MassDEP Guidance for Disposal Site Risk Characterization

Part 2 - Human Health Risk Assessment

Chapter 11
Method 3 Risk Characterization

11.0 Method 3 – Risk Characterization Introduction

This chapter provides guidance on conducting a Method 3 Human Health Risk Characterization. The Human Health Risk Characterization is one of *four* distinct assessments that comprise a complete Method 3 Risk Characterization: the risks to human health, safety, public welfare and the environment 310 CMR 40.0901(4). The Method 3 Human Health Risk Characterization is the most site-specific of the three risk characterization methods available under the Massachusetts Contingency Plan (MCP), a Method 3 assessment is an option at all Massachusetts General Law, Chapter c.21E (c.21E) sites.

The specific regulations concerning the Method 3 risk characterization process begin at 310 CMR 40.0990 of the MCP. Readers are reminded that general requirements applicable or potentially applicable to all risk characterizations are found in 310 CMR 40.0900 through 40.0960 and are described in Chapters 1 through 17 of this guidance document.

The Method 3 Human Health Risk Characterization involves five steps: hazard identification, dose-response assessment, exposure assessment, risk characterization and uncertainty analysis.

A Method 3 Risk Characterization Is Complete If the following 4 assessments have been conducted:

- Risk to Human Health (Chapter 11)
- Risk to Safety (Chapter 13)
- Risk to Public Welfare (Chapter 13)
- Risk to the Environment (Chapters 14 -17)

The scope and level of effort needed to complete each component of a Method 3 Risk Characterization will vary depending upon site conditions.

Hazard Identification determines whether a contaminant causes adverse effects and identifies those effects. This step describes why the contaminant is of regulatory concern (see Section 11.1).

Dose-Response Assessment describes the relationship between the exposure and the likelihood and/or severity of an adverse effect (see Section 11.2).

Exposure Assessment identifies potential pathways and routes of exposure, characterizing the populations exposed, and determining the frequency, duration, and extent of exposures (see Section 11.3).

Risk Characterization combines information from the previous three steps to describe the type (e.g., noncarcinogenic, or carcinogenic) and magnitude of risks to exposed populations (see Section 11.4). The resulting risks are then compared to the risk management criteria promulgated in the regulations.

Uncertainty Analysis identifies the nature and, when possible, the magnitude of the uncertainty and variability inherent in the characterization of risks (see Section 11.5). The results of any risk assessment reflect scientific uncertainty resulting from limitations in available data and assumptions that are made in the absence of such data, and the variability in exposure and toxicological response expected given the diversity within the human population. The major uncertainties and limitations in the risk characterization should be explicitly discussed.

Each of these risk assessment steps is described in detail in this chapter.

Risk assessment assumptions are data-informed decisions about exposure factors in a risk assessment. The use of the word "assumptions" does not imply a lack of data or rigor. U.S. EPA states that these values are "based on general scientific knowledge of the phenomena in question and are also matters of policy concerning the appropriate way to bridge uncertainties that concern potential risk to human health" (U.S. EPA, 2005a).

Risk assessment is the tool used throughout regulatory processes to inform decisions to determine, for example:

- "How clean is clean enough?" at a disposal site
- Drinking water standards for public water supplies
- Impacts of a proposed facility seeking a source permit

No Significant Risk under the MCP (310 CMR 40.0006) means "a level of control of each identified substance of concern at a site or in the surrounding environment such that no such substance of concern shall present a significant risk of harm to health, safety, public welfare or the environment during any foreseeable period of time". Note that oil and/or hazardous material (OHM) determined to be below background levels need not be included in risk estimates in the disposal site Risk Characterization (40.1020(2)). Risk limits reflect risk management decisions established to ensure that no potential receptor groups are exposed to multiple chemicals, through multiple pathways and multiple exposure routes related to a disposal site that exceed predetermined levels of risk. The cancer risk limit evaluates the excess lifetime cancer risk from exposures at a site. The non-cancer risk limit evaluates the estimated "allowable" dose - a dose which would not be expected to result in adverse health effects from exposures at a disposal site.

Under the MCP the cumulative cancer risk limit is an **Excess Lifetime Cancer Risk (ELCR) of one-in-one hundred thousand and the cumulative non-cancer risk shall not exceed a Hazard Index equal to one** for chronic exposures. Under Method 3, remediation of the disposal site is required if: (1) exposure point concentrations (EPCs) exceed any applicable or suitably analogous public health standards, or (2) the estimated cancer or non-cancer risks associated with exposure to OHM exceed the Cumulative Receptor Risk Limits (310 CMR 40.0993(10)). Remedial alternatives must be evaluated to determine if they eliminate "Significant Risk" as defined in the MCP.

MassDEP's Office of Research & Standards (ORS) has developed and published risk characterization tools known as Shortforms to assist risk assessors. The Shortforms are an optional tool designed to streamline the Method 3 risk assessment and review process. While Method 3 risk assessments are site-specific, some exposure scenarios are sufficiently standardized for a template approach. MassDEP has assembled the recommended exposure assumptions and toxicity information into the Shortform spreadsheets in Excel to calculate risk for

each of these standard scenarios. The Shortforms incorporate standard inputs for assessing exposures and equations that are used to estimate human health cancer and non-cancer risks. Shortforms are available in Excel spreadsheets for a variety of receptors (resident, construction worker, office and school worker, park visitor, trespasser) and environmental media (soil, water, and air) and for many OHM. However, it is important to note that the Shortforms do not address all potential OHM and/or all exposure pathways, and do not sufficiently assess short-term acute exposure risk. If chronic exposure results in potential health risks, the risk assessor must ensure that there is no potential for acute health risks. The output of the Shortforms is a series of summary tables that describe the EPCs, toxicity information, and potential chemical-specific, medium-specific, and cumulative health risks. These output tables can be submitted as an appendix to the narrative of the Human Health Risk Characterization portion of a Method 3 Risk Characterization only when all site OHM and exposure pathways are addressed and potential short-term acute risks are either not associated with site or have been otherwise addressed. **Any modifications made to the Shortforms must be justified and documented in the risk characterization**. The failure to document and justify modifications to the Shortforms used in a Method 3 risk assessment is considered a violation of the MCP and the risk assessment will be rejected by the Department. If the Shortforms are used, the other required information discussed in this document should still be provided.

11.1 Hazard Identification

The hazard identification portion of an MCP Method 3 Risk Characterization describes the hazards associated with each OHM selected as a Contaminant of Concern (COC). The hazard identification discusses whether exposure to a particular contaminant can cause an increase of particular adverse health effects and whether the adverse health effects are likely to occur in humans.

The hazard identification section of the risk assessment should contain:

(1) identification of the OHMs which have been selected as COCs (see Chapter 7),
(2) a summary of the analytical data which have been collected for these OHMs relevant to risk assessment presented by specific environmental medium, and
(3) a description of the potential health effects (with references) which may be associated with exposure to each OHM or references to readily available, and reputable sources of toxicity information for the OHM.

11.1.2 Toxicity Profiles. The purpose of the toxicity profile is to consolidate available toxicological information about the COCs and as a tool for risk communication to the general public. Toxicity profiles should focus on COCs that are one of the primary contributors to risk at the site of concern. A toxicity profile is a compilation of toxicological information on a COC included in a Method 3 Human Health Risk Characterization. In general, a toxicity profile provides a thorough toxicological assessment of the available information observed in animal, epidemiological and other studies, including the adverse effects on organ systems, developmental/reproductive toxicity, toxicokinetics, mechanisms of toxicity, carcinogenicity, and genotoxicity for the chemical. If this is based on reputable, authoritative assessments (e.g., ATSDR *Toxicological Profiles*), a summary, with detailed references to all sources, is sufficient. A toxicity profile should also include a summary in language that is understandable to non-scientists.

Toxicity profiles serve a couple of purposes. They provide an assessment and summary of the potential adverse human health effects which may be associated with exposure to the OHM under evaluation and contain references for the dose-response assessment. Toxicity profiles also serve as reference material for non-toxicologists, including community members who are involved with or interested in activities at the site and who want to understand the potential health impacts associated with contaminants at the site.

There are readily available sources of reputable, authoritative toxicity assessments for many OHM at sites, such as U.S. EPA's *Toxicological Reviews* and ATSDR's *Toxicological Profiles* for various chemicals. The hazard identification should reference toxicological sources for each COC. If an assessment of potential health effects has not been published by a reputable and authoritative source and a COC is a significant contaminant at the site based on concentration, mass, exposure or risk potential, the hazard identification should include a thorough toxicological assessment for that contaminant prepared by the risk assessor or a toxicologist.

Information in toxicity profiles may also be used to justify grouping chemicals by health endpoint and mechanism of toxicity to estimate more detailed Hazard Indices. The reader should refer to Section 11.4.2 for more information on calculating endpoint-specific Hazard Indices.

11.2 Dose Response Assessment

The dose-response assessment describes the observed effects in humans and/or laboratory animals associated with specific exposures (or doses) of the COC. This information is obtained from published peer reviewed literature or government agencies describing epidemiologic or toxicologic studies involving the specific chemical. For most chemicals reported at c.21E disposal sites, the dose-response information needed to conduct a risk assessment may be found in secondary sources published by U.S. EPA or other government agencies, as described below.

The dose-response relationship(s) for each OHM which has been selected as a COC must be identified in the risk assessment report. This information is later coupled with knowledge of the nature and magnitude of potential exposures to characterize (and where possible, to quantify) potential risk.

The dose-response information may be divided into three major categories:

- Noncarcinogenic effects.
- Carcinogenic effects.
- Relative absorption factors (RAFs) are used to relate the toxicity information identified from the scientific literature to the exposure pathways of concern at the disposal site under investigation (see 11.2.4).

Research on chemical effects and methods for extrapolating from high dose studies in animals to environmental exposure levels in humans has continued since this guidance was originally published in 1995. This work has improved collective understanding of the exposures, the adverse outcomes and the associated modes of action for COCs. In addition, the variability within populations and uncertainty in the estimates are better characterized.

These research efforts have led to an increased utilization of chemical-specific information on effects, exposure, and mode of action to better characterize the variability and uncertainty in the available information and to acknowledge the science policy underlying the use of default approaches when chemical-specific information is limited.

> ***All*** chemicals selected as Contaminants Of Concern (COCs) should be evaluated for potential *noncarcinogenic* health effects. In addition, any contaminant determined to be *carcinogenic* to humans, or *likely to be carcinogenic* to humans should also be evaluated for its potential carcinogenic effect.

The MCP requires the use of toxicity values developed by MassDEP and also specifies the sources of values to be used when MassDEP has not developed values (See Section 11.2.3.1). When a toxicity value is not available from any of the sources listed in the MCP, derivation of toxicity values should be performed by an experienced risk assessor/toxicologist.

Sections 11.2.1 (non-cancer) and 11.2.2 (cancer) describe the bases and current practices for deriving toxicity values for use in risk assessment.

11.2.1 Non-cancer Effects.

Chemicals may be classified as carcinogenic, based on amount and type of evidence, yet all chemicals exhibit non-cancer toxicity. Consistent with current risk assessment practice, non-cancer toxicity is typically treated as if there is an identifiable exposure threshold (both for the individual and for populations) below which there are no observable adverse effects (U.S. EPA, 2002a). All chemicals, including those that are mutagenic or carcinogenic, have non-cancer effects.

Historically, animal study data and human epidemiological data were evaluated to determine a no observed adverse effect level (NOAEL) or a lowest observed adverse effect level (LOAEL), which were used as the point of departure (POD). The POD is defined in the IRIS glossary (U.S. EPA, 2025) as the "dose-response point that marks the beginning of a low-dose extrapolation." Beginning in 1996, benchmark dose modeling (BMD), a standardized method for estimating an effect level from the study dose-response data, has replaced the NOAEL/LOAEL approach as the preferred method for deriving a POD (U.S. EPA, 2000a, 2012a). The benefits of the BMD approach are that it relies on more than a single data point as the basis for the POD, using the shape of the dose response curve, study variability and a defined response rate to estimate a consistent POD. Regardless of the method for selection of the POD, the POD from the test population is extrapolated to the human population, including susceptible members of the population, using data-informed extrapolation methods and uncertainty factors (U.S. EPA, 1994, 2002, 2011, 2012b, 2014a). Additional uncertainty factors may be applied to account for limitations in the available toxicity information, including (1) extrapolating from subchronic to chronic exposure duration, (2) from a LOAEL to a NOAEL, (3) if the BMD approach is not used, and (4) a lack of data for multiple organ systems (U.S. EPA, 2002a, U.S. EPA 2006c).

The oral reference dose (RfD) and inhalation reference concentration (RfC) are non-cancer toxicity values derived by U.S. EPA using the most relevant peer reviewed toxicology and epidemiology literature, and extrapolation methods. Chronic RfDs and RfCs are estimates (with uncertainty spanning perhaps an order of magnitude) of a dose or exposure over a chronic duration (up to a lifetime) to the human population (including sensitive subgroups). This estimate represents a level that is likely to be without an appreciable risk of deleterious effects during a lifetime (U.S. EPA, 2025).

The oral RfD is typically in units of milligrams of chemical per kilogram of body weight per day (mg/kg-day), and the inhalation RfC is in units of milligrams of chemical per cubic meter of air (mg/m^3). A subchronic RfD or RfC is an estimate (with uncertainty spanning perhaps an order of magnitude) of exposure for a subchronic duration (up to 10%

of average lifespan) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime (U.S. EPA, 2025).

11.2.2 Carcinogenic Effects

Carcinogens cause cancer by multiple modes of action. Carcinogenic risk assessment is based on the concept that any exposure results in some increase in cancer risk, and that there is no threshold for chemical carcinogenesis. (U.S. EPA, 2005a).

U.S. EPA determines the weight of evidence for carcinogenic potential (or hazard) of a chemical based on the available toxicity data and, based on this evaluation, selects one of five cancer descriptors: (1) carcinogenic to humans, (2) likely to be carcinogenic to humans, (3) suggestive evidence of carcinogenic potential, (4) inadequate information to assess carcinogenic potential, or (5) not likely to be carcinogenic to humans (U.S. EPA, 2005a). Chemicals reviewed by U.S. EPA before 2005 were evaluated using the previous cancer descriptors (U.S. EPA, 1986, 1996, 1999); therefore, U.S. EPA cancer values have a mix of cancer classification language depending on the chemical and time of the evaluation.

U.S. EPA's (2005a) Cancer Guidance reviewed the available science underlying our understanding about how carcinogens cause cancer – carcinogenic modes of action - and presents cancer risk assessment approaches.

The dose-response assessment method used for a carcinogenic chemical is informed by what is known about the mode of action, the sequence of key events and processes that result in cancer formation (U.S. EPA, 2005a):

- The default dose-response assessment method is to assume linear increase in risk of cancer as the dose increases;
- Chemicals with sufficient evidence that exposure during early life increase the risk of cancer relative to exposures beginning after adolescence are evaluated using linear dose response methods and data with exposure periods including early life (U.S. EPA, 2005b,c, 2006a,b); and
- Chemicals with evidence of early life susceptibility and/or mutagenic mode of action without sufficient data for dose-response assessment of early life exposures are evaluated using the default age-dependent adjustment factors (ADAFs) for exposures to age groups between birth and 16 years of age (U.S. EPA, 2005b, 2006b).

The ability of a chemical to increase the incidence of cancer in a target population is described by one of two measures: (1) the cancer slope factor (CSF) for oral and dermal exposures or (2) the inhalation unit risk (IUR) for inhalation exposures.

Cancer risk for both the CSF and IUR are usually estimated from animal bioassay data. The point of departure (POD) is identified using the dose-response data in the range of the data, e.g., a 10% response rate yielding an estimate of the dose associated with a 10% response rate (i.e., Benchmark Dose 10% or BMD_{10}), then the lower confidence level of the POD, the $BMDL_{10}$, is used to create a line to zero dose/the origin. The slope of this line is the CSF - based on the 95% lower bound (lower confidence limit) on the POD, the $BMDL_{10}$.

The CSF is expressed as the risk per unit dose and is typically given in units of $(mg/kg\text{-}day)^{-1}$. The CSF is an upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime exposure to an agent (U.S. EPA, 2005a). This estimate, usually expressed in units of proportion (of a population) affected per mg/kg-day (sometimes written $(mg/kg\text{-}d)^{-1}$).

The IUR is the upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 microgram per cubic meter ($\mu g/m^3$) in air (U.S. EPA, 2025). The interpretation of an IUR would

be as follows: if UR = 2×10^{-6} per µg/m³, 2 excess cancer cases (upper bound estimate) are predicted to develop per 1,000,000 people if exposed daily for a lifetime to 1 µg of the chemical per m³ of air.

11.2.3 Sources of Non-cancer and Cancer Toxicity Values.

There are several sources of toxicity values. Note that sources differ in the frequency at which they are updated and the level of review they receive. Method 3 risk characterizations should use current toxicity values.

11.2.3.1 MassDEP-Derived Toxicity Values

The MCP requires that primary consideration be given to information developed by the Massachusetts Department of Environmental Protection (MassDEP) (310 CMR 40.0993(5)).

Toxicity values for specific chemicals are listed at 310 CMR 40.0993(6):

> *When identifying toxicity values for use in a Method 3 Risk Characterization, the following toxicity values shall be used:*
> *(a) For perchlorate, a chronic and subchronic RfD of 7E-5 mg/(kg-day);*
> *(b) For methyl tert-butyl ether, a chronic RfD of 1E-1 mg/(kg-day);*
> *(c) For methyl tert-butyl ether, a subchronic RfD of 1E0 mg/(kg-day);*
> *(d) For tetrachloroethylene, an oral cancer slope factor of 2E-2 per mg/(kg-day);*
> *(e) For tetrachloroethylene, an inhalation unit risk of 3E-6 per ug/cubic meter; and*
> *(f) For the sum of the following per- and polyfluoroalkyl substances (PFAS), a chronic and subchronic reference dose of 5E-6 mg/(kg-day):*
> *1. Perfluorodecanoic acid (PFDA);*
> *2. Perfluoroheptanoic acid (PFHpA);*
> *3. Perfluorohexanesulfonic acid (PFHxS);*
> *4. Perfluorononanoic acid (PFNA);*
> *5. Perfluorooctanesulfonic acid (PFOS); and*
> *6. Perfluorooctanoic acid (PFOA).*

This list of chemicals and toxicity values, including for PFAS, may be revised and expanded; the risk assessor is responsible for checking for updates.

Toxicity values for other COCs should be chosen in accordance with the following hierarchy (310 CMR 40.0993(7)):

> *(a) Toxicity values adopted or otherwise published by MassDEP;*
> *(b) Toxicity values listed in U.S. EPA's Integrated Risk Information System (IRIS) database; and*
> *(c) Other U.S. EPA and non-U.S. EPA sources including, but not limited to, U.S. EPA Provisional Peer Reviewed Toxicity Values (PPRTVs); Minimum Risk Levels (MRLs) published by US Agency for Toxic Substances and Disease Registry (ATSDR); and values published by California Environmental Protection Agency.*

In selecting a source for a toxicity value pursuant to 310 CMR 40.0993(7)(c), there should be a preference for toxicity assessments that are informed by current scientific information and account for the most sensitive endpoints. The primary sources of toxicity values are discussed below. The risk assessor must provide justification for using any toxicity value other than those adopted or otherwise published by MassDEP. If the risk assessor chooses to use less health protective values, a detailed and compelling explanation for the selection of the less conservative value must be provided.

ORS develops chronic and subchronic RfDs and RfCs, and lifetime CSFs and URs for some OHM, including those for which no values are available from U.S. EPA. These values are based on available toxicological data, typically standard U.S. EPA approaches for developing these values. More recent toxicological information can be found in the toxicity file (vLookup) of the current Shortforms.

11.2.3.2 EPA Integrated Risk Information System

The Integrated Risk Information System (IRIS) is an U.S. EPA database that contains RfDs/RfCs/CSFs/IURs which represent a consensus judgement of U.S. EPA. It is the preferred source of toxicity information. The IRIS database is available on-line.

11.2.3.3 Other Preferred Sources of Toxicity Values.

California Office of Environmental Health Hazard Assessment (OEHHA). OEHHA develops oral and inhalation toxicity values for non-cancer and cancer health effects for contaminants in air, water, and soil, for use by their regulatory agencies.

Agency for Toxic Substances Disease Registry (ATSDR). ATSDR produces Toxicological Profiles for many hazardous substances found at National Priority List (NPL) sites. ATSDR develops minimal risk levels (MRLs) for threshold effects for acute (1-14 days), intermediate (> 14-364 days) and chronic (365 days and longer) exposure durations. An MRL is defined as an estimate of the daily human exposure to a substance that is likely to be free of risk of adverse non-cancerous effects over a specified duration of exposure. ATSDR often does not evaluate carcinogenicity. MRLs are derived using a risk assessment methodology similar to the method U.S. EPA uses to derive reference doses and reference concentrations for lifetime exposure.

Other U.S. EPA Program Values Including Provisional Peer-Reviewed Toxicity Values (PPRTVs). PPRTVs are toxicity values primarily derived for use in U.S. EPA's Superfund Program. PPRTVs are derived from a review of relevant scientific literature using U.S. EPA methods, sources of data and guidance, including new approach methodologies. PPRTV assessments are developed in response to requests from U.S. EPA's Superfund Program to the Superfund Health Risk Technical Support Center. Other U.S. EPA programs (e.g. drinking water) may also develop toxicity values that may be useful.

U.S. EPA COMPTOX Dashboard.
U.S. EPA's COMPTOX Dashboard (https://comptox.epa.gov/dashboard/) can be used to locate IRIS and PPRTV toxicity values, as well as additional toxicological information, physical/chemical properties, environmental fate and transport, safety, and exposure data.

11.2.3.1 Calculation of a value using toxicity information from the literature.

If no toxicity value is available from the sources listed above, dose-response values may be derived by a qualified risk assessor or toxicologist if adequate toxicity studies are available, *or* if more recent, credible, and relevant data become available. De novo derivation of toxicity values must be submitted to MassDEP/ORS for review. The review and approval by the Department of such a proposed value would depend upon the justification and documentation provided to support it. The development of an alternative value when U.S. EPA or MassDEP derived toxicity values are available is rarely justifiable and the risk assessor should contact the MassDEP ORS early in the site assessment process for prior approval before proceeding.

11.2.4 Relative Absorption Factors (RAFs)

The RAF is used to account for differences in the absorption of a COC under exposure conditions at the disposal site (exposure route and matrix) relative to the absorption of the COC under the experimental conditions on which the dose-response value is based (i.e., study conditions). RAFs are used *in lieu of absorption efficiencies* to ensure that the exposures evaluated at the disposal site are comparable to the toxicity information identified in the literature.

Deriving RAFs involves thorough examination of the available data addressing issues including, but not limited to, data quantity and quality, target organ concentrations and differences in metabolic activation or detoxification across exposure routes. Existing RAFs from MassDEP should be used whenever available. RAFs are listed in the vlookup Table of MassDEP's Risk Assessment Shortforms. RAFs are also listed in the toxicity.xls spreadsheet in the Method 1 Standards. The procedure outlined below for deriving an RAF should only be used when an RAF is not available from MassDEP. For proposed RAFs for chemicals not addressed by MassDEP, the burden of proof to support the appropriateness of the RAF rests with the risk assessor and must be provided to MassDEP for review.

The toxicity values used in quantitative risk assessment are typically based upon controlled laboratory experiments in which animal test species are exposed in some manner to the chemical under study. Many important features vary from study to study: the test animal may vary (e.g., mice, rats, rabbits or even humans may have been used); the chemical may be administered orally via gavage or in food or water, dermally, via inhalation or injected; and the material may be administered in different matrices (e.g., pure, dissolved in drinking water, dissolved in solvent or mixed with food). At disposal sites, the exposures of concern may not correspond to the conditions under which the toxicity information was derived. Typical site-related exposure pathways include but are not limited to the incidental ingestion of contaminated soil, dermal contact with contaminated soil and ingestion of contaminated drinking water.

The RAF is used to adjust the calculated dose (e.g., from soil ingestion) in such a way that it is comparable to the toxicity information from the point of the study from which the dose-response information is derived (e.g., a study in which rats were administered a chemical dissolved in solvent by gavage).

A unique RAF may need to be determined or estimated for a chemical for each combination of toxicity value and route of exposure. This means that multiple RAFs may be required to conduct the quantitative risk assessment. To estimate an RAF, two factors must be identified, considering all relevant extrapolation factors used to develop the toxicity value, e.g., toxicokinetic and other data-derived factors, as well as data quantity and quality:

- the absorption efficiency for the chemical via the route and medium of exposure being evaluated for the disposal site, and
- the absorption efficiency for the route and medium of exposure in the experimental study which is the basis of the dose-response value for the chemical in question.

Thus, the RAF adjusts the dose (or exposure) estimates based on these ***two*** absorption efficiencies. The RAF is calculated as follows:

$$\boldsymbol{RAF = \frac{Absorption\ Efficiency\ \ SITE\ route/medium\ of\ exposure}{Absorption\ Efficiency\ STUDY\ route/medium\ of\ exposure}} \qquad \textbf{(11-1)}$$

It is *very* important to determine whether the toxicity value is based on an *absorbed* or *applied* dose as well as whether differences exist in toxicokinetic factors across the exposures. The above equation is for a dose response value based on an applied dose. In its most simple form, if the dose response value has been derived from an absorbed dose, then the RAF is equal to the absorption efficiency via the route and medium under consideration.

11.3 Exposure Assessment

The exposure assessment is a critical component of the site assessment process as it describes, both qualitatively and quantitatively, the contact between the contamination and the people or organisms that are potentially affected by the contamination. The exposure assessment must be consistent with the primary questions asked in the risk characterization process:

> ***Given the current and identified foreseeable uses of the site, would the OHM present pose significant risk of harm to human health, safety, public welfare, or the environment if no further remedial action were to occur?***
>
> or
>
> ***If a proposed remedial alternative is implemented and meets its identified remediation goals, will a condition of no significant risk of harm to human health, safety, public welfare, and the environment be achieved given the current and identified foreseeable uses of the site?***

Whether the risk characterization is a **baseline** assessment (which answers the first question) or an evaluation of a proposed remedial alternative, the exposure assessment must incorporate site conditions associated with both current use and identified foreseeable uses of the site and surrounding environment.

There are two outputs or findings of the exposure assessment: exposure profiles and quantitative estimates of exposure. An exposure profile is a narrative description of the exposures which are or may occur at the disposal site, and the information is often summarized in one or more tables for easy reference (Section 11.3.2 below). The quantitative estimates of exposure translate the narrative exposure profile into a series of equations resulting in numerical estimates of exposure (detailed in Section 11.3.4.1). These numerical estimates are used in the risk calculations.

The exposure assessment begins with a description of the physical characteristics of the disposal site. This information is typically collected as part of a Phase I (310 CMR 40.0480) or Phase II (310 CMR 40.830) site investigation, although the type of information needed and the appropriate level of detail should reflect the nature and complexity of the site as well as the point in time at which the risk characterization is being performed. Relevant site information would include, but is not limited to:

- The address and location of the disposal site;
- A detailed map, including GIS coordinates, of the site and surrounding area;
- A description of the land uses at and surrounding the disposal site;
- A listing and description of natural resources and vegetation at or near the disposal site (e.g., surface waters, wetlands, forests, grassy areas, etc.);
- A summary of the current and historical uses of OHM;
- A description of any known and relevant releases which may have occurred and the likely nature and

extent of the resulting contamination;
- A summary of site hydrogeological characteristics, including depth to groundwater, direction and rate of flow, nearby drinking water supplies, soil types, etc.;
- A summary of background concentrations of OHM;
- Other sites or potential sources and releases in the vicinity.

Location information may be available through the Massachusetts Geographic Information System (MASS-GIS) which provides color plots or digital data of wetland areas, sole source aquifers, endangered species habitats and other natural resource areas, as well as Environmental Justice areas, permitted facilities and other c.21 E sites. MassGIS data and information can be found at https://mass.gov/orgs/massgis-bureau-of-geographic-information.

Exposure to contamination occurs wherever OHM from the site and human activities co-occur, as represented by the Conceptual Site Model (CSM). The CSM is a site-specific description of what and how contaminants entered the environment, how they were transported within the system, and pathways (including routes) of exposure to and identification of human and environmental receptors. CSM development is an iterative process and is detailed in Chapter 2.

