating information over the life cycle of the project that helps determine whether a model and its analytical results are of sufficient quality to serve as the basis for a decision. Model quality is an attribute that is meaningful only within the context of a specific model application. In simple terms, model evaluation provides information to help answer the following questions: (a) How have the principles of sound science been addressed or applied during model development? (b) How is the choice of model supported by the quantity and quality of available data? (c) How closely does the model approximate the real system of interest? (d) How well does the model perform the specified task while meeting the objectives set by quality assurance project planning? Model evaluation steps are outlined in Figure 10-1.

Model application (i.e., model-based decision making) is strengthened when the science underlying the model is transparent. The elements of transparency emphasized in this guidance are (a) comprehensive documentation of all aspects of a modeling project (suggested as a list of elements relevant to any modeling project) and (b) effective communication between modelers, analysts, and decision makers. This approach ensures that there is a clear rationale for using a model for a specific regulatory application.

Model Corroboration is a qualitative and/or quantitative evaluation of a model's accuracy and predictive capability. It involves comparison of model results to site data and is akin to the evaluation step formerly referred to as "validation."

Box 10-1
Model Evaluation Terminology
(From U.S. EPA 2009)

Model evaluation is defined as the process used to generate information to determine whether a model and its analytical results are of a quality sufficient to serve as the basis for a decision.

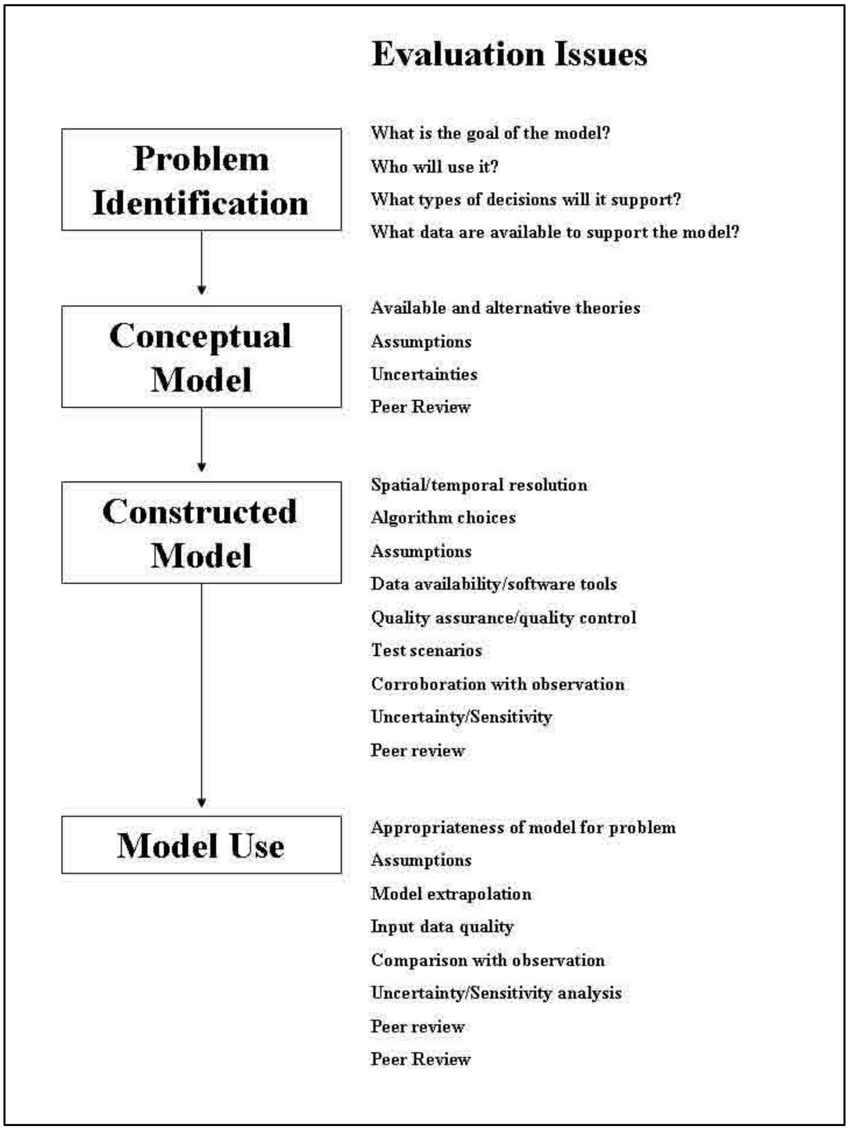
Model corroboration includes all quantitative and qualitative methods for evaluating the degree to which a model corresponds to reality.

Uncertainty analysis investigates the lack of knowledge about a certain population or the real value of model parameters.

Sensitivity analysis is the study of how a model's response can be apportioned to changes in model inputs (Saltelli et al. 2000)

Verification refers to activities that are designed to confirm that the mathematical framework embodied in the module is correct and that the computer code for a module is operating according to its intended design so that the results obtained compare favorably with those obtained using known analytical solutions or numerical solutions from simulators based on similar or identical mathematical frameworks.

Figure 10-1
Computational Model Evaluation Process
(National Academy of Sciences, 2007)



10.4.2.2 Modifying the Models Used to Develop Method 1 Standards

Risk assessors are not limited to using the models employed by MassDEP in setting the Method 1 standards. Selection of a different model is an option, as long as the chosen model is fully documented and evaluated consistent with the principals and practices described by the National Academy of Sciences (NAS 2007) and EPA's guidance (U.S. EPA 2009). Nevertheless, the documentation needed to apply a different model would be extensive. Consequently, it is likely that risk assessors will most often opt to use MassDEP's Method 1 models with site-specific input values.

To provide a starting point for modifications of Method 1 models, this section outlines the models and assumptions that were used to develop the Method 1 standards. Key Method 1 modeling procedures and assumptions are described below and summarized in Table 10.2. More details are provided in Appendix 8-A and 8-B.

Method 1 Models for Leaching of Contaminants from Soil

As stated in Chapter 9, the Method 1 Soil Standards listed in Tables 2,3 and 4 (310 CMR 40.0975(6)(a), (b) and (c)) consider the potential for contamination in soil to leach into the groundwater and to result in adverse impacts on the aquifer. The parameters selected for input into the models were based upon assumptions about a "typical disposal site". 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, alternative model parameters may be used to demonstrate that the concentrations of OHM 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.

The result of Method 2 modifications of the Method 1 soil standards is an alternative set of soil standard(s) 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)).

Method 1 Model for Volatilization of Contaminants from Groundwater to Indoor Air

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 used to develop the Method 1 Standards was the Heuristic Model for screening-level calculations developed by Johnson and Ettinger (1991). The development of GW-2 standards based upon this model is described in Appendix 8-B.

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. However, *in a Method 2 Risk Characterization, a computational model alone cannot be used to rule out impacts on indoor air via vapor intrusion*. Only direct measurements may be used for this purpose. Alternative (Method 2) groundwater standards must be based on direct measurement of concentrations.

The result of a Method 2 modification of the Method 1 GW-2 standards is one or more alternative groundwater standards which are both demonstrated to be protective of potential indoor air exposures *and* equal to or less than the groundwater Method 3 Ceiling Limit listed in Table 6 of the MCP (310 CMR 40.0996(7)). If the site-specific volatilization-based groundwater concentration is greater than the groundwater Method 3 Ceiling 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 Method 3 Ceiling Limit in Table 6 are adopted as the Method 2 GW-2 standards (310 CMR 40.0982(4)).

Method 1 Standards for Discharge to Surface Water

The MCP GW-3 standards consider potential impacts from the discharge of contaminated groundwater into a surface water body. Method 1 GW-3 standards are developed considering dilution and attenuation. The standards incorporate a simple dilution factor of ten (10) which is based upon the experience of MassDEP Bureau of Water Resources (BWR) in writing groundwater and surface water discharge permits.