Temporal measures of exposure define the extent of a receptor's contact with a contaminated medium. These measures include the exposure duration, frequency, and exposure period. The exposure period is the length of time over which an exposure occurs. It forms an important link between the toxicity and the exposure assessments, as different toxicity values are designated for specific exposure periods. The following types of exposures, corresponding to different exposure periods, should be considered:

- Acute exposures to evaluate non-cancer risk (one to several days);
- Short-term exposures (several days to several months) to account for developmental effects;
- Subchronic exposures to evaluate non-cancer risk (several months to seven years),
- Chronic exposures to evaluate non-cancer risk (greater than seven years);
- Lifetime exposures for exposure to carcinogens (typically 30 years and averaged over a lifetime of 70 years).

All assessments conducted under the MCP must consider subchronic and chronic or lifetime exposures and risks if applicable. Assessments of OHM associated with developmental effects must consider short-term exposures. Assessment of acute exposures and risks is only required for OHM commonly associated with acute toxicity (e.g., cyanide). The type of exposure that poses the greatest risks depends upon the toxicity and associated values of the contaminants of concern and the concentration to which a person is exposed over the relevant exposure period. Contaminant concentrations cannot be measured over entire chronic and lifetime exposure periods, so it is often necessary to use currently available data to estimate longer term exposures. For media in which concentrations may change over time, the data must be analyzed to obtain a health protective estimate of exposure over the time period of concern (310 CMR 40.0920).

MCP risk characterizations and Imminent Hazard evaluations typically use the “exposure factor” approach whereby exposure estimates are developed by combining various exposure factors such as OHM concentrations, ingestion rates, body weight, etc. to estimate the exposure of the OHM received by the receptor and develop risk calculations. Approaches beyond the “exposure factor” approach may be applicable for some sites and/or COCs, including biologically-based models and biomonitoring when health risks have been linked to internal concentrations of the COC. For some contaminants, biologically based models have been developed to estimate the concentration of an OHM in the exposure media that is associated with a biological measure of exposure (e.g., blood lead concentration and the IEUBK model). Biomonitoring data, such as OHM concentrations in

serum or urine can provide a measure of past and/or current exposure to COCs at a site. The use of serum or urinary levels is evolving and have been applied to several contaminants (e.g., Aylward, 2010).

11.3.1 Basic Approach/Assumptions

The basic approach which should be taken in an exposure assessment for an MCP risk characterization is to produce an assessment which is both realistic and health protective. The regulations (310 CMR 40.0992(2)) stipulate that the objective of a Method 3 risk characterization is to provide a health-protective estimate of the impact that the OHM may have on the receptors at the site and in the surrounding environment. However, the assessment should not be a "*worst case*" exposure assessment unless there are site-specific justifications for performing such an evaluation. (Worst case assessments are useful screening tools which may demonstrate that risks are clearly insignificant, but they are not useful in determining whether realistic risks are significant.) For example, use of a worst-case scenario may be useful for quickly evaluating risks using default assumptions when development of site-specific assumptions would be time-consuming but unnecessary for determining a condition of No Significant Risk. Conversely, the assessment should not represent an "*average case*" which may underestimate potential risks experienced by a large portion of the exposed subpopulation and thus would not be health protective. This section presents guidance on identifying receptor groups that are likely to be most susceptible to effects of contamination at the site, and on selecting exposure parameters that will result in an appropriately health-protective estimate of risk to that receptor group.

11.3.2 Development of Exposure Profiles

Exposure profiles provide a narrative description of how exposure takes place at the disposal site. The exposure profiles assist the risk assessor in identifying appropriate values for the exposure variables (such as intake rate, frequency of exposure, etc.). Exposure profiles are often referred to as "*exposure scenarios*" (e.g., resident, park visitor, etc.).

The *U.S. EPA Guidelines for Exposure Assessment* (2019) describes exposure scenarios (exposure profiles) as containing the "*facts, data, assumptions, inferences, and sometimes professional judgment*" about how the exposures take place. Since these factors determine the magnitude of exposure (and thus the magnitude of the risk posed by the disposal site), it is important that there be a clear description and summary of this information. The exposure profiles allow anyone concerned about the disposal site to read and understand what was considered in the risk characterization and the basis for the decision on the need or lack thereof for remedial action.

Note that the information which goes into an exposure profile (the receptors, exposure points (EPs), EPCs, etc.) comes from the site investigations. Thus, the investigations must be designed in such a way to provide the risk assessor with information suitable for the risk characterization. It is critical to involve the risk assessor in the sampling plans. The exposure attributes are interrelated (e.g., the location of the Exposure Points depends on the migration of the OHM and the activities of the receptors). The information should be collected and processed in an iterative manner and reflected in updates of the CSM, as detailed in Chapter 2.

The Exposure Profile should contain information to completely describe each receptor's exposures to OHM at the disposal site.

- ***Who*** is exposed? The exposure profile should be developed for each receptor likely to be present at the disposal site or in the surrounding environment, and who, as a result, would likely be exposed to OHM.

- ***Where*** does the exposure occur? Is the contamination limited to the area near the original source, or has/will migration of contaminants result in potential exposures at a more distant point?

- ***What*** are the receptors exposed to? What OHMs are present at the disposal site? What concentrations of the material have been reported?

- ***When*** does the exposure occur? Are the exposures likely under current site conditions, or will the exposure be of concern if the site use changes in the future?

- ***How*** does exposure occur, and how often? What receptor actions or activities result in contact with the OHM? Do these events happen every day or are they rare incidents?

If exposure scenarios are identical to those in the Method 3 Shortforms, detailed exposure profiles are not needed as part of the Method 3 risk assessment as the Shortforms can be used to assess many standard exposure scenarios. If other site uses and activities not covered by the Shortforms are identified for quantification of risk, exposure profiles should be developed for the receptors identified for all current and foreseeable uses of the site. The number and content of the exposure profiles will vary from site-to-site, reflecting the nature and complexity of the exposures which may occur.

There are several ways to streamline this process and minimize the number of exposure profiles needed. If the current use of the site is residential, then separate exposure profiles need not be developed for less intensive uses and less susceptible receptors. For a property where the frequency and intensity of exposure is low, and the use and activities are predicted to remain the same in the future, an activity and use limitation (AUL) is required, as detailed in Section 3.3 of this Guidance Document (MassDEP, 2025).

Another situation conducive to streamlining exposure profiles is when two (or more) hypothetical receptors with similar sensitivities to OHM in question, share the same exposures, but the magnitude of exposure is demonstrably greater for one. In this case, a detailed exposure profile may be developed for the more exposed receptor, accompanied by the conclusion that lesser exposed receptors will also be protected.

Exposure scenarios (and EPCs) should be developed for current surficial soil activity (0-3 feet), current utility repair (from ground surface to the utility-specific depths for existing utilities), future utility installation and repair (0-6 feet), current and future excavation and construction activities (ground surface to 15 feet or the bottom of contamination), and future uses that are not precluded by an AUL (0-15 feet for future residential use, 0-15 for future commercial use without obligations to maintain barriers or prevent soil relocation, etc.). This is consistent with the requirements of 310 CMR 40.0924(7).

11.3.2.1 Identification of Potential Human Receptors

Section 310 CMR 40.0921 of the MCP contains regulations specific to the identification of human receptors at waste sites. The documentation of the risk characterization should contain a description of the potentially exposed persons who live, work, play, visit, or otherwise come to the disposal site or the surrounding environment. In identifying these receptors, the risk assessor must consider not only those people currently associated with the disposal site, but also those who may frequent the site in the future if the use of the site (foreseeable use) were to change.

The human receptors are described as subpopulations (subsets of the more diverse overall population of Massachusetts) rather than specific individuals so that the results of the risk characterization can be generalized.

For example, "*children*", a specific, identifiable group within the larger general population of humans, are often identified as receptors of concern at disposal sites. Note that while the receptors are described in terms of "subpopulations" or "subgroups", the product of the risk assessment is still an estimate of the risk that applies to the protection of an *individual* within that group. The MCP focuses on individual risk, *not* population risk.

While receptors are described as subgroups of the general population, MCP risk characterizations are conducted and applied in ways that protect individuals from harmful health effects.

The receptor groups are described in terms that highlight their relationship to the site and the unique characteristics of the subpopulation. For example, the term ***site residents*** describes a diverse group which lives (or may in the future live) at the disposal site. For the purposes of the risk characterization the site residents should be further divided into subpopulations based upon their potential for greater exposure (vulnerability) and greater physiological response to contamination (susceptibility) and include sex and age if those factors are indicative of a higher exposure potential or greater susceptibility to the effects of environmental contamination. Young children and women of child-bearing age are often chosen as receptors of concern in residential locations because of these factors (U.S. EPA, 2006d). Table 11.1 shows the age ranges of children typically chosen to evaluate different types of exposures in a residential setting.

At industrial locations, adults, including women of child-bearing age may be the most susceptible receptors as children may not be present or occupational exposures may drive risk estimates. Identification of the most sensitive subpopulation should be done on a site-by-site basis.

Table 11.1

Examples of Receptors Exposed to Soil in Residential Settings

Exposure of Concern	Typical Subpopulation Evaluated	Discussion *(The youngest person in any age group is judged to be most susceptible to contaminants in soil)*
Acute Exposure, Non-cancer Effects	1-year-old child	A 1-year-old child is the youngest likely to play outside.
Subchronic Exposure, Non-cancer Effects	1-year-old child	A 1-year-old child is the youngest likely to play outside.
Chronic Exposures, Non-cancer Effects	Child, between 1 and 8 years old	1-8 is the youngest age group likely to play outside in a residential setting.
Chronic Exposures, Cancer Risk	Resident, between 1 and 31 years old.	Based on EPA policy, residents are assumed to live at one location for 30 years. Age bins are 1-8, 8-15, 15-31.
Chronic Exposures, Mutagenic Risk	Resident, between 1 and 31 years old.	Based on U.S. EPA policy, residents are assumed to live at one location for 30 years. Age bins are 1-2, 2-6, 6-16, and 16-31.

Examples of Receptors Exposed to Soil in Residential Settings		
Exposure of Concern	**Typical Subpopulation Evaluated**	**Discussion** *(The youngest person in any age group is judged to be most susceptible to contaminants in soil)*
	Air and water exposures are evaluated beginning at year zero (i.e., birth). Children less than one year old are considered to have limited direct exposure to soil. However, migration of site contaminants in soils to indoor dust and on outdoor surfaces (e.g. playground structures), can result in exposures via hand-to-mouth ingestion and dermal contact for children less than one year of age. These exposure pathways should be identified and considered where appropriate.	

For the purposes of Method 3 Risk Characterizations performed under the MCP, the receptor subpopulation of concern would be characterized by those individuals whose activities (described by the frequency and duration of the actions) represent a full and unrestricted use of the site (considering the current and foreseeable uses identified). The quantitative exposure assessment should describe a health-protective estimate of a representative individual within that subpopulation. Note that the "*fullest use*" means that high-end values for exposure frequency and duration should be used, but not necessarily the highest possible values.

The subpopulations or receptor groups evaluated in the quantitative risk assessment should represent the most susceptible individuals and groups of all of those who are exposed to contamination at the site in question. Higher susceptibility is used here to mean a higher probability of experiencing adverse impacts from exposure. Susceptibility is determined by the combination of the intensity of exposure and the physiological sensitivity to toxic effects. Examples of receptor groups that are often identified as the most susceptible subpopulations include, but are not limited to:

- In typical residential areas, children are usually considered among the most susceptible receptors because (1) their activities are likely to result in more intense exposures than those of adults, (2) they intake higher amounts of soil by incidental ingestion, due to more frequent hand-to-mouth activity, (3) their lower body weights result in higher normalized doses, and (4) childhood development of the brain and other organ systems occurs through structured developmental pathways that can be very sensitive to toxics (Ginsberg, 2004; U.S. EPA, 2006a; U.S. EPA, 2008; U.S. EPA, 2019). Note that the first two factors relate to higher exposure intensity, the third translates to higher internal dose, and the fourth translates to periods of higher sensitivity to the effects of an exposure, all of which combine to make children generally more susceptible than adults to the contamination.

- In typical industrial areas, adults who work at the site are often considered as one of the most susceptible subgroups because their exposure frequency is higher than for others who may be exposed on occasion. Because some toxicants negatively affect development, workers who are women of child-bearing age, or who are pregnant or nursing should be identified as a susceptible subgroup. The effects of concern in these cases may be developmental effects on fetuses and infants, not necessarily effects on the mother herself. Fetuses are considered more sensitive than adults to some contaminants because shorter-term exposures on the order of days to months may be sufficient to cause adverse developmental effects. Infants are more susceptible because they may be exposed to significant levels of contaminants that may be concentrated in

breastmilk. Because of their low body weight, an infant's exposure can lead to a relatively high normalized dose. Infants and young children are more sensitive than adults to the toxic effects of chemicals, such as lead, TCE, some PFAS chemicals, and mutagenic chemicals (Beath, 2003; Ginsberg, 2004; U.S. EPA, 2005b; Sly and Flack, 2008; MassDEP, 2014a).

- In a childcare setting, adult caregivers may be more susceptible to health effects from chronic exposures since they may be exposed over a period of 7 years or more while children would only be present for a few years. Children may be more susceptible to health effects from subchronic exposures because of their relatively low body weight.

Exposure assessments should use mid-range estimates of population-based exposure factors, such as intake rates, contact rates and body weights, which are known to vary among individuals within the specified receptor group (see the MassDEP Shortforms for default values). In contrast, the values used for frequency and duration of exposure should reflect realistic values for receptors making the fullest use of the site or resource (given the current and future uses determined for the location) while considering climatic conditions in Massachusetts. For example, residential soil exposures are assumed to occur five days per week and seven months per year even if current residents are not choosing to spend that much time out of doors. This mix of mid-range and health protective values is intended to produce realistic upper-end exposure estimates which will be protective of public health and produce risk estimates which will be valid for comparison to the MCP Cumulative Risk Limits.

Exposure estimates calculated as described herein are generally considered to be protective of public health in that they are not likely to be underestimates of the "actual risk" for individuals in the specified receptor subpopulation.

11.3.2.2 Identification of Exposure Pathways and Routes.

The ***Exposure Pathway*** is the term used to describe the course that the OHM takes from the source of the material to the receptor of concern. The term encompasses the source, the migration pathway, the Exposure Point, the receptor, and the exposure route. Identifying and describing exposure pathways is a requirement for developing the CSM (Chapter 2).

The mechanism by which a receptor contacts the OHM is called the *Exposure Route*. Typical exposure routes described at c.21E disposal sites include:

- **INGESTION** of contaminated soil, sediment, water, or food
- **INHALATION** of contaminated air or fugitive dust
- **DERMAL CONTACT** with contaminated water, soil, or sediments

Exposure Definitions

Sources of contamination include waste materials or contaminated soil from which contaminants are migrating to other media and/or locations.

An **Exposure pathway** describes the course a chemical takes from a source to an exposed person or organism.

An **Exposure Point** is the place where a person or organism may come into contact with the contamination.

An **Exposure route** is the way a person or organism contacts contaminants (by ingestion, inhalation, or dermal contact).

A receptor may be exposed to OHM at one ***or more*** Exposure Points, and at each Exposure Point the receptor may be exposed via one **or more** routes. The exposure profile for the receptor should describe such multiple exposure scenarios in a way which makes clear that the combination of exposures to the receptor is being addressed in the risk assessment.

As detailed in the CSM discussion in Chapter 2, the receptors and exposure routes evaluated in the risk characterization are linked with site contaminants at the Exposure Points by exposure routes. The identification of Exposure Points (EPs) and calculation of EPCs are described below.

For receptors to be exposed to a contaminant at or from a disposal site, a realistic pathway must be established leading from the source of the OHM to the receptor. The point at which the contact occurs is referred to as the *Exposure Point.* Potential Exposure Points must be identified per 310 CMR 40.0924. The route by which the material travels from the source to the Exposure Point is called the *migration pathway*. The CSM identifies exposure pathways by which contaminants travel from source areas to Exposure Points. Potential points of exposure may be distant from the original source material, so the risk assessor must consider the current and future migration pathways to identify all potential Exposure Points.

Exposure Point means a location of potential contact between a human or environmental receptor and a release of OHM. An Exposure Point may describe an area or zone of potential exposure, as well as a single discrete point (310 CMR 40.0006).

While the regulations and guidance use the term *Exposure Point*, the term often describes an area of a disposal site or surrounding environment and not necessarily a single, discrete point. The Exposure Point should be an area within which the receptor has an equal likelihood of exposure, such as "a backyard" or "a playground". If there are areas within the site which receptors frequent at a higher rate (such as the area surrounding playground equipment within a larger playground) then those areas should be evaluated as separate and distinct Exposure Points. Additional examples of Exposure Points include, but not limited to:

- An area where people come into contact with contaminated soil;
- A drinking water well or a potential drinking water well location;
- A building or part of a building into which contaminants in air are migrating and accumulating in the indoor air; or
- An area in which ambient air contains elevated concentrations of site-related contaminants.

In general, an Exposure Point for soil, sediment or surface water should be delineated by the distribution of OHM in the environmental medium. For example, for soil, an Exposure Point should be a contaminated area within which the exposure of concern is likely. The area outside the boundaries of the contamination should not be included in the Exposure Point, and data from those areas should not be included in the concentration estimate, as inclusion may decrease the EPC.

11.3.3.1 Estimating Exposure Point Concentrations - General Considerations.

Exposure Point Concentrations (EPCs) should represent a conservative estimate of the arithmetic mean concentrations to which an individual may be exposed over the exposure period at the Exposure Point. Groundwater and air concentrations should also represent a conservative estimate of the temporal mean for the exposure period of concern and should also consider temporal trends. In all cases, the objective is to estimate the concentrations in a way that minimizes underestimation of the EPCs.

Section 11.3 described four types of exposures that may be evaluated in disposal site risk assessments: acute, subchronic, short-term, and chronic or lifetime exposures. For each type of exposure, the risk assessment should focus on the time-segment during which the highest dose is likely to be received, and the EPC should be a conservative estimate of the average exposure concentration over that time period. More specifically:

- **For acute exposures** (one to several days), the EPC should represent a conservative estimate of the concentration to which a receptor might be exposed over the period of one to several days. Generally, the highest detected concentration should equal the EPC when a one-time exposure could result in adverse health effects, as is the case for cyanide.
- **Short-term** exposures (up to 90 days) should be evaluated over the minimum number of days that could result in the health effect of concern using the highest mean concentration measured or predicted over that period of time.
- **Subchronic exposures** (several months to seven years) to media in which concentrations may fluctuate seasonally (e.g., groundwater and air) should be evaluated over the months during which the mean concentration is highest. For seasonal soil exposures that occur in the warmer months, **subchronic exposures** should be evaluated over the period of time when exposures are likely greatest, typically warm season months.
- **Chronic exposures** (typically 30 years averaged over a 70-year lifetime) should be evaluated over the seven-year period during which exposures are likely to be highest.

For environmental media other than soil or sediment (groundwater, surface water, air), concentrations may change over time. However, data for chronic and lifetime exposures (7 and 30 years respectively) will generally not be available, so a conservative estimate of mean concentrations that doesn't underestimate the mean for those time periods must be based on available data and site information. If the data suggest or show an increasing trend, the EPC estimate should reflect the predicted increase, and the assessment report should fully describe uncertainty about that estimate. However, such an estimate should only be used for preliminary site management decisions. Given the uncertainty associated with exposure estimates where contamination is increasing, such estimates should not be used to support a conclusion that "no further action" is required.

Where EPCs are, or may be, increasing at an exposure point, a conclusion that "No Significant Risk" exists at the site cannot be supported.

If the data suggests a decreasing trend in concentration, it may be appropriate to use current values as an estimate of the long-term average. Including historical data in the calculation may lead to exposure estimates that are not consistent with respect to current or future conditions and could lead to risk management decisions that are problematic. For example, it would be inappropriate to conclude that groundwater remediation is necessary in a situation where the concentrations have decreased to concentrations that are below levels of concern for human health and are continuing to decrease.

Exposure Points (EPs) and EPCs are addressed in separate sections of the MCP (310 CMR 40.0924 and 310 CMR 40.0926, respectively), but in practice, the identification of EPs and the calculation of EPCs are inextricably linked. For that reason, they are discussed together for each environmental medium in the subsections that follow.

11.3.3.2 Groundwater/Drinking Water Exposure Points and Exposure Point Concentrations

A drinking water EPC must be a conservative estimate of the temporal mean for the exposure period of concern and shall consider temporal trends (310 CMR 40.0926(7)(b)). At any one location, groundwater contaminant levels may fluctuate over time. Temporal fluctuations may be caused by seasonal or shorter-term changes in precipitation, tidal influence, or changes in water withdrawal rates. At the same time, the levels may trend

upwards or downwards due to remediation or fate and transport processes. Such variations can introduce uncertainty into the estimation of EPCs. As noted in Section 11.3.4, the recommended approach to identifying the EPCs depends upon the pattern of temporal changes, specifically whether concentrations are trending upward or downward or fluctuating over time.

EPCs for private and public water supplies are addressed separately in the two sections that follow.

11.3.3.2.1 Private Well Exposure Points and Exposure Point Concentrations

Within a GW-1 area, the risk assessment should address both the risks associated with any private well in use and the foreseeable risks from the installation of a private supply well anywhere within the contaminated area. Thus, the Exposure Points of concern should include both existing water supply wells and the groundwater at any location where a well could potentially be installed. In other words, the groundwater at each monitoring well should be considered a foreseeable Exposure Point (310 CMR 40.0926(7)(a) and (b)). Future potential wells (or those installed after release notification) are not considered Exposure Points in areas where access to a public water supply is available in accordance with 40.0932(5)(d)(3).

Regardless of the risk assessment method employed, EPCs and risks should be evaluated separately for each drinking water well in use and for each location (monitoring well) where a drinking water well could be installed within the contaminated area.

In general, BWSC recommends against averaging concentrations detected in different monitoring wells because monitoring wells are seldom clustered closely enough to lie within an area that would affect a single well.

Instead of calculating the risk from every monitoring well, the monitoring wells with the highest levels of contamination should be selected to represent potential supply well locations for the risk assessment. At some sites, one monitoring well may clearly represent the highest contaminant levels. At other sites where the groundwater is contaminated by a mixture of contaminants of varying relative concentrations, several monitoring wells may have to be evaluated as potential supply well locations. Note that per the definition of Potential Drinking Water Source Area in 40.0006, all groundwater more than 500 feet from a public drinking water distribution pipeline is considered GW-1, and disposal sites in these areas cannot achieve a Permanent Solution unless groundwater is suitable for drinking water use. And, per 40.0924(6)(a) and (b), the EP "in GW-1 areas" is the groundwater resource itself, as mentioned in the next section for public drinking water wells.

A three-month average for a subchronic evaluation should be based on samples collected at a time when the concentrations can reasonably be expected to represent a maximum for the year. One sampling round is insufficient to obtain a reliable concentration estimate, and confirmatory samples should always be collected. Sample collection should consider the likely location of future private drinking water wells (i.e., overburden vs. bedrock), as most monitoring wells are overburden, and most private drinking water wells in a good part of the state are bedrock wells.

11.3.3.2.2 Public Drinking Water Well Exposure Points and Exposure Point Concentrations

Unless a specific exception applies (such as 40.0924(6)(c) when performing a future evaluation of petroleum hydrocarbons in a public water supply), the groundwater itself in GW-1 areas is assessed as drinking water to ensure that the groundwater is protected as a water supply resource. This rule applies to all Method 1, 2 and 3

risk assessments.

> **For groundwater in GW-1 areas, *the Exposure Points are 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 itself* (310 CMR 40.0924(6)(a) and (b)).**

There is an exception to this provision for petroleum hydrocarbons in areas designated as groundwater category GW-1 solely based on being located within a Zone II or Aquifer Protection District that overlays or is contiguous with a Zone II. The MCP, at section 310 40.0924(6)(c), states:

the Exposure Point shall be the existing Public Water Supply well(s) for the evaluation of current and future drinking water exposures to petroleum hydrocarbons at or from the disposal site and the Exposure Point Concentration shall be identified pursuant to 310 CMR 40.0926(7)(e)".

As written at (310 CMR 40.0924(6)(c), this exception only applies where:

- A Phase II Report for the disposal site pursuant to 310 CMR 40.0830 has been submitted;
- The disposal site is located at a distance greater than 1,000 feet from a Public Water Supply well;
- It has been demonstrated that the requirements at 310 CMR 40.1003(5)(a) and (b) and 310 CMR 40.1003(7)(a) have been met to address any NAPL present;
- It has been demonstrated through adequate characterization of horizontal migration that groundwater petroleum hydrocarbon concentrations are:
  - not detected at or above analytical limits appropriate for a GW-1 area at the downgradient edge of the plume, at least 1,000 feet from the Public Water Supply well(s); and
  - decreasing within the boundaries of the plume; demonstration of diminishing contaminant concentrations within the plume shall consider both the spatial and temporal distribution of the contamination and other measures indicative of biodegradation of the contaminants.
- It has been demonstrated through adequate characterization of vertical migration that contamination has not entered bedrock, including through the submittal of a profile sectional map showing the following information:
  - known or inferred depth to bedrock;
  - depths to the top and bottom of the plume throughout the length of the plume; and
  - existing well screen depths in comparison to the plume; and
- It has been demonstrated that there is no potential EPC in accordance with the criteria specified at 310 CMR 40.0926(7)(e).

As previously noted, groundwater contaminant levels may fluctuate over time for a variety of reasons, and the recommended approach to identifying the EPCs depends upon the pattern of temporal changes. Sampling and assessment of groundwater that may be impacted by a release of OHM and drawn into a public water supply system is aimed at preventing the degradation of water resources and protecting water system users from adverse impacts.

11.3.3.2.3 Groundwater EPCs for Comparison to Drinking Water Standards

Massachusetts Drinking Water Quality Standards (310 CMR 22.00) are considered "*applicable or suitably*

analogous standards" under the MCP (40.0924(6)(b)) (App.1b). One of the conditions necessary to achieve a condition of No Significant Risk of harm to public health is that no EPC of OHM is greater than an applicable or suitably analogous standard. Thus, each EPC, including those measured at monitoring wells, is compared with drinking water standards as a component of the Method 3 risk characterization. In general, the Massachusetts Maximum Contaminant Levels (MMCLs) are compared with arithmetic mean concentrations at the Exposure Point. The arithmetic mean of four quarterly samples representing the seasonal variation at an Exposure Point should be used for comparison to drinking water standards in a similar manner as an MCP risk assessment.

It is possible to meet drinking water standards and still fail a Method 3 risk assessment, with respect to HI or ELCR. An example is arsenic, where the MMCL of 10 ug/L would result in an unacceptable ELCR in the residential drinking water shortform. This can also happen with soil where the arsenic Method 1 standard is based on a statewide background value whereas a Method 3 is site-specific, with the possibility of a much lower background level.

It is important to distinguish between the application of Method 1 GW-3 standards by BWSC under the MCP and the enforcement of drinking water standards by the Bureau of Water Resources (BWR). The aim of the requirements under the MCP is to *protect* water resources and *prevent* adverse impacts on water supplies. In contrast, MassDEP's BWR controls the quality of water distributed by public water supply systems to protect the end users. Therefore, water sampling and data analysis procedures required by the two Bureaus may differ somewhat. Nothing in this guidance document is intended to limit, expand, or change the requirements set by BWR for water suppliers.

11.3.3.2.4 Groundwater Exposure Point Concentrations in GW-3 Areas

GW-3 standards are set at levels that would protect surface water from contaminants that might be discharged to surface water via contaminated groundwater. In the requirements for identifying groundwater Exposure Points in Method 3 risk assessment, the MCP states: "*In areas where the groundwater is categorized as GW-3 only, groundwater Exposure Points shall be determined based on site-specific conditions, and potential current and future exposures*" (310 CMR 40.0924(6)(b)(3). This provision supports site-specific assessment of potential surface water impacts. It allows the risk assessor to consider site-specific factors such as distance to surface water and contaminant distributions in the plume to evaluate whether the groundwater contaminants are likely to reach surface water and pose a risk of harm. If the plume in question is stable, it may be appropriate to average concentrations within the plume instead of treating each well as an Exposure Point.