- The groundwater attenuation factor is a value based on the organic carbon portioning coefficient (Koc) using the following criteria.
  - Chemicals with a Koc less than 1,000 were assigned an attenuation factor of 2.5.
  - Chemicals with a Koc between 1,000 and 100,000 were assigned an attenuation factor of 25.
  - Chemicals with a Koc greater than 100,000 were assigned an attenuation factor of 100.

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 OHM in the groundwater at the point of discharge. The risk assessor may opt to apply a computational model to determine whether the groundwater concentration at the site will significantly affect surface water and when determine a groundwater concentration (i.e., a Method 2 standard) that would represent a condition of No Significant Risk for this pathway.

Only the attenuation component of GW-3 standards may be modified. The factor of 10 for dilution at the point of discharge to surface water cannot be increased or eliminated.

The result of a Method 2 modification of the Method 1 GW-3 standards is an alternative set of groundwater standards which are both demonstrably protective of receiving surface water bodies *and* equal to or less than the groundwater Method 3 Ceiling Limit listed in Table 6 of the MCP (310 CMR 40.0996(7)). If the calculated site-specific surface water risk-based concentration is greater than the groundwater Method 3 Ceiling Limit, (or if the site-specific information indicates that material will not discharge to a surface water body at significant levels), then the Method 3 Ceiling Limit in Table 6 of Subpart I is adopted as the Method 2 GW-3 standard (310 CMR 40.0982(4)).

10.4.2.3 Selecting or Developing New Models to Compute Method 2 Standards

As previously stated, Method 2 is most often based either on site-specific data (Section 10.4.1) or by modifying the computational models used for the Method 1 Standards (Section 10.3.2.2). Employing different models is less common, but it is not prohibited. The process of selecting, developing and/or evaluating models is complex and resource-intensive, and comprehensive guidance for doing so is beyond the scope of this guidance document. Users in need of such guidance are referred to U.S.EPA's *Guidance on the Development, Evaluation and Application of Environmental Models* (U.S.EPA 2009). EPA's guidance draws heavily from the National Academy of Sciences' *Models in Environmental Regulatory Decision Making* (NAS 2007), which provides a context for understanding and applying U.S.EPA's guidance. The reader is referred to these publications for detailed and complete guidance on developing and evaluating computational models.

The basic steps in modeling for environmental decision making are presented in Box 2 of EPA's guidance (U.S.EPA 2009). An abbreviated summary follows:

- **Problem Identification and Specification**
    - Definition of model purpose
    - Specification of modeling context
- **Model Development**
    - Conceptual model formulation
    - Computational model development
- **Model Evaluation**
    - Model testing and revision
- **Model Application**
    - Model use

10.4.2.4 Considering Uncertainty in Computational Models

There is considerable variability in the scope, complexity, and reliability of available models. Although computational modeling has become an integral part of the site assessment and risk characterization process, there has been little standardization or evaluation 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 caution in the evaluation, utilization, and interpretation of modeling results. The risk assessor must justify and document the use of a computational model as part of a Method 2 Risk Characterization (310 CMR 40.0985(1) and 40.0986(1)).

10.5 General Requirements for Method 2 Risk Characterization

Employing Method 2 is not limited to identification of alternative standards. The standards are applied in the context of a complete risk assessment. The process for a Method 2 Risk Characterization will follow the same methodology as a Method 1 Risk Characterization (310 CMR 40.0973 and 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 and 40.0973(1))
- 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, 40.0974 and 40.0975)
- Compare the Exposure Point Concentrations to Applicable Method 1 and Method 2 Standards (310 CMR 40.0973 and 40.0982)
- Clearly State Conclusions of the Risk Characterization (310 CMR 40.0973 and 40.0988).

These risk characterization steps are discussed in detail for Method 1 in Chapter 9 of this document, and the reader is referred there for specific requirement.

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