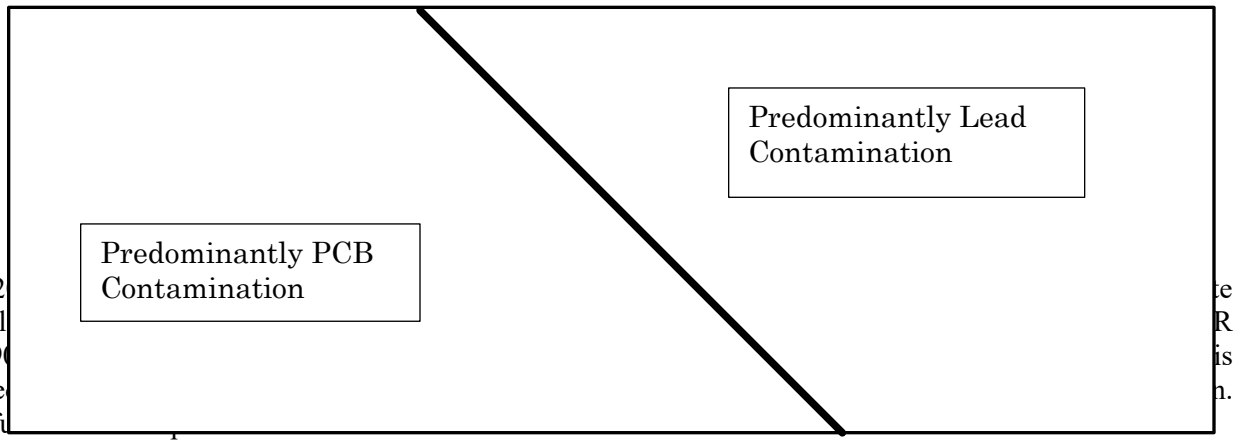
11.3.3.3 Soil Direct Contact Exposure Points and Exposure Point Concentrations

Direct contact with soil can result from such diverse activities as work, play and gardening on residential properties including but not limited to; recreational activities on public and private land; landscaping of commercial properties; grading or excavation of soil for construction or utility repair; agricultural work; outdoor work on industrial properties; and exploration of any area that appeals to young people's curiosity. Exposure occurs primarily by dermal contact, followed by absorption of contaminants from soil and incidental ingestion of contaminated soil. Gastrointestinal and pulmonary absorption from particulate inhalation is also evaluated for construction workers. To calculate an EPC for a particular Exposure Scenario, the selected soil samples should be representative of the area and depth within which the particular exposure is likely to occur.

In general, the EPC should be a conservative estimate of the arithmetic mean soil concentration at the Exposure Point. This practice treats soil concentrations as remaining constant over time and exposure as being equally likely at any location within the Exposure Point. As long as these conditions hold true, the arithmetic mean concentration in the exposure area will represent the mean concentrations with which a person comes into contact with soil over time.

In cases where different combinations and/or levels of contaminants are present in different parts of a possible Exposure Point (e.g., a play park or a yard), and the proportion of a receptors time spent in either of them is unknown, those areas should be assessed as separate Exposure Points. The risk assessor should try to divide exposures within the areas based on the likely frequency, intensity or duration of time spent in each area. Treating areas with different levels or combinations of contaminants as separate Exposure Points will ensure that exposure in either area will not be underestimated. Figure 11.1 below illustrates a yard where the contamination is predominantly PCBs in one part of the yard and predominantly lead in the other portion of the yard. In cases like this, the area should be divided into separate Exposure Points.

Figure 11.1
Example of Contamination in a Yard



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(a) a judgmental sampling approach is appropriate for characterizing the soil Exposure Point Concentration, pursuant to 310 CMR 40.0926, where the contamination has originated from a known source or sources; there is evidence that the contamination is limited to a defined area; the area with the highest concentrations within the Exposure Point can be clearly identified; and there is no evidence, including site history, that the soil has been significantly redistributed since the release;
(b) except as provided in 310 CMR 40.0904(4)(c), a systematic sampling approach is required for characterizing the soil Exposure Point Concentrations where the soil contamination has not been attributed to a known source; the contamination may not be limited to a defined area; it is not possible to identify the area with the highest concentration within the Exposure Point; or the soil may have been significantly redistributed since the release; and
(c) notwithstanding 310 CMR 40.0904(4)(b), a judgmental sampling approach may be supported where specific circumstances support a technical justification that judgmental sampling provides a conservative estimate of exposure.

The MCP at 310 CMR 40.0926(8)(a) sets forth regulations for calculating EPCs corresponding to either of the sampling approaches described above:

> *1. For Exposure Points where judgmental sampling has been implemented in accordance with 310 CMR 40.0904(4), the arithmetic mean of data from the Exposure Point may be used as an Exposure Point Concentration, provided that 75% of the data points used in the averaging procedure are equal to or less than the applicable standard or risk-based concentration limit, and no data point used in the averaging is ten times greater than the applicable standard or risk-based concentration limit; Otherwise,*
>
> > *a. the maximum concentration from the Exposure Point may be used as the Exposure Point Concentration; or*
> >
> > *b. the arithmetic mean may be used to determine the Exposure Point Concentration, supported by a technical justification that considers the size of the data set, density, and potential biases of the sampling, and other relevant factors.*
>
> *2. For Exposure Points where systematic sampling has been implemented in accordance with 310 CMR 40.0904(4), the 90th percentile Chebyshev non-parametric upper confidence limit on the mean of the concentrations within the Exposure Point may be used as the Exposure Point Concentration.*
>
> > *a. If the 90th percentile Chebyshev non-parametric upper confidence limit on the mean is determined not to provide a suitable estimate of the Exposure Point Concentration, an alternative conservative estimate of the arithmetic mean may be used to determine the Exposure Point Concentration, supported by technical justification. Such technical justification shall document the determination that the 90th percentile Chebyshev non-parametric upper confidence limit on the mean is not suitable, and the suitability of the alternative approach, considering the size of the data set, density and potential biases of the sampling, applicable statistical analyses of the data, and other relevant factors.*

In summary, the MCP requires different sampling approaches for different types of sites, and the requirements for calculating EPCs differ depending on the sampling approach used. The two subsections that follow discuss in more detail the requirements for calculating EPCs based on data from judgmental and systematic sampling. The risk assessment should discuss the available data and the sampling approaches used to collect the samples. In some circumstances it may be appropriate to combine judgmental and gridded sampling in an EPC if it is done in a conservative manner.

11.3.3.3.1 Direct Contact Exposure Point Concentrations from Judgmental Sampling Data

For sites/releases where contamination is from a known source, and where the extent of contamination is well-defined, the available information may be sufficient to support judgmental sampling (also discussed in Section 4.3.1). Fuel leaks and road spills are examples of sites where judgmental sampling is often justifiable. Where judgmental sampling is used, the EPC should be based on the calculated arithmetic mean, qualified by the "75/10" rule (See 310 CMR40.0926(8)(a)1., quoted above).

Data from judgmental sampling is biased and does not represent the population of concentrations present within the Exposure Point. It therefore cannot be used to calculate an upper confidence limit (UCL) on the mean because applying statistical methods to biased data will lead to biased and unreliable results that will not be

accepted by MassDEP (as discussed in Section 4.3.2.1).

Judgmental sampling data should never be used to calculate the upper confidence limit on the mean because it can result in biased and unreliable results.

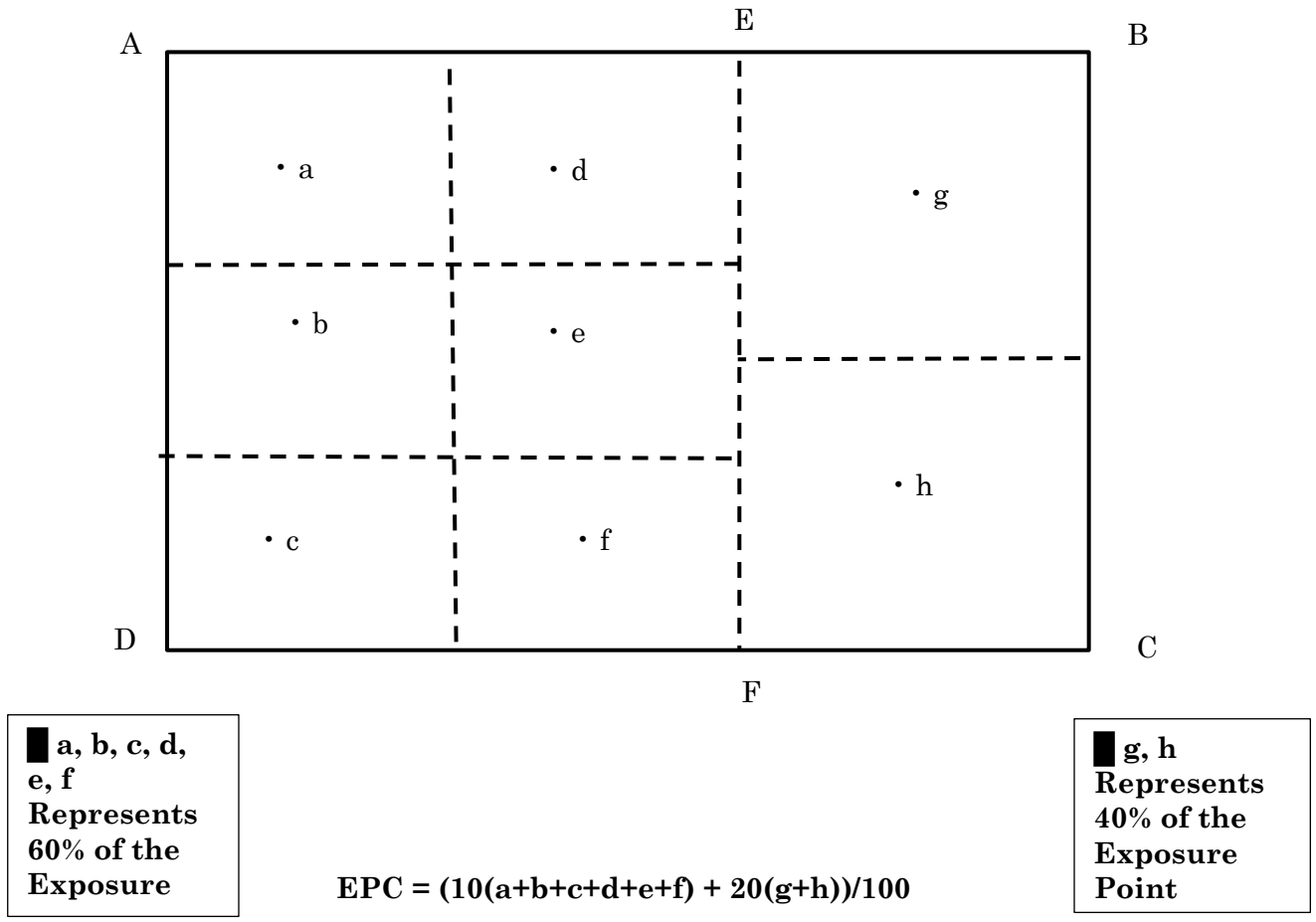
Nevertheless, a conservative estimate of the mean is required (310 CMR 40.0926(5)). One way to obtain a conservative estimate is by using the data obtained from the portion of the Exposure Point with the highest contaminant concentrations.

Judgmental sampling is inherently site-specific. Designing a judgmental sampling plan must consider a variety of issues, including but not limited to, the source of the contamination and the release mechanism, the fate and transport characteristics of the COC, the possible transport pathways including migration through groundwater, site geology and soil type, site topography, lateral movement of free product through soil, leaching potential, contaminant variability and the possible lateral and vertical extent of the contamination. Consequently, it is not possible to offer generic guidance for identifying Exposure Points and calculating EPCs for judgmental sampling projects. Method 1 Standards can be used as risk-based concentration limits when determining whether the 75/10 rule is met.

Using a Weighted Mean

In some cases, judgmental sampling locations may be unevenly distributed throughout the Exposure Point being evaluated. A weighted mean can provide a spatially representative mean from unevenly distributed sampling results. Figure 11.2 illustrates a situation where the sampling locations are not evenly distributed and shows the weighted mean calculation for the sampling locations depicted.

Figure 11.2
Biased Sampling Example: a weighted mean



This example represents a simple approach to obtaining a weighted average. A more refined technique involves dividing an area into polygons and constructing a polygon around each data point so that each polygon contains the locations that are closer to the data point at its center than any other data point. Thiessen polygons are an example of this technique. The boundaries of the polygon define the area that is closest to the sampling point relative to all the other sampling points.

11.3.3.3.2 Using Composite Soil Samples with Judgmental Sampling

In composite sampling, materials from several different discrete sampling locations (grab samples) are combined to form a single sample for chemical analysis. Where information on spatial variability is not needed, compositing can reduce analytical costs. Compositing is generally more applicable to judgmental than systematic sampling, considering that (a) characterizing variability is a major advantage of systematic sampling,

and (b) information on concentration variability is lost when grab samples are combined.

The concentration of a composite soil sample estimates the arithmetic mean within the volume of soil from which the grab samples were collected. However, the concentration detected in a composite is representative of the mean concentration in the soil volume if and only if: (1) the grab samples are representative of the area (2) the composite sample is well mixed and (3) the process of compositing does not result in analyte loss (for volatile and semi-volatile contaminants). The representativeness of the composite result can be evaluated by comparing it to the mean concentration of a set of single location samples with the concentration of a composite of sample collected from the same area. While it is possible to use results of composite samples from one portion of the Exposure Point with the results of discrete samples from other parts of the Exposure Point to calculate a mean for the entire Exposure Point, caution should be used to ensure that the combined mean accurately represents the Exposure Point as a whole.

11.3.3.3.3 Direct Contact Exposure Point Concentrations from Systematic Discrete Sampling Data

The 2024 revision of the MCP specifies the use of systematic sampling where "*the soil contamination has not been attributed to a known source; the contamination may not be limited to a defined area; it is not possible to identify the area with the highest concentration within the Exposure Point; or the soil may have been significantly redistributed since the release"* (310 CMR 40.0904(4)(b). The regulations allow for exceptions where "*specific site circumstances support a technical justification that judgmental sampling provides a conservative estimate of exposure" (310 CMR 40.0904(4)(c).* However, in general, judgmental sampling is not appropriate for sites that have no known or suspected source.

The MCP requires a "conservative estimate of the mean" (310 CMR 40.0926(5)). Given the level of variability typical of soil and sediment concentrations, the error associated with the simple mean can be significant. For sites where systematic sampling is used, the MCP allows the 90th percentile Chebyshev non-parametric upper confidence limit (UCL) on the mean to be used as the EPC (310 CMR 40.0926(8)(a).

U.S. EPA guidance has provided the formula for calculating the Chebyshev nonparametric upper confidence limit (EPA, 2002b, Exhibit 12):

$$= X + \left(\sqrt{\frac{1}{\alpha} - UCL_{(1-\alpha)\ x\ 100\%} 1} \right) \times \frac{S_x}{\sqrt{n}} \qquad \textbf{(11-2)}$$

Where:

X	=	sample mean
α	=	0.1 to compute the 90% UCL
S_x	=	standard deviation
n	=	number of samples (number of values in the data set)

The Chebychev nonparametric UCL may also be computed using statistical software packages. In addition to various commercially available packages, EPA's ProUCL software offers a convenient way to calculate UCLs (U.S. EPA, 2022). **If ProUCL is employed, MassDEP strongly recommends using Version 5.1 and not Version 5.2.** See Chapter 4 for additional information.

Consistent with other provisions of the MCP, exceptions to the general rule may be allowed. Specifically, the risk assessor may opt to calculate a different UCL (e.g., parametric instead of non-parametric, but only when the distribution of the data support one vs. the other) or to use a different approach to obtaining a conservative estimate of the mean:

> *If the 90th percentile Chebyshev non-parametric upper confidence limit on the mean is determined not to provide a suitable estimate of the Exposure Point Concentration, an alternative conservative estimate of the arithmetic mean may be used to determine the Exposure Point Concentration, supported by technical justification. Such technical justification shall document the determination that the 90th percentile Chebyshev non-parametric upper confidence limit on the mean is not suitable, and the suitability of the alternative approach, considering the size of the data set, density and potential biases of the sampling, applicable statistical analyses of the data, and other relevant factors. (310 CMR 40.0926(8)(a)(2)(a).*

Note that one of the considerations listed in the text above is the size of the data set. MassDEP would consider the use of a simple mean for a large data set to be a sufficiently conservative estimate of the mean. The availability of a very large data set (e.g., >60 samples for soil) may provide a technical justification for basing the EPC on the simple arithmetic mean instead of the UCL.

11.3.3.3.4 Direct Contact Exposure Point Concentrations from Systematic Incremental Sampling Data

As detailed in Section 4.3.2.3, Incremental Sampling Methodology (ISM) is a soil sample collection and processing protocol aimed at increasing sample representativeness and reducing data variability. Where ISM is being applied, a sampling grid is laid out over the area to be sampled. The area covered by the sampling grid is referred to as a decision unit in the technical literature on ISM. In MCP risk assessment terms, the decision unit is an Exposure Point (or exposure area). In residential areas, each parcel should be sampled as one or more separate Exposure Point(s). In areas where residential development is possible but does not yet exist, decision units for incremental sampling should be a quarter acre, corresponding to a small residential parcel that would represent a potential future Exposure Point.

Sampling grids for incremental sampling should correspond to Exposure Points (or exposure areas) being evaluated in the risk assessment.

As detailed in Section 4.3.2.3, the sampling grid guides the collection of 30 to 60 discrete grab samples (increments), which are combined into a single large "incremental sample." This process is repeated twice so that a total of three separate samples are obtained for laboratory analysis. Each of the 3 sample results is essentially the average concentration from at least 30 increments, and the mean of the three results represents 90 increments (grab samples). MassDEP accepts the arithmetic mean of the three incremental sample results as a conservative estimate of the mean concentration within the Exposure Point (Section 4.3.2.1).

Where incremental sampling is employed, the arithmetic mean of three incremental sampling results is acceptable as the EPC.

A major limitation of incremental sampling is the equipment used to grab samples only captures the top few inches of soil. Consequently, depending on the vertical distribution of contaminants, incremental sampling may or may not be representative of the depths of concern (down 3 feet for surface soil). To justify using incremental samples from the top few inches to represent the top three feet of soil, data demonstrating that deeper soil is not more contaminated must be provided.

11.3.3.4 Exposure Point Concentrations for Consumption of Homegrown Fruits and Vegetables

Consumption of fruits and vegetables grown in contaminated soil will result in exposure to soil contaminants if the plants take up a portion of the contaminants from the soil. This pathway must be considered in the risk characterization where current and/or future gardening is likely or may occur in residential scenarios.
If residential gardening is a likely or foreseeable site activity, the MPC (310 CMR 40.0942(1)e) provides two approaches to consider:

1. A Method 1 risk characterization is considered to be protective of this exposure and may be used if Method 1 is otherwise applicable: or
2. A Method 3 risk characterization may be used.

If a Method 3 Risk Characterization is chosen, the risk associated with the ingestion of produce from gardening must be quantitatively evaluated unless the gardening and produce ingestion has been addressed through the implementation of Best Management Practices (BMPs) (MassDEP, 2014b) for current Gardening and/or the recommendation of BMPs for future gardening. Where BMPs are used, the risk characterization must include documentation and discussion of the concentrations of contaminants in the soil, acknowledgement of the potential for uptake into edible plants and the potential for exposure that may result from harvesting and consuming plants grown in contaminated soil. The risk characterization must also include a description of the gardening BMPs that are intended to minimize or eliminate such exposure.

Where BMPs are not used, the method chosen to quantitatively evaluate consumption of homegrown produce in a Method 3 risk characterization is at the discretion of the risk assessor. However, the chosen method must be discussed and supported in the risk characterization.

Method used to quantify the ingestion of homegrown produce in the Shortform
One quantitative approach that may be used in Method 3 risk characterizations is the approach used in the Shortforms, which uses plant uptake factors derived from published literature to quantify the exposure. This approach is used in the Shortforms for a small set of chemicals. Soil to plant uptake factors are provided in the vlookup toxicity file of the Shortforms. Additional details and assumptions used in the plant uptake factor approach are available in Table R-8 of the Residential Soil Shortform (Produce worksheet).

The contaminant concentration in the produce (plant) is related to the soil concentration and the plant uptake factor, as follows:

$$[OHM]_{plant} = [OHM]_{soil} \times K_{sp\ plant/soil} \qquad (11\text{-}3)$$

$[OHM]_{plant}$ = plant contaminant concentration (mg OHM/kg)
$[OHM]_{soil}$ = soil contaminant concentration (mg OHM/kg soil)
Ksp plant/soil = plant/soil uptake factor (kg soil/kg plant)

When estimating contaminant concentrations in produce, the uptake factors and produce consumption estimates must have comparable units. Plant uptake factors are generally reported on a dry weight basis. When that is the

case, dry weight produce concentrations must be used with the intake estimates that are expressed in terms of dry weight, not wet weight. If data are reported as wet weight, an approximate conversion of 0.1 (or 10%) is an acceptable conversion from wet to dry weight, unless there is information to indicate the plant(s) under consideration are known to have low water content in which case, a plant-specific conversion may be necessary. Risk assessors are encouraged to contact ORS for additional guidance when attempting to use novel approaches to quantify this exposure pathway.

11.3.3.5 Exposure Point Concentration for Inhalation of Particulate Matter from Contaminated Soil

Inhalation of airborne particulate matter is of concern in cases where contaminated soil is unvegetated or is likely to be graded or excavated for site work or for development.

The EPC (mass of contaminant/volume air) can be calculated as follows:

$$\mathbf{EPC_{air} = [OHM]_{PM10} \times [PM_{10}]_{air} \times CF} \qquad \textbf{(11-4)}$$

Where:

EPC air	=	EPC of the contaminant (ug contaminant/m^3air)
[OHM]PM10	=	OHM concentration in the respirable particulate fraction (mg contaminant/kg PM10)
[PM10]air	=	Respirable particulate concentration in air (ug PM10/m^3 air)
CF	=	Conversion factor (10^{-9} kg/ug)

In other words, the contaminant EPC is essentially the product of the estimated airborne PM10 concentration and the estimated concentrations of contaminants present in the PM10 particulate fraction.

11.3.3.5.1 Estimating the Concentration of Contaminants in the PM10 Particulate Fraction

To date, MassDEP has recommended using the bulk site soil concentration of a contaminant as an estimate of the concentration in the PM10 soil fraction. However, this practice undoubtedly underestimates the contaminant concentration in the PM10 fraction, because a high percentage of the contamination in bulk soil samples is associated with the smallest particles (See Section 4.3.4 in Chapter 4) and smaller particles are more likely to be suspended in air. This error should be reduced to the extent practicable. There is no perfect way to estimate PM10 contaminant concentrations, but there are several options for accounting for the relationship between particle size and concentration, including:

- Sieving soil samples prior to analysis (EPA, 2016) to obtain the smallest particle fraction possible. This will improve the PM10 soil fraction concentration estimate, but respirable particles cannot be completely separated from larger ones by sieving.
- Using an adjustment factor consistent with the technical literature on concentration differences associated with various particle size fractions.
- Conducting air sampling to collect ambient PM10 samples that can be analyzed for contaminant concentrations. This approach requires specialized sampling equipment and may not be practical at some sites. In addition, the contaminants detected in the PM10 sample may be from sources other than the site.

While each approach has drawbacks, any one of them could provide a more accurate PM10 concentration than simply using bulk soil concentrations.

11.3.3.5.2 Estimating the Airborne PM10 Concentrations

When evaluating exposure to airborne particulate matter at a sparsely vegetated or unvegetated site, or at a construction site, it should be assumed that all the airborne PM10 is affected by the contaminated area. This may overestimate the contribution of site soil to airborne particulate concentrations, but in most cases the data necessary to obtain a more accurate estimate for these conditions is not feasible or available. However, on a site-specific basis, with appropriate justification (e.g. dense vegetation), the percentage of PM10 that is soil-derived may be reduced to as low as 40% (Thurston and Spengler, 1983). Site-specific information used to adjust the PM10 percentages must be supported with documentation.

Default values for concentrations of PM10 from one of two situations are usually required. The first situation is an open field condition, in which contaminated soil is sparsely vegetated or bare, and soil particulate matter readily becomes airborne. The second situation is a grading or excavation scenario, in which earth working activities may raise elevated levels of dust.

For open field situations, a default value of 30 ug/m^3 should be used as an estimate of the ambient PM10 concentration. This value has been used for many years for MCP risk assessments. It represents the highest (from 17 sampling stations) annual arithmetic mean concentration (rounded from 32 ug/m^3) measured in Massachusetts in 1994 by DEP's Air Quality Surveillance Branch (MassDEP, 1994).

For grading and excavation scenarios, a default PM10 value of 60 ug/m^3 should be used to estimate ambient concentrations. This value is rounded from the arithmetic mean of 61 ug/m^3, which is the 24-hour maximum PM10 value from 20 samplers (at 17 locations) in the Commonwealth during 1994 (1994 Air Quality Report, Commonwealth of Massachusetts). A contribution factor of 100% should be used to estimate the portion of ambient particulate level contributed by the construction activities.

There are several uncertainties associated with use of the default PM10 values, including:

- The published 24-hour averages may underestimate PM10 concentrations attained during the workday.
- The sampling locations are not necessarily located near construction activities or large areas of sparsely vegetated soil.

Nevertheless, MassDEP recommends using a default value when a PM10 estimate is necessary.

In lieu of site-specific risk estimates from exposure to airborne particulates at construction sites, several investigators have proposed using risk-based particulate concentrations of site-related contaminants to calculate the airborne PM10 concentration that would pose a significant risk (LSPA, 2016; Weidner et al., 1997). To guard against exposures that could pose a significant risk, ambient PM10 concentrations would then be monitored, and exposure-reduction measures would be taken if the levels exceeded the risk-based PM10 concentration. This approach has the advantage of eliminating the need to measure contaminant concentrations in the dust. One disadvantage is that non-site PM10 sources may contribute to the measured ambient PM10 concentrations. Another drawback is that it does not provide prospective risk estimates. However, in certain cases, this approach may provide a practical way of ensuring that dust raised by

construction activities will not pose a significant risk.

11.3.3.6 Coal Tar Exposure Points and Exposure Point Concentrations

The 2024 revision of the MCP includes several provisions aimed at ensuring that direct contact with coal tar waste deposits is identified as a human health risk, and that site management decisions prevent direct contact. These include:

- 310 CMR 40.0924(11)(b): Visible coal tar waste deposits shall be considered distinct Exposure Points.

- 310 CMR 40.0926(8)(a): For Exposure Points where direct contact with visible coal tar is possible, the EPC shall be based on the concentration known or estimated to be present in the coal tar itself.

In effect, these provisions mean that the coal tar EPCs must be based on concentrations of the tar's constituents, and that those concentrations may be estimated rather than measured.

Coal tar is a by-product of three industrial processes - the production of coal gas (town gas), the production of coke and via coal liquefaction. Only the first of these (coal gas) has been employed extensively in Massachusetts. Coal tar waste originating from the production of coal gas has been identified at many waste sites in Massachusetts. The coal tar provisions in the 2024 MCP pertain only to coal tar waste itself, not to materials that incorporate coal tar or one of its byproducts. Specifically, it does not include wood to which creosotes have been applied or asphalt pavement into which coal tar, coal tar creosotes or coal tar pitch has been incorporated. While pitch and creosote contain many of the same organic compounds as coal tar, they have different origins and enter the environment through incorporation into building materials:

- Coal tar creosotes are produced by the distillation of tar coal. Coal tar creosotes have been used in the United States as wood preservatives for over 100 years (ATSDR, 2024).

- Coal tar pitch is a byproduct of coal tar distillation. The most viscous grade of coal tar pitch is used in certain industrial processes and in sealcoat on parking lots and driveways, mainly in areas east of the Rocky Mountains (USGS, 2019).

At some sites, constituents of creosote or pitch may be a COC. In such cases, the risk from those constituents should be evaluated using regular MCP risk assessment framework and procedures. In contrast to coal tar, creosote and pitch are not presumed to pose a risk although they may in some instances.

As a result of historical waste management practices, coal tar waste deposits are generally found at or near the former gasification facilities where they were generated. The main exception is coal tar that has migrated to an adjacent river and been transported some distance downstream.

The coal tar waste provisions of the 2024 MCP apply only to actual coal tar deposits. They do not apply to materials that contain coal tar such as creosote, pitch or related contaminants.

Coal tars are mixtures of hydrocarbons, phenols, and heterocyclic oxygen, sulfur, and nitrogen compounds (NTP, 2021). In some cases, other process by-products (e.g., cyanide) may also be present. The number of

PAHs that have been detected in coal tar is far greater than the number analyzed in MCP site investigations. The composition of different coal tars varies and depends upon the type of coal used as a source material and the gasification process that used to generate coal gas as well as the aging of the coal tar. Moreover, large variations have also been found between separate samples from the same site. Nevertheless, different coal tars are consistently found to be primarily composed of PAHs, with naphthalene typically being present at percent levels. While risk assessments of coal tar and PAHs have focused on cancer potency, non-cancer effects are also a concern for several PAHs, including naphthalene and should be assessed.

Given that coal tar at any site contains over 400 organic compounds, and possibly thousands (IARC, 1985), it would be prohibitively expensive and time-consuming to quantify all the constituents in samples of coal tar for site assessment purposes. The coal tar matrix also poses significant challenges for an analytical chemist due to its complex nature and potential to cause issues with analytical equipment. As a means to avoid some of these complications, MassDEP recommends that investigators rely on the range of concentrations reported in the published literature to estimate EPCs. In lieu of using published literature, the risk assessor may assume coal tar poses significant risk of harm to human health whenever there is potential for exposure based on the known constituents and toxicity of coal tar.

To assess the risk posed by coal tar waste deposits, it is acceptable to estimate EPCs from data reported in the technical literature.

- **A quantitative estimate may be based on upper end concentrations from reported concentration ranges, but all types of compounds must be included.**
- **A qualitative approach is another option (that we believe most practitioners will choose). The risk assessor may simply state that, the EPCs of organic compounds in coal tar exceed concentrations that would pose a significant risk of harm to human health, welfare and the environment.**

Table 11.2 summarizes key findings on coal tar composition and toxicity that have been reported in the literature. These findings support MassDEP's approach to coal tar assessment and management. The findings highlighted in the table are examples from the literature that may be cited by risk assessors to support the assessment of coal tar deposits. Specifically, these findings would support a qualitative risk assessment conclusion that coal tar waste deposits at a site would pose a significant risk for direct contact exposures.

Table 11.2 Composition and Toxicity of Coal Tar

Finding	Relevant to	Reference
"Coal tar is known to be composed of hundreds to thousands of organic compounds, mostly polycyclic aromatic hydrocarbons (PAHs)."	Composition	Brown et al., 2006
"Over 400 compounds have been identified in coal-tars, and probably as many as 10,000 are actually present."	Composition	IARC, 1985
The results from a comprehensive analysis of 16 different coal tars from U.K. sites showed that the number of PAHs per sample ranged from 301 to 729, and the number of alkyl PAHs per sample ranged from 136 to 202.	Composition	Gallacher et al., 2017
The analysis of 11 samples from 10 MGP sites in the eastern United States showed that the total PAH concentration in the most contaminated sample was 241,328 mg/kg (24%) and the total PAH concentration for the least contaminated sample was 24,581 (2.4%).	Composition	Brown et al., 2006

Finding	Relevant to	Reference
Naphthalene was the most prevalent compound in all eleven coal tars samples from the Northeastern studies. The naphthalene component ranged from 0.7% to 6.8%.	Composition	Brown et al., 2006
"Alkylated PAHs form an important group of compounds that are often ignored in environmental analysis due to difficulties in obtaining accurate measurements." *"Alkylated PAHs have been shown to contribute substantially to the toxicity of PAH mixtures. . ."*	Composition & Toxicity	Gallacher et al., 2017
Coal tars and coal-tar pitches are known to be human carcinogens based on sufficient evidence of carcinogenicity from studies in humans.	Toxicity	NTP, 2021
In a study comparing the tumorigenicity of two coal tar mixtures to that of benzo[a]pyrene after 2 years of feeding [mice], coal tar has been shown to cause more cancers than benzo(a)pyrene alone.	Toxicity	Culp et al., 1998
While it is generally accepted that PAHs can significantly impair ovarian function and fertility, less is known regarding heterocyclic, substituted, halogenated, and alkylated PACs.	Toxicity	Perono et al., 2022
Naphthalene vapors pose a risk of harm to health at levels well below the odor threshold. The RfC for naphthalene is 0.003 mg/m3, while the odor threshold is 0.4 mg/m3, a difference of two orders of magnitude.	Toxicity	MassDEP Method 1 Standards spreadsheets, 2024

The presence of accessible visible coal tar wastes must also be assessed to address the risk of harm to public welfare (310 CMR 40.0994(4)(d)). Requirements for characterizing and controlling the risk of harm to public are detailed in section 310 CMR 40.0997. These requirements aim to minimize or eliminate accessibility to coal tar waste deposits, so compliance with them will also effectively eliminate the possibility of exposure and the risk of harm to human health.

MassDEP expects that human exposure to coal tar waste deposits will effectively be eliminated by compliance with the provisions of 310 CMR 40.0997.

For coal tar from 3-15 feet below ground surface, it is not typically considered accessible under current conditions (unless there is a site-specific reason). However, future exposure to the coal tar must be addressed either by removal of the coal tar or placement of an Engineered Barrier **AND** an AUL must be implemented in accordance with 310 CMR 40.0997(3).

11.3.3.7 Exposure Point Concentrations Related to Fish Consumption

As is the case for exposures to other media, the EPC for fish consumption must be a conservative estimate of the mean concentration in edible fish tissue. Several cautions apply:

- At sites where enough fish can be collected for a representative sample, tissue concentrations should be measured directly. This typically means fish fillets but may be whole fish in some situations.
- Concentrations estimated from surface water levels and a generic bioconcentration factor are highly uncertain. If tissue concentrations cannot be measured and must be estimated, it may be appropriate to use upper-end water concentrations and BCF values to ensure that the EPC is a conservative estimate. Measured data are always preferable to modeled data, whenever possible.
- Estimates should be based on skin-on filets to account for cooking methods in which higher levels of contaminants present in and beneath the skin are included in prepared food.

Fish consumed by people who catch fish recreationally and their families include large fish, which often have higher contaminant levels. Large fish are often excluded from the mix of fish analyzed in Massachusetts' monitoring programs in order to obtain comparable data from different water bodies. As a result, the available monitoring data should not be used in a risk assessment.

Ideally, sufficient data would be available to calculate EPCs for each fish species present so that the risk assessment could consider exposures to populations partial to eating certain species. In some cases, it may not be possible to catch a total number of fish to calculate the mean concentration with a reasonable degree of certainty. The risk assessor and project manager must then decide how to deal with the uncertainty. One option would be to use the highest concentration detected and to describe the uncertainty in the risk assessment report.

The MassDEP Fish Ingestion Technical Update (2008c) discusses fish consumption rates and recommends a rate of 32 g/day for an adult and 16 g/day for a child.

MassDEP recommends against reducing fish consumption exposure factors when assessing small streams. Instead, MassDEP treats all water bodies the same so that fish can be safely caught from place to place throughout the season. This guidance accords with 310 CMR 40.0923, which states that any risk characterization should evaluate a full and unrestricted use of the resource. In the case of lakes, ponds, rivers and streams, the full and unrestricted use of the resource includes the consumption of fish caught by recreational anglers. Evaluation of full and unrestricted use also applied to marine and estuarine systems.

11.3.3.8 Surface Water Exposure Point Concentrations for Swimming

Surface water Exposure Points may be limited to areas near a shoreline or may include a whole pond or river segment. The EPC used to evaluate swimming exposures should represent conservative estimates of the arithmetic mean concentration within the Exposure Point (area). If contamination is reaching a surface water body by groundwater discharge or by surface runoff, near shore areas may be more heavily contaminated, the EPCs for younger children who stay closer to shore should reflect this.

11.3.3.9 Sediment Exposure Points and Exposure Point Concentrations for Wading

In most situations where a person may be exposed to contaminated sediment, the Exposure Point is a limited area where there is access from the shore of a lake or pond, or from the bank of a stream. In such cases, judgmental sampling is used to assess contaminant concentrations. The arithmetic mean concentration may be used to estimate the EPC.

11.3.3.10 Indoor Air Exposure Point Concentrations

In 2016, MassDEP published *Vapor Intrusion Guidance: Site Assessment, Mitigation and Closure* (MassDEP, 2016). This provides guidance for evaluating the vapor intrusion pathway, assessing indoor air exposure and risk, and mitigating vapor intrusion conditions. This section focuses on indoor air sampling considerations related to assessing exposure and risk. The Vapor Intrusion Guidance should be used as the primary reference for identifying Exposure Points and Calculating EPCs in Indoor Air Exposures for MCP Risk Characterization.

Previously, in 2002, MassDEP published indoor air sampling guidance prepared by ORS (MassDEP, 2002a). That document lays out ideal sampling durations to obtain representative concentrations for estimating chronic, sub-chronic and acute exposures. It also emphasized the importance of sampling duration and frequency in covering

changes in conditions and concentrations that might occur on a seasonal, daily, or hourly basis. The 2002 guidance remains a useful reference for evaluating the sources of uncertainty inherent in indoor air data.

MassDEP developed a list of Typical Indoor Air Concentrations or "TIACs" (MassDEP, 2008a) available at https://www.mass.gov/files/documents/2016/10/nu/vapor-intrusion-guidance-10-14-2016.pdf. This list provides the 50th, 75th and 90th percentile values based on data sets from several recent studies of indoor air quality in residential structures. In the absence of well-documented and generically-applicable commercial TIACs, these values were used to develop both the residential and commercial/industrial Threshold Values (TVs). The application of these values is discussed in the *Vapor Intrusion Guidance* (MassDEP, 2016). More recent indoor air data sets may be applicable but require thorough documentation and support.

11.3.3 Quantitative Estimations of Exposure

In the next step of the risk assessment Exposure Points, Exposure Point Concentrations, the receptors of concern, and the potential exposures experienced by the receptors are quantified. This information is used to estimate risk, as described in Section 11.4.

This section of the guidance describes (a) the differences between exposure and dose, (b) the different types of doses which may be employed in the risk assessment, (c) the common factors used to estimate exposure, and (d) the pathway-specific equations employed to quantify exposure.

11.3.3.1 Quantitative Estimates: Concepts and Terminology.

The concept of exposure is complex, and the numerical value calculated by the risk assessor will depend upon the nature of the exposure pathway under investigation, the duration of the exposure, and the health effects associated with the chemicals of concern.

The U.S. EPA Exposure Assessment Group defines *exposure* as the amount of material in contact with an organism and available for absorption. The material which reaches the organism's absorption barrier (such as the skin, lung, or gastrointestinal tract) is referred to as the *applied dose*, while the *absorbed* (or *internal*) *dose* is defined as the amount of material which actually crosses the organism's skin or lungs (and enters the bloodstream/circulatory system). [Note that exposure is often thought of as the "*potential dose*" and taken as an approximation of the applied dose, as it represents the amount which could be absorbed if it were 100% bioavailable.]

The type of exposure or dose used to characterize risk will depend upon the exposure pathway under evaluation and the nature of the toxicity information available for each chemical.

Inhalation exposures are evaluated using the EPC in combination with a published Reference Concentration or Unit Risk value.

Oral and dermal exposures are evaluated by modifying the applied dose with a Relative Absorption Factor (RAF) to ensure that the calculated exposure is comparable to the Reference Dose or Cancer Slope Factor employed. See Section 11.2.4 for a discussion of RAFs.

Where appropriate, the equations given in the following pages include an RAF. Under certain conditions the quantitative estimate of exposure will in fact be an estimate of the applied dose (or exposure) rather than an absorbed dose. For simplicity, the term "average daily dose" is used to describe the product of an "average daily

exposure" and a RAF.

11.3.3.2 Average Daily Doses (ADD) and Average Daily Exposures (ADE)

Quantitative estimates of exposure include the Average Daily Dose (ADD) and Average Daily Exposure (ADE). It may be necessary to calculate several different Average Daily Doses (ADDs) and Average Daily Exposures (ADEs) of OHM to a receptor to evaluate all relevant exposure scenarios. For the inhalation route of exposure ADEs are calculated; for other routes of exposure ADD are calculated. For OHM that are considered carcinogenic, a lifetime ADD (LADD) or lifetime ADE (LADE) must be calculated. For non-carcinogens, all appropriate ADDs and ADEs must be calculated considering all relevant exposure durations (*chronic, subchronic and/or acute*).

The equations presented below outline the procedure for the calculation of an Average Daily Dose of an OHM. Depending upon the duration of the exposure under evaluation and the type of health effect (cancer or non-cancer) of concern, the calculations may yield one of several results:

Lifetime Average Daily Dose (LADD): A LADD in units of milligrams per kilogram body weight per day (mg/kg-day) should be calculated to estimate carcinogenic risk. The total intake during that exposure is normalized to a lifetime, taken to be 70 years. Note that exposure may occur for all or some fraction of the receptor's lifetime.

Chronic Average Daily Dose ($ADD_{chronic}$): Chronic human exposures are defined by MassDEP to be those lasting seven years or more. The ADDchronic (in units of mg/kg-day) is calculated for the characterization of potential non-cancer risk resulting from long-term exposures, and the value must be an estimate of exposure experienced by the receptor *during the period of exposure*.

Subchronic Average Daily Dose ($ADD_{subchronic}$): Subchronic human exposures are defined by MassDEP to be those lasting from several days up to seven years. The ADDsubchronic (in units of mg/kg-day) is calculated for the characterization of potential non-cancer risk associated with shorter duration exposures, and the value must be an estimate of exposure experienced by the receptor *during the period of exposure and be appropriate for the effect*.

Acute Dose Calculations (ADD_{acute}): The acute exposure may range from instantaneous to up to several days and is expressed as the ADD_{acute} (in units of mg/kg-day) The averaging period should be equivalent to *the period of exposure and be appropriate for the effect of concern. Exposures of concern may be less than a day and in this case should be compared directly to the highest measured or modeled exposure concentration without additional averaging, unless a compelling justification is provided.*

11.3.3.3 General Form of Dose Equations

The general form of the equations to estimate average daily dose (ADD) and average daily exposure (ADE) is presented as:

$$ADD = \frac{(Total\ Amount\ of\ OHM\ Contacted) * (Relative\ Absorption\ Factor)}{(Body\ Weight) * (Averaging\ Period)}$$

(11-5)

And

$$ADE = \frac{(Concentration\ of\ OHM\ Contacted)}{(Averaging\ Period)}$$

(11-6)

Note that "*dose*" is taken to be "*exposure*" normalized to the receptor's body weight and adjusted for absorption/bioavailability (as described in section 11.2.4).

At c.21E disposal sites it is common to have situations where a receptor may be exposed to a chemical through multiple exposure pathways, such as ingesting contaminated soil and absorbing the material following dermal contact with contaminated soil. **In such cases, the doses of an OHM received via different routes of exposure are assumed to be additive unless there is strong evidence otherwise**.

$$Cumulative\ Risk = \Sigma(Chemical\ i, Exposure\ Pathway\ j)$$

(11-7)_

General equations for the calculation of Average Daily Dose and Average Daily Exposure are presented in this section for some frequently encountered exposure pathways. These equations are not intended to represent the universe of potential approaches and they must be tailored to site-specific conditions. It is expected that additional exposure pathways may be identified, and an average daily dose may be calculated, using appropriate models, for each receptor of concern.

There are a few common exposure factors that are employed in virtually all the exposure equations, and the discussion which follows describes some of the issues which may arise when using these elements. Exposure factors which are specific to a particular pathway are discussed in the subsection which presents the equations for that pathway.

The daily dose(s) of each OHM calculated for each potential receptor should be summarized in the risk characterization report in a manner which is clear and concise. Summary tables presenting the equations and the exposure factors which are data-informed assumptions used to calculate the daily dose should also be presented and well-referenced. If unmodified Method 3 Shortforms are used there is presumptive acceptance of the results by MassDEP, provided all OHM and exposures of concern are addressed. As noted within the Shortforms, any modifications to the Shortforms must be well-documented and justified. If a pathway has a potential to drive risk for a receptor at a site and is not included in a Shortform, the pathway should be evaluated. For instance, the construction worker Shortform evaluates soil exposure. If contact with contaminated groundwater is a potential risk driver for construction workers, that pathway should also be evaluated. Note also that acute exposures are NOT comprehensively addressed in the Shortforms yet and should be addressed if an issue at a site.

11.3.3.4 Descriptions of General Exposure Factors

There are eight exposure factors which recur throughout the equations used to estimate the dose of OHM experienced by a potential receptor:

- Chemical Concentration (C)
- Body Weight (BW)
- Frequency of Exposure (EF)
- Duration of the Exposure Event (ED)
- Duration of the Exposure Period (EP)
- Relative Absorption Factor (RAF)
- Averaging Period (AP)
- Units Conversion Factors (CF or C)

Units of Chemical Concentration

The concentration of the OHM used to quantify exposure is the EPC, described in section 11.3.5. The EPC is expressed in terms of mass of the material per unit mass (or volume) of the exposure medium: mg OHM/kg soil, ug OHM/liter water, and ug OHM/m^3 air. When concentrations are expressed in terms of parts-per-million (ppm), parts-per-billion (ppb), or parts-per-trillion (ppt), care must be taken to convert the concentrations to the appropriate units.

Soil, sediment, food: 1 mg/kg = 1 ug/g = 1 ppm
1 ug/kg = 1 ppb
1 ng/kg = 1 ppt (part per trillion)

Water: 1 mg/liter = 1 ppm
1 ug/liter = 1 ppb
1 ng/liter = 1 ppt

Air: Air data in mg/m^3 can be converted to ppm volume (ppmv) using the following equation:

$$1ppm = \frac{1\ \frac{mg}{m^3} * 22.4 * \frac{T}{273^oK} * \frac{P}{760\ Torr}}{M.W.}$$

(11-8)

Where T is the air temperature (often assumed to be 25 °C or 298 °K) and P is the atmospheric pressure (often assumed to be 1 atmosphere or 760 Torr), and M.W. is the molecular weight of the chemical under evaluation.

EPC should *not* be adjusted for receptor exposure frequency, duration, etc., as those factors are generally addressed in the exposure calculations.

Body Weight

A receptor's body weight is relevant throughout the dose equations as dose is expressed in terms of mass of contaminant per unit body weight per day (typically, mg/kg-day). When each receptor of concern is identified, the receptor is often described in terms of occupation (resident, construction worker), age (a child ages 1 to 6 years) and sometimes gender. The receptor's body weight is dependent upon their age and gender. Since body weight is easily measured, there are numerous summaries of age and gender-specific body weights. Additional

information is available in the Exposure Factors Handbook (U.S. EPA, 2019). There are also descriptions of exposure parameters included in the "EXP" tab of the Shortform workbooks.

The receptor body weight (**BW**, typically expressed in kilograms, kg) must be matched to the age and gender identified in the exposure profile. Since exposure is often assumed to occur over a period of several years, the changes in body weight that might occur during the period of exposure must also be considered and adjusted over time.

Even within a given age/sex combination, there is some variability of body weight for that subpopulation. For example, some 8-year-old boys weigh more/less than other 8-year-old boys. For body weight this variation is well defined, and the distribution of body weights for this subpopulation of concern may be used as part of a probabilistic assessment of exposure (U.S. EPA, 2014b). For evaluations requiring a point estimate of body weight, ORS recommends using the 50th percentile body weight for that subpopulation, unless there is strong evidence that the potentially exposed subpopulation is biased in some manner. Note that for a normal distribution, the 50th percentile approximates the arithmetic mean.

Frequency of Exposure and Duration of the Exposure Event

A receptor may be exposed to OHM continuously, at regular intervals, or in a sporadic manner. The Frequency of Exposure (**EF**) and the Duration of the Exposure Event (**ED**) in combination describe the pattern of exposure being modelled.

The frequency of exposure term describes how often the exposure event occurs over a given period of time. The term answers the questions: *How many times a day does exposure occur? How many times per week?*, *per month?*, *per year?* Exposure Frequency may, in fact, be a string of terms which ultimately reduce to one expression:

$$\frac{1\ event}{day} * \frac{3\ days}{week} * \frac{4\ weeks}{month} * \frac{12\ months}{year} = \frac{144\ events}{year} \qquad \textbf{(11-9)}$$

The Duration of the Exposure Event, as the name implies, describes how long each individual exposure event might last. The term is somewhat more complex than it sounds, however, because it must be consistent with the scale of the contact rate for the exposure being modelled. Contact rates are generally on the scale of days. The ingestion pathway is typical of this case. While estimates have been published on the amount of water ingested during a *day*, there can be no reliable estimate of average *hourly* ingestion rates as drinking water is a sporadic event depending upon thirst and habit. For such exposures (including drinking water ingestion, soil ingestion and dermal contact) **ED is by definition 1 day/event**. During that "1 event" the receptor is assumed to receive the daily intake of the contaminant.

Duration of the Exposure Period

The exposure period (EP) describes the length of time over which the receptor comes into contact with the OHM. The exposure period depends upon the type of activities which lead a receptor to be exposed. Remember that the receptor may be exposed continuously, at regular intervals, or sporadically, depending upon the activity being modelled, so the exposure period would be the length of time between the first exposure experienced and the last. The EP term is typically expressed as some unit of time: days, months, years.

Averaging Period

The equations which follow calculate *average* daily doses or *average* daily exposures, and the averaging period (AP) is the time (in days, months, or years) over which the total intake is normalized.

A Lifetime Average Daily Dose (LADD) or Lifetime Average Daily Exposure (LADE) (for inhalation exposures) is calculated for the evaluation of *cancer risk*. While the duration of the exposure period (EP) might range from one day to an entire lifetime, the total intake during that exposure is normalized to 70 years (a lifetime). The averaging period is thus assigned a value of 70 years, and, for exposures lasting less than a lifetime, the values for EP and AP will be different.

For the evaluation of *non-cancer risk*, however, the Average Daily Dose (ADD) or Average Daily Exposure (ADE) calculated should be representative of the exposure received while exposure is on-going (i.e., during the exposure period). Thus, the duration of the exposure period (EP) and the averaging period (AP) for a chronic, subchronic or acute ADD and ADE are variable factors depending upon the exposure being modelled, *but the AP is set equal to EP by definition*.

Relative Absorption Factor

As described in the Dose-Response section of this guidance, the Relative Absorption Factor (RAF) relates the exposure and absorption estimated for the exposure pathway under evaluation to the exposure and absorption in the toxicological study on which the toxicological dose-response information is based. The RAF is dimensionless and is chemical- and pathway-specific.

EXPOSURE DURATION OR PERIOD (EP) and AVERAGING PERIOD (AP)

The Averaging Period (AP) used in the equations to calculate dose will be equal to the Exposure Period (EP) for the evaluation of ***non-cancer*** risks. When estimating ***cancer*** risk, AP is always equal to a lifetime (70 years) while EP may vary depending upon the exposure under investigation:

Example: The risk assessor is asked to evaluate the carcinogenic risk associated with a seven-year exposure to chemical A. Estimation of carcinogenic risk requires the calculation of a Lifetime Average Daily Dose. Thus, the Averaging Period used for calculating the LADD would be 70 years while the Exposure Period would be equal to 7 years.

The risk assessor is also asked to evaluate the likelihood of non-carcinogenic health effects associated with that same seven-year exposure. The assessor would calculate an Average Daily Dose Chronic ($ADD_{chronic}$) where EP = 7 years and AP = 7 yrs.

Units Conversion Factors

One of the most valuable habits a risk assessor can develop is to routinely conduct a units analyses on the equations used to quantify exposure. The exposure factors and analytical data used for a given calculation may come in several forms. For example, EPCs in drinking water may be in milligrams per liter or micrograms per

liter; EPC from air may be in units of parts per billion or micrograms per cubic meter. Units analysis will reveal whether units conversion factors are necessary to ensure that the result of the calculation (the dose) is expressed in the correct units (mg/kg-day).

Use of unit conversion factors (C) is equivalent to multiplication by one. The numerator and denominator of the factor must be an equivalent quantity expressed in different terms. It is not uncommon to need several conversion factors in the same equation to reconcile the dimensions of mass, volume, and time.

EXAMPLES OF UNITS CONVERSION FACTORS (C)		
Relationship	The numerator and denominator may be reversed depending upon the form of the equation.	
1,000,000 mg = 1 kg	$C = 10^{6}$ mg/kg	$C = 10^{-6}$ kg/mg
1 year = 365 days	C = 365 d/yr	C = 0.00274 yr/d
1,000 liters = 1 meter^3	$C = 10^3$ l/m^3	$C = 10^{-3}$ m^3/l

11.3.3.5 Estimating Exposure Point Concentrations - General Considerations

Sampling and Analysis

Sampling and analysis should be performed in consultation with a risk assessor and should fully cover the nature and extent of contamination at the site and allow for complete evaluation of exposure pathways. Detection limits should be adequate for determining whether there is a condition of No Significant Risk at the site. Sampling and analysis are discussed in detail in Chapter 4.

Averaging

The EPC should represent the arithmetic mean of the concentrations to which an individual may be exposed over the exposure period at the Exposure Point.

As previously stated, the EPC should be compatible with the toxicity values that will be used to characterize health risks. Chronic and subchronic reference doses are generally based on time-weighted averages of exposure concentrations used in toxicological experiments and are expressed in terms of an allowable average daily dose or exposure. Therefore, the EPCs used with those reference doses should approximate the time weighted average concentration to which the receptor may be exposed at the Exposure Point during the exposure period being evaluated. Cancer slope factors are also based on an average daily dose, and EPCs for evaluating cancer risks should represent the average daily dose for a 30-year exposure.

Four types of exposures are routinely evaluated in disposal site risk assessments: (1) acute (typically one to several days, but possibly shorter depending on the effect of concern) exposures to contaminants with non-carcinogenic effects, (2) subchronic (typically several months to seven years, but potentially shorter) exposures to contaminants with non-carcinogenic effects, (3) chronic exposures (greater than seven years) to contaminants with non-carcinogenic effects and (4) lifetime exposures (typically 30 years and averaged over a lifetime of 70 years)

to carcinogens. For each type of exposure, the risk assessment should focus on the time-segment during which the highest dose is likely to be received. The EPC should be a conservative estimate of the average exposure concentration over that time period. For example, to evaluate three-month subchronic drinking water exposure when the concentration in the water supply is known to fluctuate seasonally, the EPC should represent the highest average to which a person could be exposed within a three-month time frame.

Acute Exposures

For acute exposure assessments, the EPC should represent a conservative estimate of the concentration to which a receptor might be exposed over the period of toxicological concern, often one day to several days but potentially less than one day. Generally, the highest detected concentration should be employed when one-time exposure could result in adverse health effects (e.g., cyanide).

11.3.4 Exposure Equations

The following equations, organized by exposure medium, are provided to assist the risk assessor in quantifying a receptor's potential exposure to OHM at a c.21E disposal site. The variables specific to each equation are discussed in this section while variables common to most of the equations were presented in the previous section. Default exposure factors for these variables in the equations are provided in MassDEP's risk assessment Shortforms.

11.3.4.1 Air Exposure Equations

Generally, air concentrations are used to evaluate the risk of harm to health from inhalation exposure in conjunction with RfCs and IURs. These values are intended to be used in combination with Average Daily Exposures expressed as applied concentrations, *not* dose. In the absence of RfCs or Unit Risk values, an oral Reference Dose or Slope Factor may be used to estimate risk by converting the Reference Dose to a Reference Concentration and the Cancer Slope Factor to an Inhalation Unit Risk (U.S. EPA, 1994).

Calculation of Average Daily Exposure for Air

Gaseous OHM (for example, OHM volatilized from contaminated soil or groundwater) may be inhaled by the receptor of concern whenever the receptor is at the disposal site. The Average Daily Exposure to the contaminated air (ADE_{air}) is dependent upon the frequency and duration of the assumed exposures. The result of this calculation is an estimate of applied concentration, *not* dose. Note that the equation is a simple adjustment of the EPC to account for time the receptor spends in the area with contaminated air.

$$\boldsymbol{ADE_{air} = \frac{[OHM]_{air} * EF * ED * EP * C}{AP}} \qquad \textbf{(11-10)}$$

Where:

ADE_{air} = Average Daily Exposure to the concentration of gaseous OHM in the air at the Exposure Point during the period of exposure (dimensions: mass/volume; typical units: microgram per cubic meter or ug/m^3)

[OHM]$_{air}$ = EPC of gaseous OHM in the air at the Exposure Point during the period of exposure (dimensions: mass/volume; typical units: microgram per cubic meter or ug/m^3)

EF = Exposure Frequency. Number of exposure events (frequency) during the exposure period divided by the number of days in the exposure period (dimensions: events/time; typical units: events/day)

ED = Exposure Duration. Duration of each exposure event (dimensions: time/event; typical units: hours/event)

EP = Duration of the exposure period (dimensions: time; typical units: years)

AP = Averaging Period (dimension: time; typical units: years)

C = Appropriate units conversion factor(s) (e.g., 10^{-6} kg/mg, 1 week/7 days)

As an example, for a receptor in an office setting, if the receptor was exposed 8 hours per day, and worked 5 days per week in the office, over the course of 50 weeks per year, for a total period of 20 years, the Average Daily Exposure would be:

$$\boldsymbol{ADE_{air}} = \frac{[\boldsymbol{OHM}]_{air} * \left(8\frac{hour}{event}\right) * \left(1\frac{event}{day}\right) * \left(5\frac{day}{week}\right) * \left(50\frac{week}{year}\right) * (20\ year) * \left(\left(\frac{1\ day}{24\ hour}\right) * \left(\frac{1\ week}{7\ day}\right) * \left(\frac{1\ year}{52\ week}\right)\right)}{(20\ year)} = \boldsymbol{0.23\ [OHM]_{air}} \quad \textbf{(11-11)}$$

Where:

$$ED = 8\frac{hour}{event}$$

$$EF = \left(1\frac{event}{day}\right) * \left(5\frac{day}{week}\right) * \left(50\frac{week}{year}\right) = 250\frac{events}{year}$$

$$EP = 20\ years$$

$$AP = 20\ years$$

$$C = \left(\frac{1\ day}{24\ hour}\right) * \left(\frac{1\ week}{7\ day}\right) * \left(\frac{1\ year}{52\ week}\right) = \left(\frac{1}{8736}\right)\frac{year}{hour}$$

For receptors that may be exposed constantly (such as for many residential exposures), the Average Daily Exposure would be equal to the EPC:

$$\boldsymbol{ADE_{air}} = [\boldsymbol{OHM}]_{air} \quad \textbf{(11-12)}$$

11.3.4.2 Soil Exposure Equations

The Average Daily Dose (ADD_{soil}) received by a receptor via direct contact with soil containing OHM is the sum of the average daily doses resulting from absorption via dermal contact with the contaminated soil and the incidental ingestion of that soil. Additional soil-related exposures may result from the inhalation of fugitive dust originating from the contaminated soil. Particulate inhalation and particulate incidental ingestion are typically only included for construction workers or individuals engaged in dust-generating activities in open fields.

$$\boldsymbol{ADD_{soil}} = \boldsymbol{ADD_{dermal\ absorption}} + \boldsymbol{ADD_{ingestion}} + \boldsymbol{ADD_{particulate\ ingestion}} + \boldsymbol{ADD_{particulate\ inhalation}} \quad \textbf{(11-13)}$$

Dermal Contact with Contaminated Soil

Dermal absorption of OHM is a potentially significant route of exposure whenever direct contact with soil may occur. In fact, dermal absorption from soils may be more significant than incidental ingestion for chemicals which have a percent absorption exceeding about 10%, typically volatiles and semi-volatiles (U.S. EPA, 1992; U.S. EPA, 2004). Even chemicals exhibiting percentage absorption of less than 10% may contribute significantly to cumulative risk estimates and thus, these chemicals must also be evaluated. The absorption of OHM from soil depends upon chemical-specific factors as well as the characteristics of the soil (such as particle size and organic carbon content). Massachusetts has developed weighted skin-soil adherence factors (MassDEP 2002c).

The Average Daily Dose due to dermal contact with OHM contaminated soil ($ADD_{dermal\ absorption}$) may be calculated:

$$ADD_{dermal\ absorption} = \frac{[OHM]_{soil} * SA * SAF * RAF_{derm} * EF * ED * EP * C}{BW * AP} \quad \textbf{(11-14)}$$

Where:

ADD_{derm} = Average daily dose of OHM received through dermal absorption through soil, during the period of exposure (dimensions: mass/mass-time; typical units: mg/kg-day)

$[OHM]_{soil}$ = Representative concentration of OHM in the soil at the Exposure Point during the period of exposure (dimensions: mass/mass; typical units: mg/kg)

SA = Skin surface area in contact with the soil on days exposed (dimensions: area/time; typical units: cm^2/day)

SAF = Soil Adherence Factor: Mass of soil adhered to the unit surface area of skin exposed (dimensions: mass/area; typical units: mg/cm^2)

RAF_{derm} = Relative Absorption Factor (unitless)

EF = Exposure Frequency: the number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time; typical units: event/day)

ED = Exposure Duration: the typical duration of each exposure event (dimensions: time/event; typical units: day/event)

EP = Exposure Period: the period over which exposure may occur (dimension: time; typical units: years)

BW = Body Weight of the receptor of concern during the averaging period (dimension: mass; typical units: kg)

AP = Averaging Period (dimension: time)

C = Appropriate units conversion factor(s)

Incidental Ingestion of Contaminated Soil

The Average Daily Dose due to the incidental ingestion of OHM contaminated soil (ADD_{soil}) may be calculated:

$$ADD_{ingestion} = \frac{[OHM]_{soil} * IR * RAF_{ing} * EF * ED * EP * C}{BW * AP} \quad \textbf{(11-15)}$$

Where:

ADD_{ing} = Average daily dose of OHM received through the ingestion of soil, during the period of exposure (dimensions: mass/mass-time; typical units: mg/kg-day)

$[OHM]_{soil}$ = EPC of OHM in soil (dimensions: mass/mass; typical units: mg/kg)

IR = Daily soil ingestion rate on days exposed during the exposure period (dimensions: mass/time; typical units: mg/day)

RAF = Relative Absorption Factor (unitless)

EF = Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time; typical units: events/day)

ED = Average duration of each exposure event (dimensions: time/event; typical units: day/event)

EP = Duration of the exposure period (dimensions: time; typical units: years)

C = Appropriate units conversion factor (typically 10^{-6} kg/mg)

BW = Body weight of the receptor of concern during the averaging period (dimensions: mass; typical units: kg)

AP = Averaging Period (dimension: time; typical units: years)

DERMAL EXPOSURES: COMPARISON WITH EPA-RECOMMENDED METHOD

Equation 11-16 expresses the U.S. EPA recommended approach of estimating dermally absorbed doses from *any chemical* present in soil. The U.S. EPA equation (U.S. EPA, 2007; equation 23) is based upon an experimentally determined (or theoretically derived) absorption fraction (ABS) to determine the absorbed dose per event:

$$Where: DA_{event} = C_{soil} * CF * AF * ABS \quad \textbf{(11-16)}$$

DAevent = Absorbed dose per event (mg/cm^2-even

Csoil = Contaminant concentration in soil (mg/kg)

CF= Conversion Factor (10^{-6} kg/mg)

AF = Adherence factor of soil to skin (mg/cm^2-event)

ABS = Absorption Fraction (unitless)

Note that C_{soil} and AF of the U.S. EPA equation correspond to [OHM]soil and AF in Equation 11-16. The Absorption Fraction (ABS) of the U.S. EPA equation is incorporated into the Relative Absorption Factor (RAF) shown in Equation 11-16 (See Section 11.2.4 for a discussion of the derivation of RAFs).

Ingestion of Contaminated Particulates – Gastrointestinal Absorption

Exposure calculations are presented below for ingestion of contaminated particulates. The equation below is used to estimate the dose received from inhaled particles that are swallowed and move into the GI tract.

$$\mathbf{ADD_{inh\text{-}gi}} = \frac{[OHMsoil]*RCAF_{inh-gi}*[PM10]*VR*RAF*EF*ED*EP*C1*C2*C3}{BW*AP} \qquad \textbf{(11-17)}$$

Where:

$ADD_{inh\text{-}gi}$= Average Daily Dose due to coughing up from the lungs and swallowing in the GI tract, (dimensions: mass of chemical per unit body weight per day, typical units: mg/kg-day)

$[OHM_{soil}]$= Concentration of OHM in soil, (dimensions: mass/mass, typical units: mg/kg)
$RCAF_{inh\text{-}gi}$= Relative Concentration Adjustment Factor, gastrointestinal (unitless)
[PM10]= Concentration in air of particulates less than 10 microns in diameter, (dimensions: mass/volume, typical units: µg/m^3**)**
VR = Ventilation rate for the receptor of concern during the period of exposure. (dimensions: volume/time; typical units: m^3/hour)
RAF = Relative Absorption Factor (dimensionless)
EF = Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time; typical units: events/day)
ED = Duration of each exposure event. (dimensions: time/event; typical units: hours/event)
EP = Duration of the exposure period (dimensions: time; typical units: years)
BW = Body weight of the receptor of concern during the averaging period (dimension: mass; typical units: kg)
AP = Averaging Period (dimension: time; typical units: years)
C1 = Unit conversion factor for mass (typical units: 10^{-9} kg/µg)
C2= Unit conversion factor for volume, (typical units: 10^{-3} m^3/l)
C3= Unit conversion factor for time, (typical units: 60 min/hour)

The $RCAF_{inh\text{-}gi}$ value of 1.5 is recommended for construction workers only. For other exposure scenarios, such as residential exposure to particulate matter originating from a nearby site, a multiple of 2 is recommended (MassDEP, 2008)b.

Inhalation of OHM Contaminated Particulates - Pulmonary Absorption

Airborne particulates (fugitive dust) may carry OHM to receptors, resulting in soil-related inhalation exposures. The equation below is used to estimate the dose from particles between 1 and 10 µg/m^3 that reach the lungs. An Average Daily Dose due to the inhalation of OHM contaminated particulates ($ADD_{inh\text{-}p}$) may be calculated:

$$\mathbf{ADD_{inh\text{-}p}} = \frac{[OHM]_{part}*RCAF_{inh-pul}*[PM10]*VR*RAF*EF*ED*EP*C1*C2*C3}{BW*AP} \qquad \textbf{(11-18)}$$

Where:

$ADD_{inh\text{-}p}$= Average Daily Dose due to inhaled particulates entering the lungs, (dimensions: mass of chemical per unit body weight per day, typical units:

mg/kg-day)

$[OHM]_{part}$ = Representative concentration of OHM in the respirable particulates at the Exposure Point during the period of exposure. (dimensions: mass/mass; typical units: mg/kg)

$RCAF_{inh-pul}$ = Relative Concentration Adjustment Factor, inhalation. Effective Exposure concentration of respirable particulates for the lungs is 0.5 times the concentration of PM10 (MassDEP, 2008b)

[PM10]= Concentration in air of particulates less than 10 microns in diameter, (dimensions: mass/volume, typical units: $\mu g/m^3$)

VR = Ventilation rate for the receptor of concern during the period of exposure. (dimensions: volume/time; typical units: m^3/hour)

RAF = Relative Absorption Factor (dimensionless)

EF = Number of exposure events during the exposure period divided by the number of days in the exposure period. (dimensions: events/time; typical units: events/day)

ED = Duration of each exposure event. (dimensions: time/event; typical units: hours/event)

EP = Duration of the exposure period (dimensions: time; typical units: years)

BW = Body weight of the receptor of concern during the averaging period (dimension: mass; typical units: kg)

AP = Averaging Period (dimension: time; typical units: years)

C1 = Unit conversion factor for mass (typical units: 10^{-9} kg/µg)

C2= Unit conversion factor for volume, (typical units: 10^{-3} m^3/l)

C3= Unit conversion factor for time, (typical units: 60 min/hour)

For airborne chemicals which act at the point of contact (e.g. the lungs) when inhaled, the Average Daily Exposure of these chemicals calculated in the manner described in Section 11.3.4.3 would be used in combination with a *Reference Concentration* or *Unit Risk* to estimate potential risks. Under such conditions, the ADD for particulate inhalation would not be calculated.

In situations with high particulate concentrations, the larger (greater than 10 µm) inhaled particulates may result in significant *oral* exposures which should also be quantified.

11.3.4.2 Sediment Exposure Equations

The Average Daily Dose received by a receptor via direct contact (dermal absorption and incidental ingestion) with OHM-contaminated sediment is estimated in a manner like the calculation of the ADD for soil exposure, including both dermal contact with the sediment and incidental ingestion of sediment. The inhalation of fugitive dust originating from contaminated sediments would not generally be evaluated unless climatic conditions resulted in such sediments becoming dry, thus increasing the potential for dust generation. Dermal adherence for sediment should be evaluated using a dermal adherence factor of 1.0 (MassDEP, 2002c). It is reasonably conservative and acceptable to use the residential soil Shortform to screen sediment exposure by using a sediment EPC and changing the adherence factor to 1.0.

11.3.4.3 Drinking Water Exposure Equations

The exposure experienced by a receptor using contaminated water is not limited to exposure received when drinking the water but also includes inhalation and dermal pathways. Each of these exposure pathways should be evaluated separately.

Ingestion of Contaminated Drinking Water

The Average Daily Dose due to the ingestion of OHM contaminated drinking water (ADD_{oral} in mg/kg-d) may be calculated:

$$\boldsymbol{ADD_{oral}} = \frac{\boldsymbol{[OHM]_{water} * VI * RAF * EF * ED * EP * C}}{\boldsymbol{BW * AP}} \quad \textbf{(11-20)}$$

Where:

$[OHM]_{water}$ = EPC of OHM in the drinking water at the Exposure Point during the exposure period (dimensions: mass/volume; typical units: microgram per liter or ug/liter)

VI = Volume of drinking water ingested by the receptor of concern at (or from) the Exposure Point during the exposure period (dimensions: volume/time; typical units: liters/day)

RAF = Relative Absorption Factor (unitless)

EF = The exposure frequency, or the number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time; typical units: events/day)

ED = Duration of each exposure event (dimensions: time/event; typical units = days/event)

EP = Duration of the exposure period (dimension: time; typical units: years)

BW = Body weight of the receptor of concern during the averaging period (dimensions: mass; typical units: kg)

AP = Averaging Period (dimension: time)

C = Appropriate units conversion factor(s)

Dermal Absorption of OHM Via Drinking Water

U.S. EPA's Risk Assessment Guidance for Superfund Part E: Supplemental Guidance for Dermal Risk Assessment provides guidance on quantitatively evaluating dermal exposure to chemicals (U.S. EPA, 2004). Table B-3 (organic chemicals) and Table B-4 (inorganic chemicals) of U.S. EPA (2004) provide recommendations on whether to include various chemicals in quantitative calculations of dermal absorption in drinking water. The dermal average daily dose (ADD_{derm}) for contact with water in milligrams of OHM per kilogram body weight per day (mg/kg-d) can be calculated with the following equation:

$$\boldsymbol{ADD_{derm}} = \frac{\boldsymbol{DA * SA * EF_{derm} * ED * EP}}{\boldsymbol{OAE_{nc} * BW * AP}} \quad \textbf{(11-21)}$$

Where:

DA = Dermal absorption factor, (dimensions: weight/surface area-time, typically mg/cm^2-day)

SA = Body surface area exposed, (dimensions: area, typically cm^2)

EF_{derm} = Dermal exposure frequency, (dimensions: time, typically day/event)

ED = Exposure frequency, (dimensions: time, typically event/day)

EP = Exposure period, (dimensions: time, typically years)

OAE_{nc} = Oral absorption efficiency, (unitless)

BW = Body weight, (dimensions: mass, typically kg)

AP = Averaging period, (dimensions: time, typically years)

Steady State versus Non-Steady State for Organic Chemicals for Dermal Absorption from Water

The time for an organic chemical to reach steady state in the skin is a function of the chemical's molecular weight (MW) and its ability to traverse skin (expressed as a permeability constant, Kp). An exposure example where dermal absorption of COCs may be a concern is exposure during showering. If an organic chemical does not reach steady state before the shower is over (i.e., time to reach steady state, t*, is greater than the shower duration, D_s), Equation (11-22) is used to calculate the dermal dose for this non-steady state. For organic chemicals that have reached a steady state by the end of the shower, Equation (11-23) is used to calculate dermal dose.

Effective Predictive Domain for Dermal Absorption: In *Risk Assessment Guidance for Superfund, Appendix E Dermal Absorption* (U.S. EPA, 2004), U.S. EPA performed a statistical analysis to determine the range of molecular weight and Log Kow values for which valid extrapolation could be performed using the dermal absorption model. This approach used experimental data points in the derivation of the regression equation to determine the specific ranges of molecular weight and Log Kow, where the predictive power of the regression equation would be valid. The dermal absorption model is not used for organic chemicals that fall outside its effective predictive domain (EPD) when one or more chemical parameters fall outside the range of values for which the model is validated. For example, chemicals with very large or very small octanol-water partitioning coefficient (K_{ow}) values are outside of the EPD. Chemicals outside the EPD are identified with an asterisk in Tables B-2 and B-3 in the above citation as well as in Table V4 in MassDEP's Shortform Vlookup toxicity workbook. For these chemicals, the dermal dose is estimated as a function of the oral dose according to Equation (11-24) below. Note that the dermal dose in these cases is calculated as an average daily dose (ADD) or life-time average daily dose (LADD) and expressed in mg/kg-day.

Dermal Absorption of Organic Chemicals Inside the Effective Predictive Domain - *Non-Steady State.* Equation for estimating dermally absorbed dose (DA) for organic chemicals when the shower duration (D_s) is less than or equal to the time to reach steady state (t*):

$$\boldsymbol{DA = 2 * FA * C * Kp * CW * \left[\frac{(6*\tau*Ds)}{\pi}\right]^{\frac{1}{2}}} \qquad \textbf{(11-22)}$$

Where:

DA = Absorbed dose per event per area skin exposed, (unitless)
FA = Fraction absorbed, (unitless)
C = Conversion factor 0.000001, (typically m^3/cm^3)
Kp = *Strateum corneum* (sc) permeability constant, (dimensions: distance/time, typically cm/hr)
CW = [OHM] in water, EPC, (dimensions: mass/area, typically mg/m^3)
τ = (tau) - Lag time, (dimensions: time, typically hr.)
D_s = Shower Duration, (dimensions: time, typically hr.)

Dermal Absorption of Organic Chemicals Inside the Effective Predictive Domain - *Steady State.* Equation for estimating DA for organic chemicals when D_s is greater than the time to reach t*:

$$\boldsymbol{DA = FA * C * Kp * CW * \left[\left(\frac{Ds}{1+B}\right) + 2 * \tau * \frac{(1+3B+3B^2)}{(1+B)^2}\right]} \qquad \textbf{(11-23)}$$

Where:

DA = Absorbed dose per event per area skin exposed, (unitless)
FA = Fraction absorbed, (unitless)

C	=	Conversion factor, (typically 0.000001 m^3/cm^3)
Kp	=	Strateum corneum (sc) permeability constant, (dimensions: distance/time, typically cm/hr.)
CW	=	[OHM] in water, EPC, (dimensions: mass/area, typically mg/m^3)
τ	=	(tau) - Lag time, (dimensions: time, typically hr.)
D_s	=	Shower Duration, (dimensions: time, typically hr.)
B	=	Ratio of permeability of chemical in *strateum corneum* to permeability of chemical in viable epidermis, (unitless)

Dermal Absorption of Organic Chemicals Outside Effective Predictive Domain. The showering/Foster & Chrostowski model (Foster & Chrostowski, 1987) is not used for organic chemicals that fall outside its effective predictive domain. For example, chemicals with very large or very small K_{ow} values are outside of the EPD. Chemicals outside the Effective Predictive Domain are identified with an asterisk in Tables B-2 and B-3 in EPA (2004). For these chemicals, the dermal dose is estimated as a function of the oral dose according to Equation (11-24) below. Note that the dermal dose in these cases is calculated as an average daily dose (ADD) or life-time average daily dose (LADD) and expressed in mg/kg-bw. For chemicals outside the effective predictive domain, the dermal average daily dose is calculated with the following equation:

$$ADD_{derm} = DM * ADD_{ing} \qquad \textbf{(11-24)}$$

Where:

ADD_{derm}	=	Dermal (Lifetime) Average Daily Dose, (dimensions: mass/mass-time, typically mg/kg-day)
DM	=	Dermal Multiplier, (unitless)
ADD_{ing}	=	Ingestion (Lifetime) Average Daily Dose (dimensions: mass/mass-time, typically mg/kg-day)

For chemicals outside the effective predictive domain, the dermal multipliers are available in U.S. EPA 2004 and in MassDEP's Method 3 Shortform Resident drinking water spreadsheet, tab "RW-6: Dermal absorbed dose from showering.

The equation from Foster & Chrostowski for predicting stratum corneum permeability constant (Kp) for organic chemicals is:

$$Kp = 10^{[-2.8+(0.66*logKow)-(0.0056*MW)]} \qquad \textbf{(11-25)}$$

Where:

Kp	=	Stratum corneum (sc) permeability constant (dimensions: distance/time, typically cm/hr.)
MW	=	Molecular weight, chemical-specific (grams/mole)
Kow	=	Octanol-Water partition coefficient, chemical-specific (unitless)

The equation for calculating ratio of permeability of a chemical in the stratum corneum to permeability in the viable epidermis (B) is:

$$B = Kp * ((MW^{1/2})/2.6) \qquad \textbf{(11-26)}$$

Where:

B = Ratio of permeability of chemical in stratum corneum to permeability of chemical in viable epidermis, unitless
Kp = Stratum corneum (sc) permeability constant (dimensions: distance/time, typically cm/hr.)
MW = Molecular weight, chemical-specific (grams/mole)

Consistent with Risk Assessment Guidance for Superfund Part E (U.S. EPA, 2004), the following equations are used for calculating time to reach steady state (t*):

When B is less than or equal to 0.6:

$$t^* = 2.4 * \tau \qquad \textbf{(11-27)}$$

Where:

t* = Time to reach steady state (dimension: time, typically hours)
τ = (tau) - Lag time, (dimension: time, typically hours)

When B is greater than 0.6:

$$t^* = (b - (b^2 - c^2)^{1/2}) * l_{sc}^2/D_{sc} \qquad \textbf{(11-28)}$$

Where:

t* = Time to reach steady state (dimension: time, typically hours)
b = Correlation coefficient based on empirical data used to calculate t*, (unitless)
c = Correlation coefficient based on empirical data used to calculate b and t*, (unitless)
Isc = Thickness of skin (dimension: distance, typically cm)
D_{sc} = Effective diffusivity for chemical transfer through the skin (dimensions: distance/time, typically cm/hr.)

Equations for calculating b and c:

$$c = (1 + 3B + 3B^2)/(3 * (1+B)) \qquad \textbf{(11-29)}$$

Where:

c = Empirical variable used to calculate t*, unitless
B = Ratio of permeability of chemical in strateum corneum to permeability of chemical in viable epidermis, (unitless)

$$b = (2(1+B)^2/\pi) - c \qquad \textbf{(11-30)}$$

Where:

b = Empirical variable used to calculate t*, (unitless)
c = Empirical variable used to calculate t*, (unitless)
B = Ratio of permeability of chemical in strateum corneum to permeability of chemical in viable epidermis, (unitless)

Equation for calculating lag time (τ):

$$\tau = I_{sc}^2/(6*D_{sc}) \qquad (11\text{-}31)$$

Where:

τ	=	(tau) - Lag time (dimension: time, typically hr.)
I_{sc}	=	Thickness of skin (dimensions: distance, typically cm)
D_{sc}	=	Effective diffusivity for chemical transfer through the skin (dimensions: distance/time, typically cm/hr.)

The equation for calculating effective diffusivity (D_{sc}) is:

$$D_{sc} = 10^{-2.8-(0.0056*MW)} * I_{sc} \qquad (11\text{-}32)$$

Where:

D_{sc}	=	Effective diffusivity for chemical transfer through the skin (dimensions: distance/time, typically cm/hr.)
I_{sc}	=	Thickness of skin (dimension: distance, typically cm)
MW	=	Molecular weight, chemical-specific, (grams/mole)

Dermal absorption of OHM may occur while the receptor is in contact with the contaminated drinking water. Everyday activities such as showering, bathing, washing floors and cooking lead to direct contact with water and may result in dermal absorption of the chemicals.

Dermal Absorption of Inorganic Chemicals

The model above addresses only organic chemicals. The equation below estimates DA for inorganic chemicals in water:

$$DA = C * Kp * Cw * D_s \qquad (11\text{-}33)$$

Where:

DA	=	Absorbed dose per event per area skin exposed (dimensions mass/area-time, typically mg/cm^2-day)
C	=	Conversion factor, (typically 0.000001 m^3/cm^3)
Kp	=	Stratum corneum (sc) permeability constant (dimensions: distance/time, typically cm/hr.)
CW	=	[OHM] in water, EPC (dimensions: mass/volume, typically mg/m^3)
D_s	=	Shower Duration (dimension: time, typically hr.)

The permeability constant (Kp) is chemical-specific for inorganic chemicals and typically from measured values in the literature. The Method 3 Shortform toxicity file, tab V4, column E contains permeability coefficient (Kp) values for inorganic chemicals.

Inhalation of OHM Volatilized from Drinking Water

MassDEP evaluates inhalation exposures to volatilized OHM in drinking water using equations from Foster and Chrostowski (1987). ORS does not currently evaluate volatilization from water for inorganic chemicals,

cyanide, perchlorate, C19-C36 aliphatics, and PFAS chemicals. However, site-specific exposures may warrant consideration of this exposure pathway under certain circumstances. All other chemicals should be evaluated for this pathway, or a compelling argument must be made for excluding them (such as the lack of availability of required physical/chemical parameters).

The inhalation exposure concentration in the shower can be calculated:

$$IECS = [\frac{S}{R_{ae}} * \frac{(D_s + (\frac{e^{-R_{ae}*D_t}}{R_{ae}} - \frac{e^{R_{ae}\,(D_s - D_t)}}{R_{ae}}))}{D_t}] \quad \textbf{(11-34)}$$

Where:

IEC_S	=	Inhalation Exposure Concentration in shower (dimensions: mass/volume, typically µg/m^3)
S	=	Indoor air generation rate (dimensions: mass/volume, typically µg/m^3-min)
R_{ae}	=	Air Exchange Rate (dimensions: volume/time, typically 1/min.)
D_s	=	Shower Duration, (dimension: time, typically min.)
D_t	=	Total Time in Shower Room (dimension: time, typically min.)

The indoor air generation rate S is calculated:

$$S = \frac{C_{wd}*FR}{SV} \quad \textbf{(11-35)}$$

Where:

S	=	Indoor air generation rate (dimensions: mass/volume, typically µg/m^3-min.)
C_{wd}	=	Concentration leaving water droplet (dimensions: mass/volume, typically µg/l)
FR	=	Shower flow rate (dimensions: volume/time, typically 1/min.)
SV	=	Shower room air volume (dimension: time, typically m^3)

The concentration leaving the water droplet C_{wd} is calculated:

$$C_{wd} = C_{w0} * \left(1 - e^{\left(\frac{KaL*ts}{60d}\right)}\right) \quad \textbf{(11-36)}$$

Where:

C_{wd}	=	Concentration leaving water droplet (dimensions: mass//volume, typically µg/l)
C_{w0}	=	Shower water concentration, (dimensions: mass/volume, typically µg/l)
K_{aL}	=	Adjusted mass transfer coefficient, (dimensions: distance/time, typically cm/hr.)
t_s	=	Shower droplet time, (dimension: time, typically seconds)
d	=	Droplet interfacial area (dimensions: distance/time-time, typically cm/hr.-seconds)
60	=	The specific interfacial area, 6/d, for a spherical droplet of diameter d (mm), multiplied by conversion factors, hr/3600 seconds and 100 mm/cm

The adjusted mass transfer coefficient is calculated:

$$K_{aL} = K_L * \left[\frac{T_L * \mu_s}{T_s * \mu_l}\right]^{-\frac{1}{2}} \quad \textbf{(11-37)}$$

Where:

K_{aL} = Adjusted mass transfer coefficient (dimensions: distance/time, typically cm/hr.)
K_L = Overall mass transfer coefficient (dimensions: distance/time, typically cm/hr.)
T_l = Calibration water temperature of K_L (dimension: temperature, typically °K)
μ_s = Water viscosity at T_s (dimensions: distance/time, typically centipoise cp)
T_s = Shower water temperature (dimension: temperature, typically °K)
μ_1 = Water viscosity at T_l (dimensions: distance/time, typically centipoise cp)

The overall mass transfer coefficient is calculated:

$$K_L = \left[\frac{1}{k_l} + \frac{R*T}{HLC*k_g}\right]^{-1} \quad \textbf{(11-38)}$$

Where:
K_L = Overall mass transfer coefficient (dimensions: distance/time, typically cm/hr)
k_l = Liquid film mass transfer coefficient (dimensions: distance/time, typically cm/hr)
R = Universal Gas Constant, atm-m^3/mol-°K
T = Absolute temperature, (dimension: temperature, typically °K)
HLC = Henry's Law Constant, atm-m^3/mol
k_g = Gas-film mass transfer coefficient (dimensions: distance/time, typically cm/hr)

The liquid film mass transfer coefficient is calculated:

$$k_l = k_l(CO_2) * \left[\frac{MW_{CO2}}{MW_{VOC}}\right]^{\frac{1}{2}} \quad \textbf{(11-39)}$$

Where:
k_l = Liquid film mass transfer coefficient (dimensions: distance/time, typically cm/hr.)
$k_l(CO_2)$= Liquid film mass transfer coefficient for CO_2 (dimensions: distance/time, typically cm/hr.)
MW_{CO2}= Molecular weight of CO_2, g/mole
MW_{VOC} = Molecular Weight of OHM

The Gas Film Mass Transfer Coefficient k_g is calculated:

$$k_g = k_{g(H2O)} * \left[\frac{MW_{H2O}}{MW_{VOC}}\right]^{\frac{1}{2}} \quad \textbf{(11-40)}$$

Where:
k_g = Gas-film mass transfer coefficient, (dimensions: distance/time, typically cm/hr.)
$k_{g(H2O)}$ = Gas-film mass transfer coefficient of water, (dimensions: distance/time, typically cm/hr.)
MW_{H2O} = Molecular weight of water, (g/mole)
MW_{VOC} = Molecular Weight of OHM, (g/mole)

The equations above quantify exposure to drinking water through (1) ingestion, (2) dermal absorption, and (3) inhalation. Dermal absorption and inhalation pathways are difficult to quantify and rely on a combination of modelling and empirical data. Further information on dermal absorption can be found in U.S. EPA (2004). Further information on inhalation exposures during showering can be found in Foster and Chrostowski (1987).

11.3.4.4 Surface Water

Contamination in surface water can result in receptor exposures from the incidental ingestion of the water, through dermal contact with the water, and through the inhalation of material volatilized from the water. As with the drinking water evaluation, the ingestion and dermal doses are assumed to be equitoxic and the estimated values may be mathematically combined:

$$\boldsymbol{ADD_{oral-dermal} = ADD_{oral} + ADD_{dermal}} \qquad \textbf{(11-41)}$$

The assumption of equitoxicity is *not* assumed to apply to the dose received via the inhalation of volatilized material from the water, and the risk associated with this exposure must be evaluated separately using appropriate toxicity information.

Surface Water Ingestion

The equation used to estimate the Average Daily Dose received by a receptor via the ingestion of contaminated surface water ($ADD_{surface\ water\ ingestion}$) is identical to that used to evaluate drinking water ingestion exposures, which is described earlier in this section. The assumptions chosen to describe the exposure (the volume of water ingested, the duration of the exposure event, etc.) should be representative of the exposure scenario being modelled.

Surface Water Dermal Contact

The Average Daily Dose of a chemical received via dermal absorption from surface water (ADD_{dermal_SW}) may be calculated using the following equation. This approach is recommended by BWSC for all chemicals when the dermal exposure is explicitly calculated:

$$\boldsymbol{ADD_{dermal\ SW} = \frac{[OHM]_{water} * SA * K_p * RAF * EF * ED * EP * C}{BW * AP}} \qquad \textbf{(11-42)}$$

Where:

ADD_{dermal_SW} = Average daily dose of OHM associated with dermal contact exposure to contaminated water. (Dimensions: mass/mass-time; typical units: mg/kg/day)

[OHM]water = The concentration of contaminant in water which is contacting the skin during the exposure event (dimensions: mass/volume; typical units: ug/liter)

SA = Body surface area exposed to contaminated water during the exposure event (dimensions: area; typical units: cm^2)

Kp = Permeability Constant (dimensions: volume/(time * area); typical units: $cm^3/(hr * cm^2)$, which is often simplified to cm/hr)

RAF = Relative Absorption Factor for dermal contact with water (dimensionless)
Note: when the permeability constant (Kp) is used to determine the flux of contaminant through the skin, it results in an *absorbed* dose of OHM. The RAF is used here to adjust this absorbed dose to make it comparable to the toxicity value employed to estimate risk. The numerator of the RAF must be assigned a value of 1, and the denominator depends upon the absorption in the study which is the basis of the toxicity value (See Section 11.2.7). If the toxicity value itself is based on an *absorbed* dose, then the RAF dermal is one.

EF = The exposure frequency, or the number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time; typical units: events/day)

ED = The duration of each exposure event (dimensions: time/event; typical units: hours/event)

EP = Duration of exposure period (dimension: time; typical units: years)

C = Appropriate units conversion factor(s)

BW = Body weight of the receptor of concern during the averaging period (dimensions: mass; typical units: kg)

AP = Averaging Period (dimension: time; typical units: years)

Inhalation Exposures Associated with Contaminated Surface Water

Under some circumstances the volatilization of OHM from surface water may contribute to exposure of the receptor of concern. Such exposures are more likely to be of concern if the material is volatilizing into a confined space or if the concentrations in the surface water are relatively high. The exposures associated with this scenario may be evaluated following the equation presented in Section 11.3.4.1, with the [OHM]air term being either measured or modelled air concentrations of the contaminant.

11.3.4.5 Food Exposure Equations

The general form of this equation may be applied to the ingestion of contaminated fish, meat, or vegetables. The evaluation of exposure to infants from ingesting breast milk or other fluids may be estimated using the general equation for drinking water exposures in combination with the appropriate exposure factors. The average daily dose (ADD_{food}) experienced by the receptor from consuming food (e.g., garden produce) containing OHM may be estimated using the following equation:

$$ADD_{food} = \frac{[OHM]_{food} * FI * RAF * EF * ED * EP * C}{BW * AP} \quad \textbf{(11-43)}$$

Where:

[OHM]food = Representative concentration of OHM in the food of concern during the period of exposure (dimensions: mass/mass, typical units: mg/kg)

FI = Daily intake of the food of concern on days exposed during the exposure period (dimensions: mass/event; typical units: mg/meal)

RAF = Relative Absorption Factor, dimensionless

EF = Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time. typical units:

meals/day)

ED = Duration of the exposure period (dimension: time, typical units: years)

BW = Body weight of the receptor of concern during the averaging period (dimension: mass, typical units: kg)

AP = Averaging Period (dimension: time, typical units: years)

C = Appropriate units conversion factor(s)

11.3.4.6 Calculation of Lifetime Average Daily Dose (For All Media)

The Lifetime Average Daily Dose (LADD) should be calculated to reflect age-related differences in exposure rates that are experienced by a receptor throughout his or her lifetime of exposure. Because of their low body weight and behavioral characteristics, young children receive greater exposure per unit body weight than older children and adults. Furthermore, young children typically have more dermal contact with soil and more hand-to mouth activity. Therefore, the LADD should be calculated in a way that does not "dilute" the higher exposure rates experienced by young children with lower exposure rates experienced by older children and adults.

For example, a LADD (based on a 30-year exposure period) which uses an average body weight and skin surface area value for all ages of receptor (1<31) will not be protective of the high exposure rates in young children and is not a recommended procedure.

There are several averaging methods that can be used to calculate a LADD that reflects the higher exposure rates experienced by young children. One method is to calculate average annual dose rates, normalized to body weight, for each year of exposure. The sum of the dose rates is then averaged over a lifetime (70 years). The equation below shows this averaging approach. However, this type of calculation can be tedious.

$$LADD = \frac{\sum_{i=0}^{30} \frac{IR_i * EP_i}{BW_i}}{AP} \quad \textbf{(11-44)}$$

Where:

IRi = Average Intake Rate for the exposure period i (mg/day)

EPi = Exposure period for the year i, one year

BWi = Age-dependent body weight for age year i

AP = Averaging Period, lifetime (70 years)

i = Exposure year index running from ages 0 to 30

As an alternative, there is a simpler averaging approach which can be used to calculate the lifetime average daily dose. This simpler approach gives essentially the same results as the year-by-year averaging method.

The simpler averaging approach defines age bins - within the relevant exposure period - that have similar profiles with respect to exposure and toxicological effects and uses a weighted average for each of these defined age bins. Then the lifetime average daily doses in these age bins are summed. This weighted average approach, while simpler, will result in essentially the same results as the more complicated year-by-year averaging approach.

The following general formula can be used:

$$\boldsymbol{LADD} = \sum_{\boldsymbol{AgeBin-x}} \boldsymbol{LADD_{AgeBin-x}} \qquad \textbf{(11-45-a)}$$

$$\boldsymbol{LADD_{AgeBin-x}} = \frac{\boldsymbol{IR_{AgeBin-x} * EP_{AgeBin-x}}}{\boldsymbol{AP * BW_{AgeBin-x}}} \qquad \textbf{(11-45-b)}$$

Where:

$\mathbf{IR_{AgeBin\text{-}x}}$ = Average Intake rate for receptors in the AgeBin-x

$\mathbf{EP_{AgeBin\text{-}x}}$ = Exposure period for AgeBin-x; and satisfying Exposure Period $= \sum_{\text{all x}} \text{EP}_{\text{AgeBin-x}}$

$\mathbf{BW_{AgeBin\text{-}x}}$ = Average body weight for receptor in AgeBin-x

AP = Averaging Period, lifetime (70 years)

The way such age bins are defined would depend on the context in which the risk assessment is made. For example, for certain chemicals with a mutagenic mode of action, the appropriate age bins (even for the same contaminated medium and route of exposure) may be different from chemicals that do not have mutagenic effects because the mutagenic chemicals may have enhanced or different toxicological effects in various stages of life (U.S. EPA, 2005c). Residential age bins for non-cancer, cancer and mutagenic risk are presented in Table 11.4 for soil, water, and air.

Table 11.4

Residential Age Bins for Risk Calculations				
Risk Matrix	**Age Bin 1 (years old)**	**Age Bin 2 (years old)**	**Age Bin 3 (years old)**	**Age Bin 4 (years old)**
Non-cancer Soil	1-8			
Cancer Soil	1-8	8-15	15-31	
Mutagen Soil	1-2	2-6	6-16	16-31
Non-cancer Water	0-7			
Cancer Water	0-7	7-14	14-30	
Mutagen Water	0-2	2-6	6-16	16-30
Non-cancer Air	0-7			
Cancer Air	0-30			
Mutagen Air	0-2	2-16	16-30	

As an example, for an exposure period from 1 to 31 (a period of 30 years used in calculating cancer risk from exposure to soil in residential setting), age bins can be defined that include ages 1 to 8 ($EP_{1<8}$ = 7 years), ages 8 to 15 ($EP_{8<15}$ = 7 years), and ages 15 to 31 ($EP_{15<31}$ = 14 year). (Younger children have a higher soil ingestion rate compared to older children and adults (MassDEP, 2002b), and children less than age 1 are considered to not be exposed to soil.) The lifetime average daily dose for the entire exposure period is then calculated from the sum of the lifetime average daily doses for the defined age bins. For a contaminant of concern that has a mutagenic mode of action, specific age bins may be selected based on additional toxicological considerations. For example, for certain mutagens, e.g., dichloromethane, the selected age bins would be ages 1 to 2, ages 2 to 6, ages 6 to 16, and ages 16 to 31, because during each of these age periods, these chemicals have specific amplified effects. These effects can be accounted for by multiplying the lifetime average daily dose for each age

bin by an adjustment factor for each bin – represented by an Age Dependent Adjustment Factor ($ADAF_{AgeBin\text{-}x}$) for mutagenic effects.

$$LADD = \sum_{AgeBin-x} LADD_{AgeBin-x} * ADAF_{AgeBin\text{-}x} \qquad \textbf{(11-45-c)}$$

Where:

$ADAF_{AgeBin\text{-}x}$ = Age Dependent Adjustment Factor for mutagenic effects for the AgeBin-x

The appropriate age bins for each chemical mutagens and non-mutagens), and exposure pathway are included in the Method 3 Shortforms and are updated as needed. For example, the age bins and ADAFs for mutagenic carcinogens are shown in Table 11.3.

Table 11.3
Age Dependent Adjustment Factors & Age Bins for Mutagenic Carcinogens by Exposure Pathway

Soil Age Bin (years of age)	Water and Air Age Bin (years of age)	Age Dependent Adjustment Factor (ADAF)[a]
1-2 [b]	0-2	10
2-6	2-6	3
6-16	6-16	3
16-31	16-30	1

[a] U.S. EPA, 2005b

[b] Children less than one year old are considered to have limited exposure to soil so the first bin is the 1-2 year old. See previous comment regarding potential exposure to < 1-year old due to dust contaminated by OHM attributable to the site.

11.4 Risk Characterization

Risk Characterization is the final step in the risk assessment process. In this step, the results of the Hazard Identification, Dose-Response Assessment and Exposure Assessment are integrated to yield quantitative estimates of cancer and non-cancer risk. The Risk Characterization provides valuable information for risk management because it presents the numerical estimates of risk posed by the site in a context that can be used by risk managers to make decisions about remediation.

In accordance with the MCP (310 CMR 40.0993(3)), the Risk Characterization step must also include a comparison of EPCs with applicable or suitably analogous public health standards (see App. 1b).

A critical component in the presentation of risk estimates is the discussion of major assumptions, scientific judgements, and uncertainties inherent in the numerical risk estimates (sometimes called the uncertainty analysis). The importance of this component cannot be overstated. The discussion of uncertainties should place the numerical estimates of risk and hazard in the overall context of what is known about the site and what is uncertain.

The regulations provide clear direction regarding the way numerical estimates of risk are to be presented in the Risk Characterization (310 CMR 40.0993). The MCP requires that chemical specific and medium-specific estimates

of risk be combined to yield Cumulative Cancer and Non-cancer Risks for each Receptor. These Cumulative Risks are then compared with specific risk management criteria which include public health standards and Cumulative Receptor Risk Limits (310 CMR 40.0993(10)):

> *The Cumulative Receptor Cancer Risks shall be compared to a Cumulative Cancer Risk Limit which is an Excess Lifetime Cancer Risk equal to one-in-one hundred thousand. Cumulative Receptor Non-cancer Risks shall be compared to a Cumulative Non-cancer Risk Limit which is a Hazard Index equal to one. Estimated Exposure Point Concentrations shall be compared to any applicable or suitably analogous standards.*

The result of this comparison determines whether a condition of No Significant Risk of harm to human health exists or has not been achieved at the site.

This Section of the *Guidance* describes methods for characterizing cancer and non-cancer risks and discusses the interpretation of Risk Characterization results within the context of the MCP. This Section also addresses the identification of Applicable or Suitably Analogous Public Health Standards and the comparison of such standards with EPCs. Lastly, this Section addresses how uncertainties in the Risk Assessment should be addressed.

11.4.1 Non-cancer Risk

The measure used to describe the potential for noncarcinogenic health effects in a chemical is the Hazard Quotient (HQ). A Hazard Quotient is a ratio of the concentration of a COC divided by a hazard concentration or toxicological value for that COC. U.S. EPA (1989) describes a Hazard Quotient as the ratio of a single contaminant exposure level over a specified period of time to a toxicity value such as a Reference Dose for that contaminant derived over a similar exposure period. A Hazard Index (HI) is the sum of more than one hazard quotients for multiple contaminants and/or multiple exposure pathways (U.S. EPA, 1989). The HI is calculated separately for chronic, subchronic, and shorter duration exposures. A Hazard Index of 1 or less indicates that the receptor's exposure is equal to or less than the allowable exposure level, and it is considered unlikely that adverse health effects will occur. When the HI is less than or equal to 1, a conclusion of "No Significant Risk of harm to human health" based on non-cancer effects, is appropriate.

An HI of greater than 1 indicates that non-cancer health effects could occur and cannot be ruled out. It does not mean that non-cancer effects *will* occur. Uncertainty inherent in most Reference Doses precludes identifying a specific dose above which adverse effects are likely *and* below which effects are unlikely. Accordingly, the probability of an effect cannot be quantified from a HI. *For any one chemical*, the likelihood of an effect increases as the exposure level (and therefore the HI) increases.

The uncertainty inherent in RfDs for different chemicals differs both qualitatively and quantitatively because we do not have complete or absolute knowledge about the toxicity of most hazardous chemicals. The RfD is based on the existence of a threshold for the toxic effect. Therefore, the magnitude of the HQ above “1” does not indicate either the probability, nor the severity of a response. A HQ of 20, may indicate greater concern, but this doesn’t translate to a non-cancer risk of 20x the HQ of 1.

In interpreting the HI, one must consider the appropriateness of the exposure assumptions and the underlying information used to develop the RfDs.

In its most general form, the Hazard Quotient associated with a chemical via a given route of exposure is calculated as:

$$HQ = \frac{ADD}{RfD} \quad \textbf{(11-46)}$$

or, for inhalation exposures,

$$HQ = \frac{ADE}{RfC} \quad \textbf{(11-47)}$$

Where:

HQ = The Hazard Quotient associated with exposure to the chemical via the specified route of exposure.

ADD = The estimated Average Daily Dose of the chemical via the specified exposure route, mg/kg-day.

RfD = The oral Reference Dose or appropriate substitute toxicity value identified for the chemical of concern, mg/kg-day.

ADE = The Average Daily Exposure in air, ug/m^3.

RfC = The Reference Concentration or substitute toxicity value identified for the chemical of concern, ug/m^3.

The Average Daily Dose (ADD) in equation 1-46 is calculated from the EPC using exposure assumptions consistent with the Exposure Profiles developed for each receptor being evaluated. Section 11.3.4.3 of this Guidance describes the process for calculating a receptor's ADD.

The allowable dose or exposure (denominators in equations 11-46 and 11-47) will typically be the EPA Reference Dose (RfD) for most exposure routes or the EPA Reference Concentration (RfC) for air exposures. Selection of an appropriate "acceptable" dose is discussed in Section 11.2.3.

The MCP requires that *cumulative* non-cancer risks be calculated (310 CMR 40.0993). A cumulative HI represents the cumulative noncarcinogenic impact that the site has on a particular receptor group. The cumulative HI accounts for exposures that a receptor may receive from multiple chemicals and multiple exposure routes.

For each COC, separate HQs for acute, subchronic, and chronic exposures should be calculated if these have been identified as exposure periods of concern in the development of exposure profiles. After the separate HQs have been derived, the cumulative HIs should be calculated for acute, subchronic, and chronic exposures for exposure periods of concern for the site.

As shown by the following two equations, the cumulative HI can be calculated by summing the exposure route-specific Hazard Quotients for all COCs. Route-specific HIs are calculated as the sum of all chemical-specific HQs:

$$\textbf{Total HI}_{\textbf{route-specific}} = \sum \textbf{HQ}_{\textbf{chemical-specific}} \quad \textbf{(11-48)}$$

$$\textbf{\textit{Cumulative HI}} = \sum \textbf{\textit{HI}}_{\textbf{\textit{Route-specific}}} \quad \textbf{(11-49)}$$

If the risk calculations are performed using a probabilistic analysis, the risk assessor must identify the dose or concentration associated with the 95th percentile estimate of exposure (310 CMR 40.0993(4)). This dose or

concentration should be compared with the toxicity value identified following the dose-response section of this Guidance (11.3.2). This HI is then compared with the HI limit of 1 to determine whether the site poses a significant risk of harm to human health based on the risk of non-cancer health effects (310 CMR 0993(7)). If risks are compared to the HI limit with two significant figures, no justification is needed. However, if one significant figure is used, supporting documentation should reference the specific input parameters that justify a single significant figure in the risk estimate (MassDEP, 2009). The documentation of the Risk Characterization must clearly present all mathematical equations used to calculate Cumulative Non-cancer Risks (310 CMR 40.0993(13)).

11.4.2 Health Endpoint-Specific Hazard Index

If a condition of No Significant Risk does not exist at a site, one option for further evaluation would be segregating HIs by target organ. The procedure for segregating HIs by effect and mechanism of action is not simple and should be performed by a toxicologist or experienced risk assessor. Health-endpoint-specific hazard indices submitted to MassDEP must consider other toxicological endpoints that occur at higher doses (or concentrations) in addition to the endpoint that is the basis of the RfD and RfC. Considering only the endpoint used as the basis for the RfD and RfC is not health-protective and is not appropriate.

A health endpoint-specific hazard index must include all endpoints for a chemical including effects that occur at higher doses that do not form the basis of the RfD.

Segregation of HIs requires identification of the major health endpoints of each chemical, including effects observed at higher doses than the critical effect on which the toxicity value is based. In this process, RfDs must be derived for every endpoint and target organ for a given COC or set of COCs. This involves an extensive review of the toxicological and epidemiological literature for each chemical to consider every possible effect and the dose at which it occurs. This is because the critical health effect for one chemical may not be the same for other chemicals and doses of other chemicals may not be additive for that health effect. On the other hand, additive impacts could be important for other health endpoints that are only expected at higher doses.

Major effect categories that should be considered in segregating chemicals include, but are not limited to, neurotoxicity, developmental toxicity, reproductive toxicity and immunotoxicity. Adverse effects also should be categorized by target organ (e.g., hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal and dermal/ocular). The effects and mechanisms of action should be discussed in the toxicological profiles.

Once chemicals have been categorized, the Cumulative Hazard Index for chemicals with similar health endpoints and mechanisms of toxicity should be calculated. Each HI should be compared with the MCP Cumulative Receptor Non-cancer Risk Limit which is a HI equal to 1. If any of the HIs exceeds 1, then the Risk Characterization must conclude that a condition of No Significant Risk does not exist for harm to human health based on the risk of non-cancer health effects.

11.4.3 Cancer Risk

The potential for carcinogenic health effects is characterized as the Excess Lifetime Cancer Risk (ELCR). The ELCR represents the incremental probability of an individual developing cancer over a lifetime because of exposure to one or more carcinogen. For a given chemical, the estimated ELCR is the product of the receptor's quantified exposure and a measure of carcinogenic potency. The typical measures of carcinogenic potency are the EPA Cancer Slope Factor (CSF) for oral exposure and the Inhalation Unit Risk (IUR) for inhalation. All estimates should be accompanied by the weight of evidence descriptor and its narrative to convey a sense of the qualitative uncertainty about whether the agent may or may not be carcinogenic (U.S. EPA, 2005a).

The ELCR associated with exposure to a given chemical via a particular exposure pathway is estimated as follows:

$$\boldsymbol{ELCR = LADD * CSF} \qquad \textbf{(11-50)}$$

or, for inhalation exposures,

$$\boldsymbol{ELCR = LADE * IUR} \qquad \textbf{(11-51)}$$

Where:

ELCR = The Excess Lifetime Cancer Risk (ELCR) associated with exposure to the chemical via the specified route of exposure.

LADD = The estimated Lifetime Average Daily Dose (LADD) of the chemical via the specified exposure route (mg/kg-day).

CSF = The Cancer Slope Factor (CSF) identified for the chemical, appropriate to the specific exposure pathway $(mg/kg\text{-}day)^{-1}$.

LADE = The Lifetime Average Daily Exposure (LADE) to the contaminant gaseous concentration of OHM in air (ug/m^3).

IUR = The Inhalation Unit Risk (IUR) for the chemical of concern $(ug/m^3)^{-1}$.

The LADD and LADE in equations 11-50 and 11-51 are calculated from the EPC using exposure assumptions consistent with the Exposure Profiles developed for each receptor being evaluated. Section 11.3.5.7 of this Guidance describes the process for calculating a receptor's LADD.

The MCP requires that *cumulative* cancer risks be calculated (310 CMR 40.0993). The cumulative cancer risk must be estimated for all chemicals that are "Likely to Be Carcinogenic to Humans" or "Carcinogenic to Humans." For chemicals defined as having "Inadequate Information to Assess Carcinogenic Potential," or a database that provides "Suggestive Evidence of Carcinogenic Potential" the available toxicity data may be insufficient to reliably quantify cancer risks. potential carcinogenic effects of these chemicals should be discussed qualitatively in the Uncertainty Section of the Risk Assessment.

The cumulative ELCR represents the cumulative carcinogenic impact that the site has on a particular receptor group (exposed population). The cumulative ELCR accounts for exposures that a receptor may receive from multiple chemicals and multiple exposure routes.

The cumulative ELCR is calculated by summing all the exposure route-specific ELCRs. Route-specific ELCRs are calculated as the sum of all the chemical-specific ELCRs.

This is represented by the following equations:

$$\boldsymbol{Total\ ELCR_{route-specific}} = \Sigma\ \boldsymbol{ELCR_{Chemical-specific}} \quad \textbf{(11-52)}$$

$$\boldsymbol{Cumulative\ ELCR} = \Sigma\ \boldsymbol{ELCR_{route-specific}} \quad \textbf{(11-53)}$$

The Cumulative ELCR should be compared with the MCP Cumulative Receptor Cancer Risk Limit which is an ELCR equal to one-in-one hundred thousand (1×10^{-5}). If the Cumulative Cancer Risk exceeds the ELCR Limit, then the Risk Characterization must conclude that a condition of No Significant Risk does not exist and the site may pose significant risk of harm to human health based on the risk of cancer health effects.

If the risk calculations are performed using a probabilistic analysis, the risk assessor must identify the dose or concentration associated with the 95th percentile estimate of exposure (310 CMR 0993(4)). This dose or concentration should be compared with the toxicity value identified following the dose-response section of this Guidance (11.2). This ELCR is then compared with the Cancer Risk Limit of 1×10^{-5} to determine whether a Condition of No Significant Risk does, or does not, exist. ***The documentation of the Risk Characterization must clearly present all mathematical equations used to calculate Cumulative Cancer Risks (310 CMR 40.0993(13).***

11.4.4 Comparison to Applicable or Suitably Analogous Public Health Standards

The MCP requires that the characterization of risk of harm to human health include a comparison of EPCs to applicable or suitably analogous public health standards (see App. 1b). The list of such standards, as provided in the MCP includes, but is not limited to:

- Massachusetts Drinking Water Quality Standards, promulgated in 310 CMR 22.00 *(these standards are considered applicable only to category GW-1 groundwater)*.
- Massachusetts Air Quality Standards promulgated in 310 CMR 6.00; and
- Massachusetts Surface Water Quality Standards promulgated in 314 CMR 4.00.

As provided in the MCP, if any EPC exceeds an applicable or suitably analogous standard, the Risk Characterization must conclude that a condition of No Significant Risk does not exist at the site.

11.5 UNCERTAINTY ANALYSIS

The Uncertainty Analysis is a critical component of the Risk Characterization. The Uncertainty Analysis should contain a narrative section which places the numerical risk estimates in the overall context of what is known and what is not known about the site and toxicological information in the context of decisions that the site manager will make about remediation. The Uncertainty Analysis does not modify the risk characterization conclusions themselves but rather provides context for the risk conclusions to help risk managers make informed decisions about site management. A Risk Characterization is not considered complete unless the numerical risk estimates are accompanied by an explanation which interprets and qualifies the risk results and any uncertainties.

Inherent in all risk assessments are many data-informed decisions, assumptions, scientific judgements, and uncertainties that can be introduced at each step in the risk assessment process. In addition, dose response and exposure assessment guidance presented in this document are intended to produce health protective, reproducible estimates of the potential for adverse impacts. For these reasons, the numerical risk estimates calculated in the

Risk Characterization should be interpreted in light of the major uncertainties.

General sources of uncertainty in the risk assessment which should be discussed in the Uncertainty Analysis include, but are not limited to:

- Identification of all site-related contaminants in sampling of the environmental media at the site, including any data gaps in characterization of nature and extent of contamination or quantitation limits that are insufficient for the risk assessment.
- Modeling used to develop EPCs. Model uncertainty is one reason for MassDEP's preference for empirical data.
- Quantitative toxicological data used to develop cancer and non-cancer toxicity values and any existing data gaps.
- Development of Exposure Profiles and selection of exposure assumptions used in dose calculations.

Although the Uncertainty Analysis is often a qualitative evaluation of uncertainties affecting the risk estimates, the risk assessor should attempt to describe, to the extent possible, the magnitude and direction of effect that a particular area of uncertainty is likely to have on the numerical risk estimates.

11.6 SHORTCUTS

Two possible approaches that can enhance efficiencies in the risk assessment process are: (1) the use of a screening-level risk assessment using worst-case exposure assumptions; and, (2) the use of MassDEP's risk assessment Shortforms. These are discussed below.

Screening Risk Characterization

One shortcut option that may be considered is to conduct a *"Screening"* Human Health Risk Characterization using worst-case exposure assumptions (310 CMR 40.0902(5)). The objective of a screening evaluation is to quickly demonstrate that a condition of No Significant Risk exists or has been achieved at a disposal site. To do this, the risk assessor should use worst-case exposure assumptions and health-protective toxicity values. For example, the risk assessor might assign the toxicity value for the most toxic contaminants at a site to all contaminants at the site and use the maximum reported concentration for each chemical as the EPC. Assuming residential exposures at an industrial site is another possible approach that may be used in a screening risk characterization.

The objective of the screening risk characterization is to save time and money by using readily available data and information that will result in risk estimates that will not underestimate the risks posed by the disposal site. If the resulting risks are below the MCP Risk Limits, remediation would not be required based on risk of harm to human health. It is important to note that remediation may still be required based on risk of harm to the environment (Chapters 14, 15, 16 & 17), public welfare, or safety (Chapter 12) or for other site management reasons.

A screening risk characterization may also be used to demonstrate that certain exposure pathways result in low risks (at least one order of magnitude) smaller than the MCP Cumulative Risk Limits. Such a demonstration would justify the elimination of that exposure pathway from consideration in the risk characterization.

A screening risk characterization is intended as an option to reduce the cost and level of effort involved in

conducting a risk characterization, *not site characterization*. The results of a "Screening" risk characterization should never be used to justify inadequate site characterization.

MassDEP Method 3 Risk Assessment Shortforms.

The Method 3 risk assessment Shortforms are an optional tool which have been developed by MassDEP to provide a streamlined method of evaluating potential human health risks at c.21e sites. Please refer to the fuller description at the beginning of this Chapter.

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MassDEP Guidance for Disposal Site Risk Characterization

Part 2 - Human Health Risk Assessment

Chapter 12

Imminent Hazard Evaluations

12.0 Imminent Hazard Evaluations

One of the purposes of risk characterization under the Massachusetts Contingency Plan (MCP) is to identify and evaluate site conditions which may pose an *Imminent Hazard*. As defined in the MCP, "an Imminent Hazard means a hazard which would pose a significant risk of harm to health, safety, public welfare or the environment if it were present for even a short period of time" (310 CMR 40.0006).

> *The MCP contains detailed procedures for identifying and evaluating Imminent Hazards. However, it must be stressed that the overriding objective of the Imminent Hazard provisions in the MCP is to ensure* that *response actions will be taken quickly to prevent or abate exposures that pose an Imminent Hazard. The risk assessor should keep this objective in mind when reading this section of the Guidance. Taking a response action that addresses ongoing exposures right away is always preferable to conducting an evaluation to determine whether the exposures actually pose an Imminent Hazard.*

The MCP describes a risk characterization methodology to be followed when evaluating Imminent Hazards (310 CMR 40.0950). This methodology is site-specific in nature, focused on actual or likely exposures under current site conditions and considering an appropriately short exposure period. The MCP also includes specific risk limits for Imminent Hazards (310 CMR 40.0955(2)(b) and (c)). The important distinctions between a risk characterization for an Imminent Hazard evaluation and a risk characterization for purposes of a Permanent Solution is that the Imminent Hazard evaluation is much narrower in scope, it need only consider actual, current exposures, given the current site conditions and use(s), and not foreseeable future use(s) and exposures. In addition, the Imminent Hazard evaluation often focuses on only those chemicals that are most likely to pose a risk following short-term exposures, given their toxicity and site concentration.

If the results of an Imminent Hazard evaluation indicate that conditions at the site pose an Imminent Hazard, the MCP requires that an Immediate Response Action (IRA) be taken to address the condition (310 CMR 40.0411). However, one always has the option to take a response action to address a potential Imminent Hazard rather than conducting an evaluation to determine whether the conditions do indeed pose an Imminent Hazard. In fact, for any

release which a project manager believes is likely to pose an Imminent Hazard, the Department recommends taking immediate action to address the release and associated potential exposures rather than conducting an evaluation to confirm whether it is an Imminent Hazard.

The MCP provides that Imminent Hazard Evaluations may be conducted separately for safety, human health, public welfare and the environment, depending on the type of condition that triggered the need for the evaluation (310 CMR 40.0955). This is because for different types of Imminent Hazards, the situation leading to the Imminent Hazard condition and the information needed to evaluate the condition may be different.

For example, the presence of insecurely containerized oil or hazardous material (OHM) may pose an Imminent Hazard to Safety and may also pose an Imminent Hazard to Human Health. Safety and Human Health issues should be assessed separately. However, if it is concluded that conditions pose an Imminent Hazard to Safety, it would not be necessary to additionally evaluate whether those same conditions pose an Imminent Hazard to Human Health.

12.1 When Is an Imminent Hazard Evaluation Necessary?

The MCP addresses the need to conduct an Imminent Hazard Evaluation in two ways. First, there are conditions that "*pose or could pose*" an Imminent Hazard which, by regulation, trigger a 2-hour notification and an IRA. These conditions are described in Subpart C, 310 CMR 40.0311 and 40.0312. The IRA may include an Imminent Hazard Evaluation, or it may immediately implement response actions to eliminate or mitigate the condition. Second, the regulations describe general factors that must be considered in the decision about whether to conduct an Imminent Hazard Evaluation and rely on the application of professional judgement to determine when site conditions warrant such an evaluation. These factors are described in Subpart I, 310 CMR 40.0950.

12.1.1. Imminent Hazard Evaluations Following Two-Hour Notifications

The two-hour notification triggers for conditions that pose or could pose an Imminent Hazard are listed below. Refer to 310 CMR 40.0321 (among others) for more detailed information about such conditions:

> **310 CMR 40.0311(7)** requires notification to MassDEP within two hours for "any release of any oil and/or hazardous material, in any quantity or concentration, that poses or could pose an Imminent Hazard, as described in 310 CMR 40.0321 and 40.0950".
>
> **310 CMR 40.0312(2)** requires notification to MassDEP within two hours for a threat of release to the environment of OHM that is listed at 310 CMR 40.1600 or that exhibits one or more of the characteristics described in 310 CMR 40.0347, which poses or could pose an Imminent Hazard, as described in 310 CMR 40.0321, irrespective of the quantity likely to be released.

In 310 CMR 40.0321, there are subsections that detail conditions that are defined to be Imminent Hazards and conditions that could pose an Imminent Hazard, as well as provisions for rebutting the presumption of an Imminent Hazard and reserving MassDEP's authorities in this area. Each of these subsections are described below.

There are six conditions that are, by regulation (310 CMR 40.0321(1)), deemed to be an Imminent Hazard to health, safety, public welfare or the environment. These determinations may result from direct measurement, direct observation, qualitative assessment, and/or quantitative Imminent Hazard Evaluations, as applicable. Once it is determined that such a condition exists, notification to MassDEP is required within two hours and an IRA must be implemented to eliminate or mitigate the Imminent Hazard. These six conditions are:

1. A release to the environment which results in the presence of OHM vapors within buildings, structures, or underground utility conduits at a concentration equal to or greater than 10% of the Lower Explosive Limit;
2. A release to the environment of reactive or explosive hazardous material, as described in 310 CMR 40.0347, which threatens human health or safety;
3. A release to a roadway that endangers public safety;
4. A release to the environment of OHM which poses a significant risk to human health when present for even a short period of time, as specified in 310 CMR 40.0950;
5. A release to the environment of oil and/or hazardous material which produces immediate or acute adverse impacts to freshwater or saltwater fish populations; and
6. A release to the environment which produces readily apparent effects to human health, including respiratory distress or dermal irritation.

Then there are also conditions that "*could*" pose an Imminent Hazard, whether from a release of OHM to the environment (310 CMR 40.0321(2)) or from a Threat of Release of OHM to the environment (310 CMR 40.0321(3)). While these conditions also trigger notification within two hours and an IRA, the IRA may begin with a detailed Imminent Hazard Evaluation (consistent with 310 CMR 40.0950) to rebut the presumption of an Imminent Hazard (310 CMR 40.0321(4)). Such an Imminent Hazard Evaluation may show that further response actions are not necessary in the short-term.

The conditions that *could pose an Imminent Hazard to human health* are:

- A release to the environment indicated by the measurement of OHM in a private drinking water supply well at a concentration equal to or greater than ten times the RCGW-1 Reportable Concentration. (See 310 CMR 40.0321(2)(a).)
- A release to the environment for which estimated long-term risk levels associated with current exposures are greater than ten times the Cumulative Receptor Risk Limits specified for Imminent Hazards in 310 CMR 40.0993(10). Past exposures may be included in these evaluations to the extent that it is reasonable to assume, based on the Conceptual Site Model, that the past exposure has occurred and there is sufficient information available to quantify the past exposures. In such cases the Imminent Hazard Evaluation would be conducted to determine whether the

combination of the past, ongoing and near future exposures warrant immediate actions. (See 310 CMR 40.0321(2)(c).)

- A release to the environment indicated by the measurement of concentrations of hazardous material, equal to or greater than any of the concentrations listed in Table 12-1 at the ground surface or within a depth of twelve inches below the ground surface, at any location within 500 feet of a residential dwelling, school, playground, recreation area or park, unless access by children is controlled or prevented by means of bituminous pavement, concrete, fence, or other physical barrier (40.0321(2)(b)). *Note that this provision is narrowly focused on potential exposures to* children*, as the most sensitive population.*

Table 12-1: Concentrations in Soil That Could Pose an Imminent Hazard

Hazardous Material	CAS Number	Concentration (µg/g dry weight)
Arsenic (total)	7440382	50
Cadmium (total)	7440439	1,000
Chromium (VI) (or Total Chromium in the absence of Cr VI data)	18540299	200
Cyanide (available)	57125	100
Mercury (total)	7439976	400
Methyl Mercury	22967926	10
PCB (total)	1336363	10

(values current as of February 2026, 310 CMR 40.0321(2)(b))

These soil concentrations ("trigger levels") have been calculated using health-protective exposure assumptions consistent with those used in MassDEP's *Method 3 Human Health Risk Assessment Shortforms* and the risk characterization procedures for Imminent Hazard Evaluations detailed in the MCP. As such, the concentrations are appropriately used to "screen in" conditions which require at least further assessment in the short-term, if not remedial actions.

The trigger levels in Table 12-1 were derived through the evaluation of both cancer and noncancer risks: the lower of the two estimated concentrations is chosen to be the trigger level to be protective of both types of health effect. The cancer and noncancer risk limits used in deriving the trigger levels are the numerical Imminent Hazard Risk Limits specified in Subpart I (310 CMR 40.0955(2)). These risk limits are discussed in Section 12.2.8. The Department may develop new trigger levels in the future for contaminants as needed.

In evaluating cancer and noncancer risks, it is assumed that exposure would occur through direct contact with the soil: both dermal absorption and incidental ingestion. Since the trigger levels are applicable in areas where it is likely that children will have frequent exposure to surficial soil (for example, in a schoolyard, playground or residential backyard), the exposure scenario evaluated in developing the trigger levels is analogous to a residential exposure scenario.

Since young children generally experience higher rates of exposure due to the nature of their activities and their low body weights, the evaluation of noncancer risks focused on a child aged 5-6 years old exposed during the summer months (June through August) when frequent contact with soil is likely. For cancer risks, the evaluation focused on the ages of 0-to-5 years.

Exposure to contaminated soil was assumed to vary by age and time of year. For more detailed information including the exposure assumptions and equations used to calculate the Imminent Hazard trigger levels, the reader should refer to the *Method 3 Human Health Risk Assessment Shortforms* specific to evaluating residential Imminent Hazards (sf0624rsih as of 2026).

12.1.2. Imminent Hazard Evaluations Following Identification of Site Conditions of Concern

Since Imminent Hazards can occur at any point in the MCP process, the project manager should be mindful throughout all phases of site investigation and remediation of the possibility that information indicating a potential Imminent Hazard could come to light.

The MCP (310 CMR 40.0951(1)) prescribes that the decision to conduct an Imminent Hazard Evaluation must consider the location and nature of the OHM and the human or environmental receptors which may be exposed. It is important to keep in mind that when deciding whether an Imminent Hazard Evaluation is needed, that exposures must actually be occurring (or very likely to occur) in order for an Imminent Hazard to exist.

An Imminent Hazard Evaluation should be considered whenever actual (or likely) exposures to contamination at a site are occurring, such as when people are drinking contaminated water or when there is surficial soil contamination in an area where children are present, such as a playground. And while children are often considered the most sensitive receptor, adults may also be the focus of an Imminent Hazard Evaluation, particularly at sites where the presence of children is unlikely and contaminant concentrations are significantly elevated. The risk assessor should also give thought to the types of contaminants to which people are being exposed. Chemicals which can cause a severe effect after a one-time exposure, such as cyanide, certainly warrant consideration as a possible Imminent Hazard.

In deciding whether a given situation warrants further investigation as a potential Imminent Hazard, it may also be helpful to consider the following approaches.

1. The Method 2 Soil Standards listed in Table 5 of the MCP (310 CMR 40.0985(6)) were developed considering only direct contact with the soil, unlike the Method 1 Standards which also consider potential leaching to groundwater. Therefore, these Direct Contact Soil Standards can be used to roughly estimate Imminent Hazard trigger levels for OHM not listed in the table in Subpart C (310 CMR 40.0321(2)(b)) by adjusting for the difference in risk management criteria. The Method 2 Standards were calculated using long-term noncancer and cancer risk management criteria (HI = 0.2, ELCR = 1 x 10-6, respectively) that are five to ten times lower than the risk management criteria used to evaluate whether risks experienced over a "short period of time" pose an Imminent Hazard. Risk assessors can use this knowledge, along with an understanding of how

those standards were developed, to identify soil concentrations which may warrant further evaluation. In other words, multiples of the Table 5 values can be used as a "rule-of-thumb" estimates for an expanded list of Imminent Hazard trigger levels, particularly multiples of the Table 5 S-1 concentrations, as they are based on residential exposures applicable to children.

Used in this way, the Table 5 soil standards reported in the MCP can provide a general indication to the risk assessor or project manager as to when site concentrations are approaching levels which could pose an Imminent Hazard. However, it is important to understand that the presence of a chemical at levels greater than ten times the Table 5 standard does not indicate that there is an Imminent Hazard or even that there is likely an Imminent Hazard. It simply suggests that the situation may warrant further investigation. Because the Direct Contact Soil Standards incorporate considerations in addition to risk, a site-specific evaluation, even a very cursory one, may be all that is needed to rule out the possibility of an Imminent Hazard.

2. MassDEP has published spreadsheets that automate the calculation of potential cancer and noncancer health risks associated with several common exposure scenarios. These *Method 3 Human Health Risk Assessment Shortforms* are available online[1] and are periodically updated. As of March 1, 2026, the *Shortforms* include spreadsheets for the evaluation of potential Imminent Hazards for the following scenarios:
    - Exposure to soil in a residential setting (*sf0624rsih.xlsx*);
    - Exposure to soil at a park or playground (*sf0624psih.xlsx*);
    - Exposure to soil in a trespassing setting (*sf0624tsih.xlsx*);
    - Exposure to indoor air in a residential setting (*sf0624raih.xlsx*);
    - Exposure to drinking water in a residential setting (*sf0624rwih);*
    - Exposure to indoor air at a daycare setting (*sf0624dcaih.xlsx*);
    - Exposure to indoor air at a school setting (*sf0624saih.xlsx*); and
    - Exposure to indoor air at an office worker setting (*sf0624oaih.xlsx*).

    A risk assessor or project manager can use these *Shortforms* to quickly estimate potential cancer and noncancer risks associated with a given concentration of OHM for these exposure scenarios. Because of their ease of use, the *Shortforms* are ideal for the iterative process that often drives site assessment - data can be screened and the results used to determine the next steps in the investigation. When used with preliminary data or to evaluate an exposure that doesn't quite match what is in the spreadsheet, the *Shortforms* are considered screening tools – good for identifying when more investigation is needed, but not for definitively ruling out a potential Imminent Hazard. As expressed in the Shortform User Guide, any modifications of the Shortforms

[1] See MassDEP's website at https://www.mass.gov/lists/risk-assessment-information#shortforms:-method-3-human-health-risk-assessment-.

must be clearly documented and supported when used for risk characterization purposes.

On the other hand, if the site exposure conditions are consistent with those assumed in the *Shortforms* and the Exposure Point Concentration(s) are appropriately calculated, then the *Shortforms* itself can be sufficient to meet the Imminent Hazard Evaluation requirements of the MCP.

12.2 Site-Specific Imminent Hazard Evaluations for Human Health

The MCP requires that the Imminent Hazard risk characterization be conducted following the general procedures for a Method 3 Risk Characterization. Regulations specific to conducting site-specific Imminent Hazard Evaluations are found in 310 CMR 40.0950 through 40.0955.

Conducting an Imminent Hazard Evaluation using site-specific (Method 3) approach does not preclude the use of a Method 1 or 2 Risk Characterization for the site as a whole at a later point in the MCP process.

12.2.1 General Considerations for Imminent Hazard Evaluations

As in a full-scale risk characterization, the basic approach to be taken in an Imminent Hazard Evaluation is to conduct an assessment that is realistic and health protective. The MCP prescribes that the Imminent Hazard Evaluation shall be conducted in a manner which results in conservative estimates of potential exposures (310 CMR 40.0953(7)).

The "documentation of the Imminent Hazard Evaluation must clearly identify and explain the basis for all exposure parameters chosen for the risk characterization" (310 CMR 40.0953(8). MassDEP recommends using the exposure parameters in the Imminent Hazard *Shortforms* appropriate for the scenario, if available, as this simplifies the assessment, review and documentation. For example, for an Imminent Hazard Evaluation of a residential setting, the exposure factors incorporated in the residential IH Shortform should be used and referenced. Any deviation from these standard exposure assumptions must be clearly identified and appropriate justification included in the documentation.

As with other risk assessments, Imminent Hazard Evaluations should identify the receptor group(s) experiencing the greatest exposure potential or susceptibility to environmental contamination. Young children and women of child-bearing age are often selected as receptors of concern because of these factors. The risk assessor may need to evaluate several receptor groups to ensure that all sensitive subpopulations or groups are being protected. Conversely, the fact that the most sensitive receptors are being evaluated means that other (less exposed) receptors need ***not*** be evaluated.

An Imminent Hazard Evaluation will differ from a Method 3 Risk Characterization in several ways. Specifically, an Imminent Hazard Evaluation will not be as comprehensive as a Method 3 Risk Characterization conducted for purposes of documenting that a Permanent Solution has

been achieved. This narrower scope is seen in several ways, as detailed in the following sections.

12.2.2 Imminent Hazard Evaluations Focus on Current Site Activities

The Imminent Hazard Evaluation is focused on actual or likely exposures given the current site use(s) and does not evaluate potential future uses of the site. For evaluation of soil exposures, that means looking at exposure to the top layer (12 inches) of soil (310 CMR 40.0924(7)(c)). If soil excavation is occurring, the evaluation would focus on the soil being excavated. For the evaluation of drinking water exposures, the water coming out of the tap would be relevant[2]. For inhalation exposures, measured concentrations in the receptor's breathing zone would be most appropriate. If the site is currently an industrial property, then residential exposures need not be evaluated, even if the property may become residential in the future. Similarly, if the site is a residential property where only adults currently reside and there is no evidence that children visit the residential property, then exposures to children need not be evaluated[3].

12.2.3 Imminent Hazard Evaluations Focus on a "Short Period of Time"

The duration of exposure in an Imminent Hazard Evaluation is short, consistent with the definition of "Imminent Hazard". Typically, the Exposure Duration does not exceed 5 years for the evaluation of potential cancer risk and is often much shorter for the evaluation of noncancer risk. The determination of what constitutes an appropriate "short period of time" for a particular site must consider how long exposures have already been occurring and when it is expected that final remedial action will be complete at the site.

If the appropriate "short period of time" at a site is 5 years, this does not preclude the obligation to also evaluate appropriate shorter exposure periods such as acute (one-day) exposures. For example, if the chemical being evaluated is associated with severe effects which can occur from a single exposure (e.g., cyanide), the Imminent Hazard Evaluation should include an evaluation of a one-day exposure, as well as other appropriate exposures.

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[2] For Public Water Supplies in compliance with MassDEP Drinking Water Regulations (310 CMR 22.00), Imminent or Substantial Hazard Evaluations are not required as the water provided by such systems do not pose an Imminent Hazard or a Substantial Hazard by definition. (See 310 CMR 40.0951(3).) This provision minimizes duplicative regulation and allows the MassDEP Drinking Water Program to take the lead in requiring appropriate response actions in such cases.

[3] This differs from the way current activities and uses must be evaluated for the full risk assessment. In the full risk assessment, activities which are not occurring at the time of the assessment but are consistent with the current use of the site must be evaluated as part of the site's "current use". For example, in the full risk assessment, exposures to children at a residential property would need to be evaluated even if no children currently resided at the property because the presence of children is consistent with a residential use. This is another example of how an Imminent Hazard Evaluation is more limited in scope than the risk characterization used to support a Permanent Solution.

12.2.4 Imminent Hazard Evaluations Focus on Limited Exposure Points

Imminent Hazard Evaluations often focus on areas, or Exposure Points, where contaminant concentrations are highest, such as within Hot Spots. These evaluations do not have to quantitatively evaluate all potential exposures or exposure points at a site, only those exposures that have the potential to pose an Imminent Hazard.

12.2.5 Imminent Hazard Evaluations Focus on Limited Contaminants of Concern

Finally, an Imminent Hazard Evaluation can focus on a subset of the site contaminants that are most likely to pose a significant risk due to their elevated concentrations and/or toxicity. A chemical may be eliminated from the Imminent Hazard Evaluation based upon a determination that it is not likely to contribute significantly to risks. The justification to exclude contaminants from an Imminent Hazard Evaluation should be included in the documentation of the evaluation.

12.2.6 Exposure Point Concentrations in Imminent Hazard Evaluations

As noted in 310 CMR 40.0926(2), Exposure Point Concentrations (EPCs) are determined or estimated in a manner consistent with the type and method of Risk Characterization which is being performed. The objective of EPC calculations is to identify a conservative estimate of the mean concentration contacted by a receptor at an Exposure Point over the relevant exposure period. This applies to EPCs developed for Imminent Hazard Evaluations as well.

Imminent Hazard Evaluations often take place early in the site assessment process before the assessment is complete. It is not uncommon for there to be tension between the desire to gather more data to better characterize potential exposures and the need to take action to prevent, eliminate or mitigate an Imminent Hazard. ***With potential Imminent Hazard conditions, there should be a bias for action to prevent ongoing exposure even while data collection continues.***

The MCP provides for the use of the maximum measured concentration or Upper Confidence Limit (e.g., 310 CMR 40.0926(6) and (8)) as the Exposure Point Concentration as a conservative estimate of the mean under conditions common for Imminent Hazard Evaluations such as when evaluating acute exposures, conducting screening assessments or dealing with uncertainty in the data set.

As in a full risk assessment, a Hot Spot must be evaluated as a separate exposure point in an Imminent Hazard Evaluation (310 CMR 40.0953(4)). This ensures that areas with high relative contamination will not simply be averaged into larger areas of lesser contamination, thereby diluting their potential impacts.

MCP risk characterizations and IH evaluations typically use the “exposure factor” approach whereby exposure estimates are developed by combining various exposure factors such as OHM concentrations, ingestion rates, body weight, etc. to estimate the exposure of the OHM received by the receptor and develop risk calculations. Approaches beyond the “exposure factor” approach may be applicable for some sites and/or COCs, including biologically based models and biomonitoring when health risks have been linked to internal concentrations of the

COC. For some contaminants, biologically based models have been developed to estimate the concentration of an OHM in the exposure media that is associated with a biological measure of exposure (e.g., blood lead concentration and the IEUBK model). Biomonitoring data, such as OHM concentrations in serum or urine can provide a measure of past and/or current exposure to COCs at a site. The use of serum or urinary levels is evolving and have been applied to several contaminants (e.g., Aylward, 2010).

The Department may consider or develop non "exposure factor" approaches to exposure assessment evaluations for unique exposures and/or chemicals. For example, the Department may use biomonitoring methods to appraise the potential for human health risks and/or imminent hazard conditions.

12.2.7. Toxicity Information in Imminent Hazard Evaluations

The toxicity information used to characterize risk in the Imminent Hazard Evaluation must be appropriate for the type and duration of exposure being evaluated. Particularly for the evaluation of noncancer risk, there may be toxicity information available that is more appropriate for the shorter-term exposures (acute or subchronic) that is the focus of an Imminent Hazard Evaluation. The toxicity values selected for use must be clearly identified and documented (310 CMR 40.0953(8)).

It is not uncommon to find that the available toxicity information does not exactly match the Exposure Duration under evaluation (e.g., there is no acute Reference Dose to evaluate an acute exposure). In such cases it may be appropriate to use the next closest match, such as using a subchronic Reference Dose to evaluate an acute exposure. It is important to carefully consider the available toxicity information and determine the most appropriate way to use it in the evaluation.

In considering the toxicity information available to use in the Imminent Hazard Evaluation, the requirements detailed in 310 CMR 40.0993(6) and the hierarchy of toxicity values described in 310 CMR 40.0993(7) also apply per 310 CMR 40.0955(2). Again, careful consideration must be given to matching the available toxicity information with the Exposure Duration of concern in the evaluation. The reader should consult Chapter 11.2 (Dose Response Assessment) of this guidance document for a complete discussion of the information needed to describe the dose-response relationship of OHM in a risk assessment. The toxicity values selected for use must be identified and documented (310 CMR 40.0953(8)).

12.2.8 Risk Characterization in Imminent Hazard Evaluations

The MCP contains numerical cancer and noncancer risk limits that are specific for Imminent Hazard Evaluations (310 CMR 40.0955(2)). These risk limits represent a level of risk above which the Department has determined that a Remedial Action is needed in the short term to prevent, eliminate, or mitigate an Imminent Hazard.

Conditions at the site pose an Imminent Hazard if either the estimated cancer or noncancer risks for each OHM and for each receptor is ***equal to or greater than*** the specified risk limits. Note that this comparison is different than the one used in other Method 3 Risk Characterizations, which is simply "*greater than*" the applicable risk limit. As discussed earlier, the MCP has a "bias for action" to address potential Imminent Hazards. By using "*equal to or greater than*" as the form of comparison, the MCP ensures that uncertainty in the data that results in risk estimates expressed as one significant figure will not result in inaction. (In other words, the results cannot be "rounded down" to conclude there is not an Imminent Hazard.)

The documentation of the Imminent Hazard Evaluation must clearly state whether conditions at the site pose an Imminent Hazard (310 CMR 40.0955(4)).

12.2.8.1 Carcinogenic Effects

If the estimated Excess Lifetime Cancer Risk for a receptor is equal to or greater than one-in-one hundred thousand (1×10^{-5}) then the conditions at the site pose an Imminent Hazard.

The mathematical equations used to calculate the cancer risk estimates shall be clearly presented and documented. Imminent Hazard Evaluations that use the MassDEP *Shortforms* can simply reference MassDEP's documentation.

Note that while the cancer risk limit is numerically the same as that used for other Method 3 risk assessments, the risk limit applies to one OHM at a time and the duration of exposure in an Imminent Hazard Evaluation is much shorter (five years or less). Exceeding this risk limit implies that the receptor is receiving the entire "allowable" lifetime risk in a few years or less. It is therefore important to eliminate that exposure quickly. Further exposure before long-term remediation is complete could result in an ELCR above the risk limit.

12.2.8.2 Non-Cancer Effects

The MCP requires that OHM evaluated for noncancer health effects be grouped into two categories based upon the nature and severity of their potential health effects. Different risk management criteria (risk limits) apply to these two groups.

> OHM with the Potential to Cause Serious Effects.
> If the estimated ***Hazard Index is equal to or greater than one (1)*** for OHM with the potential to cause serious health effects following short-term exposure, then the conditions at the site pose an Imminent Hazard. "Serious effects" include (but are not limited to) lethality and developmental or neurological effects following short-term exposure. Chemicals of concern that would fall into this category include trichloroethylene, lead, methyl mercury, and cyanide.
>
> All Other OHM.
> For all other Contaminants of Concern, if the estimated ***Hazard Index is equal to or greater than ten (10)***, then the conditions at the site pose an Imminent Hazard.

The mathematical equations used to calculate the noncancer risk estimates shall be clearly presented and documented. Imminent Hazard Evaluations that use the MassDEP *Shortforms* can simply reference MassDEP's documentation. Any modifications to the *Shortforms* must be clearly identified and documented.

12.2.8.3 Readily Apparent Harm

A release to the environment that results in readily apparent health effects – such as respiratory distress, dermal irritation or collapse – is considered an Imminent Hazard by definition (310 CMR 40.0955(2)(d)). A quantitative evaluation is not required in such cases.

12.3 Site-Specific Imminent Hazard Evaluation for Safety

The MCP provides that conditions at the site pose an Imminent Hazard to Safety if there is a significant risk to safety under existing conditions or conditions which are about to occur. As defined in the MCP, a significant risk to safety exists at a site if a release poses a threat of physical harm or bodily injury to people. In accordance with the MCP, an Imminent Hazard evaluation for safety concerns must be conducted following the provisions detailed in 310 CMR 40.0960. Guidance relating to characterizing the risk of harm to safety is provided in Chapter 13. However, an Imminent Hazard for Safety will be narrower in scope than the evaluation described in 310 CMR 40.0960. In identifying whether an Imminent Hazard to Safety exists, the risk assessor need only focus on existing conditions (or conditions which are about to occur), and the receptors actually present given the current use of the site.

Examples of a potential Imminent Hazard to Safety include: (1) exceeding an explosive limit within a structure; (2) the presence of insecurely containerized hazardous waste (e.g., leaky drums); and (3) unsafe driving conditions from a release of oil to a roadway.

12.4 Site-Specific Imminent Hazard Evaluation for Public Welfare

An Imminent Hazard Evaluation for Public Welfare will focus on potential effects from a release or threat of release of OHM that may significantly impact the use of a site, but which are unrelated to any human health, environmental or safety concerns. Common examples of such effects include, but are not limited to, effects such as odor and taste.

For example, a condition such as an odor in a residence that prevents people from living there, or taste or odor problems in drinking water that precludes using it for consumptive purposes certainly should be considered as a potential Imminent Hazard to Public Welfare, *even if such conditions do not pose an Imminent Hazard to human health.*

The Department expects that Imminent Hazards to Public Welfare will be rare.

12.5 Site-Specific Imminent Hazard Evaluation for the Environment

The MCP (310 CMR 40.0955(3)) indicates that an Imminent Hazard to the environment consists of either a) evidence of stressed biota attributable to the release at the disposal site, including,

without limitation, fish kills or abiotic conditions; or b) a release to the environment of OHM which produces immediate or acute adverse impacts to freshwater or saltwater fish populations. Imminent Hazard Evaluations for the Environment are addressed in more detail in Chapters 14 through 17 along with guidance for handling conditions of readily apparent harm.

References:

Aylward, et al. 2010. Biomonitoring Data for 2,4-Dichlorophenoxyacetic Acid in the United States and Canada: Interpretation in a Public Health Risk Assessment Context Using Biomonitoring Equivalents. Env. Health Perspectives. V.118. no.2.

MassDEP Guidance for Disposal Site Risk Characterization

Part 2 - Human Health Risk Assessment

Chapter 13

Risk of Harm to Safety and Public Welfare

13.0 Risk of Harm to Safety and Public Welfare

Under the MCP, a Permanent Solution requires that a level of no significant risk of harm to health, safety, public welfare or the environment exists or has been achieved for any current or reasonably foreseeable future use of the site. This chapter focuses on assessing potential risk of harm to safety and public welfare.

13.1 Evaluating Potential Safety Risks

The evaluation of safety risk at a disposal site is focused on the potential for the oil or hazardous material (OHM) to pose a threat of physical harm or bodily injury to people at the site under current or reasonably foreseeable future uses. Note that it is the ***release*** or ***threat of release*** of OHM that is being evaluated for potential safety risk – any potential safety risks identified must be related to a release or threat of release of OHM.

> *Safety risks that are not related to a release or threat of release of OHM should still be addressed immediately with notification of the proper authorities but would not be considered a Response Action taken under the MCP.*

The evaluation of safety risk is always site-specific and must be explicitly conducted and addressed in the Risk Characterization regardless of which Method is used to evaluate the risks of harm to health, public welfare and the environment.

13.1.1 Overlap with Imminent Hazard Evaluations

At least for current site conditions, there is significant overlap between what constitutes a "significant risk" and conditions that would pose an "imminent hazard" (310 CMR 40.0955(1)). The identification of a potential safety risk/Imminent Hazard can occur at any time during the site assessment and cleanup process and would trigger a two-hour notification to MassDEP (310 CMR 40.0311(7)) and the implementation of an Immediate Response Action to prevent, eliminate or mitigate the Imminent Hazard (310 CMR 40.0412(1) and (3)).

13.1.2 Basis of the Safety Evaluation

The information collected during the site investigation along with the receptor information identified in 310 CMR 40.0904 through 40.0933 forms the basis of the Safety Evaluation.

13.1.3 Applicable or Suitably Analogous Standards

As with other Risk Characterization approaches, the MCP requires the comparison of site conditions to any applicable or suitably analogous standards, in this case, ***safety*** standards (310 CMR 40.0960(2)). This requirement exists for a couple of reasons.

First, M.G.L. Chapter 21E and the MCP do not waive the applicability of other laws and regulations. If there are safety standards (i.e., promulgated regulations or rules) that apply to the conditions at the disposal site, then they should be identified and compliance with the standard evaluated. Ultimately, a Permanent Solution cannot be achieved unless/until the site is in compliance with all standards applicable to the release or threat of release (TOR) of OHM.

Second, the use of existing applicable or suitably analogous safety standards is a quick and efficient way to identify potential safety issues. There may be no need to conduct a site-specific safety evaluation if a simple comparison to safety standards identifies a problem that requires an Immediate Response Action (IRA).

MassDEP does not publish a list of applicable or suitable analogous safety standards. Potential sources of such standards would include (but are not limited to) the Occupational Safety and Health Administration (OSHA) and the International Standards for Occupational Health and Safety (ISO). Applicable or suitably analogous safety standards must relate to risks posed by a release (or threat of release) of OHM.

13.1.4 No Significant Risk to Safety

Per 310 CMR 40.0960(3), a level of no significant risk to safety exists or has been achieved if the conditions at the disposal site which are related to a release of OHM do not currently and will not in the foreseeable future pose a threat of physical harm or bodily injury to people.

Examples of conditions include:

- The presence of rusted or corroded drums or containers of OHM;
- Open pits, lagoons or other structures containing OHM;
- Threats of fire or explosion as a result of a release or TOR of OHM, including explosive vapors;
- Uncontained or insecure materials that are corrosive, reactive or flammable; and
- Unsafe driving conditions resulting from a release to a roadway.

This is not a definitive list - other site conditions may also pose a safety risk and must be evaluated appropriately.

13.1.5. Documentation and Conclusion

The Risk Characterization must document the evaluation of the risk of harm to safety and must clearly conclude whether a condition of no significant risk of harm to safety exists or has been achieved at the site.

13.2 Evaluating Potential Public Welfare Risks

As described at 310 CMR 40.0994, there are two purposes for conducting a characterization of risk to public welfare: (a) to identify and evaluate nuisance conditions which may be localized, and (b) to identify and evaluate significant community effects. The characterization of risk to public welfare is focused on effects which are (or may) result from the release or TOR of OHM at the site or the implementation of a proposed remedial alternative to address such OHM.

The approach to Public Welfare Risk Evaluation depends upon the Risk Characterization Method chosen for the disposal site.

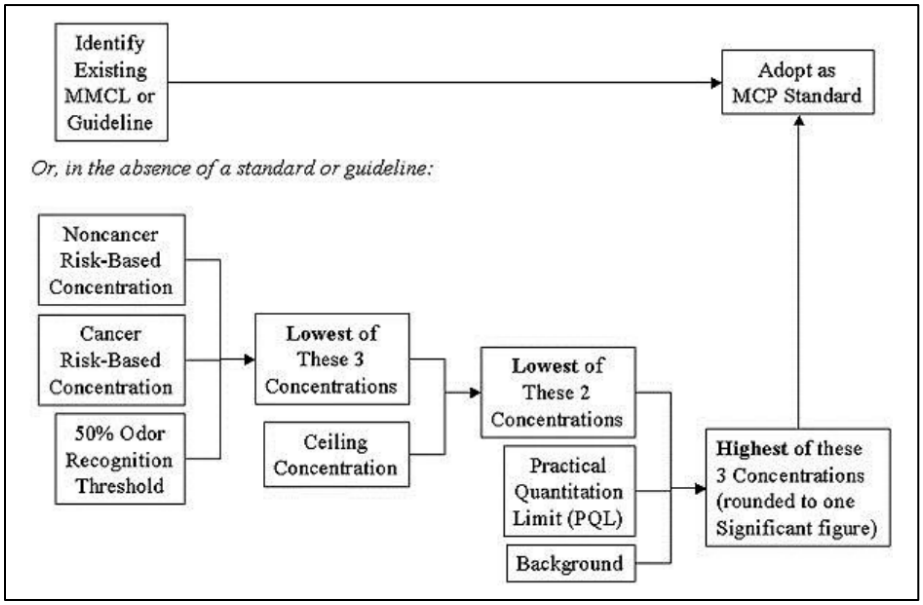
13.2.1 Methods 1 & 2 Public Welfare Risk Characterizations

The evaluation of potential risks to public welfare is built into the Method 1 and Method 2 Soil and Groundwater Standards and *a separate evaluation for public welfare is not required*.

As noted in 310 CMR 40.0973(7), a condition of no significant risk to health, ***public welfare*** and the environment exists if no Exposure Point Concentration is greater than the applicable MCP Method 1 Soil or Groundwater Standard [emphasis added]. Similar language is included for a Method 2 Risk Characterization (310 CMR 40.0988(2)).

The calculation of the Method 1 & 2 Standards takes public welfare into account in two ways. First, the derivation of the GW-1 and GW-2 standards include the use of the 50th percentile odor recognition threshold for a chemical on an equal basis with the cancer- and noncancer risk-based concentrations. If a contaminant is particularly pungent but has minimal risk to human health, the standard would be based on the potential public welfare effects (odors).

Figure 13.1: Derivation of the MCP Method 1 GW-1 Groundwater Standards



Second, the derivation of all the MCP Method 1 & 2 Standards includes a comparison to Ceiling Limits – an upper limit on how high the calculated standards can be. The standards are calculated based on health-protective exposure assumptions, and the less exposure that is assumed to occur, the higher the standard will be. These exposure assumptions are not specific to the site, however, and there is a chance that unique site conditions may create exposures that are higher than those assumed in the calculations. The use of Ceiling Limits puts an upper limit on how high allowable concentrations can go using these generic (not site-specific) assumptions. If higher allowable levels are justified, a case-specific justification can be made by using a Method 3 Risk Characterization, which would include a site-specific Public Welfare evaluation.

For the groundwater standards, the ceiling limit is 50,000 µg/L for all chemicals in all three groundwater categories. For soil, the ceiling limit depends upon both the soil category (S-1, S-2 or S-3) and the volatility of the chemical.

Table 13-1: Ceiling Limits for Soil Standards

	Soil Standards (mg/kg)		
Volatility	S-1	S-2	S-3
Low	1000	3000	5000
Medium	500	1000	3000
High	100	100	100

13.2.2 Method 3 Public Welfare Risk Characterization

A Method 3 Public Welfare Risk Characterization (310 CMR 40.0994) is a site-specific evaluation that looks at current and reasonably foreseeable site conditions to determine if there are any local nuisance conditions or community effects that would be considered a significant risk to public welfare. In addition, there are specific requirements for evaluating residual coal tar waste deposits and elevated OHM contamination remaining on the site.

13.2.2.1 Consideration of Nuisances and Other Site Conditions

The evaluation of risk to public welfare is based upon the site characterization information gathered through the site assessment process and the site, receptor and exposure information identified for the purposes of the risk characterization (310 CMR 40.0901 through 40.0930). In addition to these factors, consideration is given to the existence of nuisance conditions (odors, noise, taste), loss of active or passive property use(s), and any non-pecuniary effects not otherwise considered in the characterization of risk of harm to health, safety, and the environment but which may accrue due to the degradation of public resources directly attributable to the release or threat of release of OHM or the remedial alternative.

13.2.2.2 Consideration of Method 3 Ceiling Limits (M3CLs)

The requirements for the Method 3 Ceiling Limits (M3CLs) address the potential public welfare risks that arise when extremely elevated levels of OHM ("gross contamination") remain on-site as part of a Permanent Solution. The Public Welfare evaluation requires (310 CMR 40.0994(3)(a)) comparison of site conditions to the Method 3 Ceiling Limits as described at 310 CMR 40.0996.

Method 3 Ceiling Limits are not used to evaluate ***current*** site conditions and thus are not part of an evaluation of whether a site meets the conditions for a Temporary Solution.

Throughout the Risk Characterization process, the MCP allows the Potentially Responsible Party (PRP) flexibility to prescribe the foreseeable future uses of a site as a tool for managing potential future exposure and thus limit potential future human health risks that otherwise might occur. Any such limitations of foreseeable future uses are incorporated into a legal tool known as an Activity and Use Limitation (AUL). However, the MCP recognizes that there are limits to the reliability of models, the accuracy of risk calculations and the effectiveness of legal tools, particularly when evaluating future conditions. There is a real risk that one (or more) of these systems will fail at a site over time, whether through natural occurrences, new toxicological information, or human negligence. Where a Permanent Solution for a site includes leaving extremely elevated levels of OHM on-site, the potential risks associated with a system failure (of whatever kind) are substantial. The Public Welfare evaluation using M3CLs ensures that additional physical controls (e.g., an Engineered Barrier) are in place to appropriately manage potential future exposures.

Comparison of Site Concentrations to Method 3 Ceiling Limits (M3CLs)

The list of Method 3 Ceiling Limits can be found in Table 6 of the MCP, at 310 CMR 40.0996(7).

The comparison of site conditions to M3CLs uses the arithmetic mean (average) concentrations of OHM both at the disposal site as a whole and within any Hot Spot identified at the disposal site. Note that the regulations do ***not*** refer to these calculated means as "Exposure Point Concentrations" (310 CMR 40.0996(3)). This comparison is different from the human health risk characterization and does not allow for a "no exposure means no risk" conclusion.

The exceedance of a M3CL for one or more OHM is explicitly defined[1] as a significant risk of harm to Public Welfare for future site conditions, regardless of what other parts of the Risk Characterization may assume about (or limit) exposure. There are two exceptions to this conclusion. The first allows for a more refined comparison for the components of Total Petroleum Hydrocarbons. The second provides three physical controls under which an exceedance of a M3CL would be considered a condition of no significant risk for future conditions.

Total Petroleum Hydrocarbons (TPH)

Similar to the way the MCP handles notification requirements for Total Petroleum Hydrocarbons (310 CMR 40.0360(2)), an initial finding that TPH concentrations exceed the M3CL can be put aside if the concentrations of the Aliphatic and Aromatic Hydrocarbon Fractions comprising the TPH are less than or equal to the applicable Method 3 Ceiling Limits of such fractions in soil and groundwater. The more refined comparison using the Aliphatic and Aromatic Hydrocarbon fractions would determine if there is a condition of No Significant Risk (or not).

Physical Controls Allowing for a Condition of No Significant Risk

As noted above, where a Permanent Solution for a site includes leaving extremely elevated levels of OHM on-site, the Public Welfare evaluation using M3CLs ensures that additional physical controls are in place to manage potential future exposures. The implementation of one or more of such controls would allow for a finding that a condition of No Significant Risk exists for the site. The three additional controls are:

1. The permanent immobilization or fixation of the OHM as part of the remedial action implemented at the disposal site;
2. A physical separation of at least fifteen feet between the residual OHM exceeding M3CLs and the ground surface; or

[1] The regulations (310 CMR 40.0996(4)) actually state this as a negative: "…a level of no Significant Risk of harm to public welfare and to the environment does not exist for future conditions if the concentration of one or more oil and/or hazardous material exceeds an applicable Method 3 Ceiling Limit…"

3. The implementation of an Engineered Barrier (consistent with the requirements of 310 CMR 40.0998) to control potential future exposure to the OHM exceeding M3CLs.

These controls are the additional steps necessary for gross contamination to remain on-site as part of a Permanent Solution, even with the implementation of required Activity and Use Limitations.

Deriving M3CLs for OHM Not Listed in 310 CMR 40.0996(7)

The MCP lists Methd 3 Ceiling Limits for each of the OHMs with Method 1 Groundwater and Soil Standards. It is not uncommon for there to be additional OHM present at a site and there is a process identified to determine M3CLs for such chemicals.

First, there are default M3CLs that can be used for an oil or hazardous material for which MassDEP has not published a value in MCP Table 6.

- For contaminants in groundwater, the default M3CL is 10,000 µg/L (or 10 mg/L).
- For contaminants in soil, the default M3CL is 1,000 µg/g (or 1,000 mg/kg).

A chemical specific M3CL that is higher than the default value may be calculated, if preferred (or needed). Method 2 Groundwater and Soil Standards must be derived first, using the procedures described in the MCP at 310 CMR 40.0983 and 40.0984 for groundwater and soil, respectively. Once the new Method 2 Standards are calculated, the highest groundwater and soil standards are multiplied by ten and compared to a medium-specific ceiling limit:

- For contaminants in groundwater, Method 2 GW-1, GW-2 and GW-3 Standards are calculated following the equations and parameters described in 310 CMR 40.0983. All three standards must be calculated, even if the groundwater at the site is not GW-1 or GW-2, as no groundwater category consistently yields the highest (or lowest) standard. Then the ***highest*** of the three values is multiplied by 10, and the result compared to a value of 100,000 µg/L. The lower of these two values is selected as the Method 3 Ceiling Limit in Groundwater for that OHM. Note that no M3CL in Groundwater can exceed 100,000 µg/L.
- For contaminants in soil, Method 2 S-1, S-2 and S-3 Standards are calculated following the equations and parameters described in 310 CMR 40.0984. For the purpose of deriving a M3CL, it is not necessary to calculate all nine possible soil standards, as the S-3 standards are consistently higher than the S-1 and S-2 standards. Having determined the highest Method 2 groundwater standard (see above), it is only necessary to calculate the corresponding S-3 Soil Standard (S-3/GW-1, S-3/GW-2 or S-3/GW-3). This value (S-3/GW-?) is multiplied by 10, and the result compared to a value of 10,000 µg/g. The lower of these two values is selected as the Method 3 Ceiling Limit in Soil for that OHM. Note that ***no M3CL in Soil can exceed 10,000 µg/g***.

OHM for Which M3CLs Do Not Apply

For a handful of common soil constituents that are often naturally occurring at elevated concentrations, the Method 3 Ceiling Limits are not applicable. It is not necessary to derive a M3CL and compare site concentrations as part of a Public Welfare evaluation.

These exempted OHM are:

- Aluminum
- Calcium
- Iron
- Potassium (excluding elemental potassium) and
- Sodium (excluding elemental sodium).

In addition, asbestos is similarly excluded from the M3CL comparison, but for different reasons. First, there is no asbestos M3CL listed in Table 6 and the methods to derive a M3CL do not work for asbestos due to its unique structure and mechanism of action resulting in adverse health effects. Second, there are regulations *in addition to the MCP* which address asbestos, and which provide additional controls on potential exposure to this hazardous material, including 310 CMR 4.00, 7.00, 16.00 and 19.00.

Finally, the constituents of coal tar waste deposits are not compared to M3CLs as the risk of harm to public welfare for these materials are evaluated pursuant to 310 CMR 40.0997, as described in Section 13.2.2.3.

Ongoing Monitoring of OHM Exceeding M3CLs

Where elevated levels of OHM remain on site as part of a Permanent Solution, appropriate ongoing monitoring is required to ensure that site conditions remain consistent with a level of No Significant Risk. The results of such monitoring must be submitted to the Department.

13.2.2.3 Consideration of Visible Coal Tar Waste Deposits

The requirements for visible coal tar waste deposits address the potential public welfare risks that arise when visible coal tar waste deposits ("gross contamination") remain on-site as part of a Temporary Solution or a Permanent Solution. These requirements are modeled after those for the Method 3 Ceiling Limits described above. The Public Welfare evaluation (310 CMR 40.0994(3)(b)) requires assessing the presence of accessible visible coal tar waste deposits at the site as described at 310 CMR 40.0997.

The regulations focus on ***visible*** coal tar waste deposits. In this context, "visible" is ***not*** a synonym for "surficial". "Visible" is used here to mean that visual identification of the material, along with adequate site history, is sufficient to identify the material as a coal tar waste deposit.

This identification may be through surficial observation, but it may also occur at depth by observing material in test pits or borings. Visual identification is used for several reasons. First, chemical analysis of coal tar waste deposits can be problematic due to the high concentrations of materials within the tar and the likelihood that the material will foul the analytical equipment. Second, while the individual constituents within the coal tar waste deposits may vary due to the original feedstock, gasification process and subsequent weathering, the risk posed by these varying materials is consistently unacceptable. Third, whether the disposal site is the location of a coal gasification facility or a satellite disposal location, the volume of coal tar waste deposits is usually significant and visual confirmation of its presence at a site is sufficient to identify it as a potential concern for risk of harm to public welfare. Minimal amounts of coal tar waste deposits, if present at a site, may be readily removed and disposed of off-site. The Public Welfare Evaluation that follows is focused on coal tar waste deposits that are infeasible to remove and therefore must be managed for the long-term.

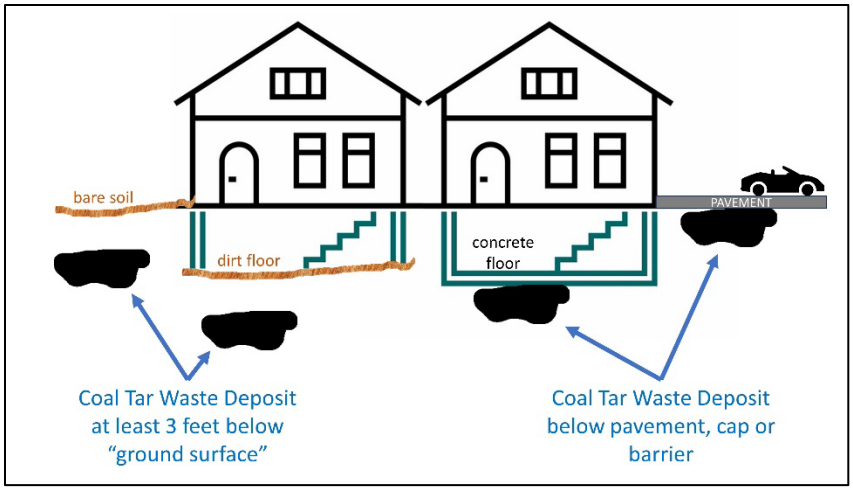
No Significant Risk Under Current Site Conditions – Coal Tar Waste Deposits

For the evaluation of current site conditions, a condition of no significant risk to public welfare exists or has been achieved if there is no easy access to any visible coal tar waste material – *specifically* the waste deposit is either three (or more) feet underground or there is some form of cap or barrier to prevent exposure (310 CMR 40.0997(2)(b)). The cap or barrier may be temporary in nature, as MassDEP encourages actions to prevent exposure to surficial coal tar waste deposits even while response actions are being evaluated for an eventual Permanent Solution. (When measuring depth from the ground surface, where the visible coal tar waste deposit is located beneath a building, the "ground surface" begins at the surface of the soil immediately below the building (310 CMR 40.0997(4)). An intact basement floor made of concrete or similar material would be considered a "barrier" for the purposes of 310 CMR 40.0997(2)(b).)

Figure 13-2 illustrates several examples in which visible coal tar waste deposits would pose no significant risk under *current* site conditions.

A finding of No Significant Risk for current conditions is a minimum requirement for a Temporary Solution at a disposal site.

Figure 13-2: Examples in which Coal Tar Waste Deposits Pose
No Significant Risk for CURRENT Site Conditions



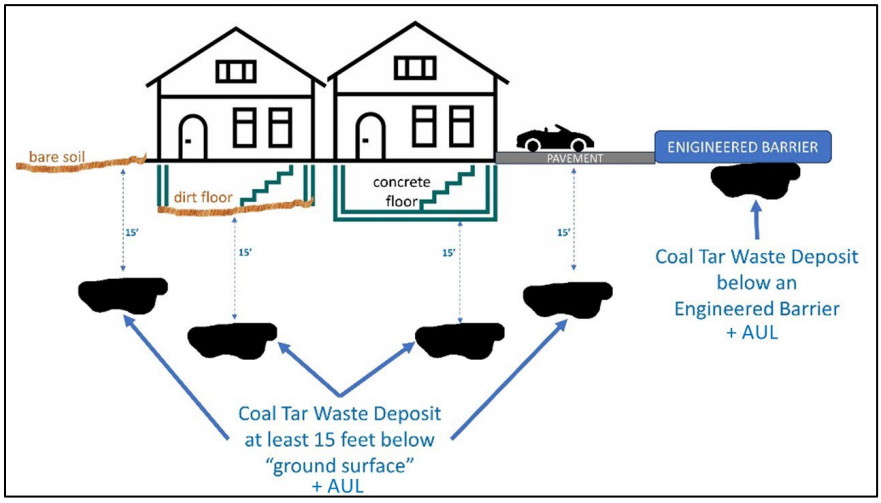
No Significant Risk Under Future Site Conditions – Coal Tar Waste Deposits

As noted above for Method 3 Ceiling Limits, the MCP allows the PRP flexibility to prescribe the foreseeable future uses of a site as a tool for managing potential future exposure and thus limit potential future human health risks that otherwise might occur. Any such limitations of foreseeable future uses are incorporated into a legal tool known as an AUL (See Chapter 3 & AUL policy WSC 25-300). However, the MCP recognizes that there are limits to the reliability of models, the accuracy of risk calculations and the effectiveness of legal tools, particularly when evaluating future conditions. There is a real risk that one (or more) of these systems could fail at a site over time, whether through natural occurrences, new toxicological information, or human negligence. As with the Method 3 Ceiling Limits, where a Permanent Solution for a site includes leaving visible coal tar waste deposits on-site, the Public Welfare evaluation ensures that additional physical controls (e.g., an Engineered Barrier) are in place to appropriately manage potential future exposures.

For the evaluation of future site conditions, a condition of no significant risk to public welfare exists or has been achieved if the remaining coal tar waste deposit is either fifteen (or more) feet underground or the material is under an Engineered Barrier to effectively manage exposure (310 CMR 40.0997(3)(b)) and an AUL is implemented as required in 310 CMR 40.1012(2). Note that these provisions are similar to, but more stringent than, those required to achieve no significant risk under current conditions: 15' vs 3' and an Engineered Barrier vs "cap". Again, where the visible coal tar waste deposit is located beneath a building, the "ground surface" begins at the surface of the soil immediately below the building (310 CMR 40.0997(4)). However, a basement floor is not considered an "Engineered Barrier" for the purposes of 310 CMR 40.0997(3)(b)2 unless it was specifically designed and constructed to serve as one pursuant to 310 CMR 40.0998.

Figure 13-3 illustrates several examples in which visible coal tar waste deposits would pose no significant risk under *foreseeable future* site conditions.

Figure 13-3: Examples in which Coal Tar Waste Deposits Pose No Significant Risk for FORESEEABLE FUTURE Site Conditions



An Activity and Use Limitation is also required whenever visible coal tar waste deposits remain on-site as part of a Permanent Solution.

13.2.3 Method 3 Public Welfare Risk Characterization Conclusions & Documentation

A level of no significant risk of harm to public welfare exists or has been achieved for all current and reasonable foreseeable future conditions if ***all*** the following conditions are met:

1. The site and the surrounding environment are free of nuisance conditions caused by site-related OHM under both current and reasonably foreseeable conditions (310 CMR 40.0994(4)(a). Examples of such nuisance-free conditions include:
    - The breathing zone of ambient and indoor air are currently and will, in the reasonably foreseeable future, remain free from persistent, noxious odors.
    - There is accessible drinking water that is and will, in the reasonably foreseeable future, remain free from noxious taste and odors.
    - Livestock is and will remain, in the reasonably foreseeable future, free from harmful effects. (No specific evaluation of livestock is required if it is reasonable to conclude that the human health and environmental risk characterizations conducted for the site are also protective of livestock exposures.)
2. There are no significant adverse impacts to any community affected resulting from site-related OHM or the selected remedial alternative, either currently or in the foreseeable future. Such adverse impacts include:
    - The existence of nuisance conditions in the community;
    - The loss of active or passive use of properties within the community;
    - The existence of non-pecuniary effects on the community that have not otherwise been considered in the evaluation of risk of harm to health, safety or

the environment, but which may accrue due to the degradation of public resources.

3. All the requirements related to the Method 3 Ceiling Limits have been met (310 CMR 40.0996(7)).
4. All the requirements related to the visible coal tar waste deposits have been met (310 CMR 40.0997).