

**GUIDANCE FOR  
HUMAN HEALTH RISK ASSESSMENTS  
FOR HAZARDOUS SUBSTANCE SITES  
IN MAINE**

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State of Maine  
Department of Environmental Protection  
and  
Center for Disease Control

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## LIST OF ACRONYMS

ATSDR	Agency for Toxic Substances and Disease Registry
CA-OEHHA	California Office of Environmental Health Hazard Assessment
COPC	Chemical of Potential Concern
CSM	Conceptual Site Model
DEP	Maine Department of Environmental Protection
EPC	Exposure Point Concentration
FTAL	Fish Tissue Action Level
IRIS	Integrated Risk Information System
IUR	Inhalation Unit Risk
MassDEP	Massachusetts Department of Environmental Protection
MeCDC	Maine Center for Disease Control
MRL	Minimal Risk Level
ORNL	Oak Ridge National Laboratory
PPRTV	Provisional Peer-reviewed Toxicity Values
PRG	Preliminary Remedial Goal
RAG	Remedial Action Guideline
RBC	Risk-based Concentration
REL	Reference Exposure Level
RfC	Reference Concentration
RfD	Reference Dose
RSL	Regional Screening Level
SF	Slope Factor
TIC	Tentatively Identified Compound
UCL	Upper Confidence Limit
UR	Unit Risk
USEPA	United States Environmental Protection Agency

## 1.0 INTRODUCTION

DEP/MeCDC's Guidance Manual for Human Health Risk Assessments at Hazardous Substance Sites was published in 1994 and has not been updated since. In the intervening years, significant advances in risk assessment methodologies have taken place. In recognition of these advances and the speed with which they occur, in 2008, DEP/MeCDC developed this more concise guidance document that focuses on issues specific to Maine risk assessments while relying heavily on USEPA guidance documents. In some cases, guidance specific to USEPA Region I, as representative of the New England area, has been incorporated. This approach will permit closer concordance between Maine and USEPA risk assessment guidance and will facilitate the completion of risk assessments at sites with both DEP and USEPA involvement. This 2008 guidance document supersedes the 1994 Guidance Manual as well as any previous risk assessment guidance documents. This guidance is available on [DEP's website](#) and is considered current unless and until a revised guidance is published and posted on the website.

The purpose of this document is to provide guidance on the standards for human health risk assessments conducted for DEP/MeCDC, thereby ensuring that assessments are of high quality, are consistent across the State, and are in agreement with DEP/MeCDC policies. This document provides guidance on the various components of site-specific risk assessments including exposure assessment, dose-response assessment, risk characterization, data presentation, and report format. Guidance on risk management, the process of determining the most appropriate means of controlling or eliminating a risk judged to be significant, is not included in this document.

Though relying heavily on USEPA risk assessment guidance, features discussed in this document which distinguish this guidance from USEPA guidance include:

- Provision of default receptors, exposure pathways, and exposure parameters that are considered to be appropriate for Maine;
- Inclusion of policies of DEP/MeCDC which may, on occasion, be different from those of USEPA; and
- Methodology for the calculation of site-specific target cleanup levels.

DEP/MeCDC encourage responsible parties to prepare and submit a work plan for the site-specific risk assessment. The work plan provides a platform for discussion between the State and the responsible party to negotiate the terms of the risk assessment. The work plan should include a schedule for completion of the risk assessment and details concerning the submittal and content of interim deliverables, prepared to facilitate State approval of the risk assessment. Suggested interim deliverables, to be submitted prior to the draft risk assessment report, include: (1) a Conceptual Site Model (CSM) identifying the media, exposure points, receptors, and exposure pathways of concern; (2) selection of chemicals of potential concern (COPCs),

receptor-specific exposure assumptions, equations to be used to estimate risks/hazards, and toxicity values for COPCs; and (3) presentation of exposure point concentrations (EPCs) and draft risk and hazard calculations. Once the work plan is agreed upon, the risk assessment will proceed more efficiently and State concurrence is facilitated.

## **2.0 USEPA GUIDANCE DOCUMENTS**

In general, human health risk assessments conducted in Maine must now follow USEPA risk assessment guidance. The most current USEPA risk assessment guidance is available on USEPA's Superfund risk assessment website (<http://www.epa.gov/oswer/riskassessment/>). A listing of relevant USEPA guidance documents along with a website link for each document is provided in Section 9.0, References.

This document identifies those components of the USEPA risk assessment guidance most appropriate for use as default Maine-specific guidance. Any responsible party who wishes to prepare a risk assessment that departs from the Maine-specific guidance identified in this document must submit justification for those departures and to obtain DEP approval for the departures. To standardize and facilitate review of submitted risk assessments, responsible parties should use the reporting format specified in the December 2001 Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part D) (<http://www.epa.gov/oswer/riskassessment/ragsd/index.htm>).

In general, it is the policy of DEP/MeCDC to follow USEPA guidance after it has been given "Interim" or "Final" status. However, draft guidance documents may be consulted and used if USEPA has no preexisting guidance for a particular topic or for information on advances in the scientific basis for risk estimations. In some cases, when USEPA staff confirms that release of a draft guidance as either "Interim" or "Final" is imminent, DEP/MeCDC may authorize its use for risk assessment. Responsible parties are encouraged to discuss any proposal to use draft guidance with the DEP or MeCDC toxicologist responsible for risk assessment oversight.

USEPA guidance is not available for petroleum contamination, which may be important for sites where hazardous pollutants and petroleum are co-mingled. Therefore, DEP has made an interim policy decision to adopt the Massachusetts Department of Environmental Protection's (MassDEP's) volatile petroleum hydrocarbon (VPH), extractable petroleum hydrocarbon (EPH) and air-phase petroleum hydrocarbon (APH) analytical methods for petroleum hydrocarbon fractions and toxicity values for these fractions for use in Maine risk assessments. Specific details concerning the MassDEP petroleum methods can be found at <http://www.mass.gov/dep/cleanup/laws/policies.htm#vph>.

### 3.0 SITE CHARACTERIZATION FOR RISK ASSESSMENT

Data collected solely for site investigation purposes (e.g., identifying contaminant sources and nature/extent of contamination) may or may not be appropriate for use in risk assessment. It is important to have input from a risk assessor/toxicologist in designing the site investigation plan when a risk assessment is planned, to ensure that enough samples meeting risk assessment goals and objectives and data quality requirements are collected.

Sufficient analytical data should be collected to not only delineate the nature and extent of chemical contamination at a site, but to also characterize exposures across the entire areas of concern, as well as “hot spot” locations. Sufficient numbers of samples should be collected such that a reliable statistical mean concentration can be calculated for use as the EPC for each COPC (see Section 6.2 for further details). The following USEPA guidance documents on sampling strategies should be consulted when formulating the site-specific sampling plan:

- Risk Assessment Guidance for Superfund, Volume I. Human Health Evaluation Manual (Part A), Chapter 4 (December 1989). <http://www.epa.gov/oswer/riskassessment/ragsa/pdf/ch4.pdf>
- Supplemental Guidance to RAGS: Calculating the Concentration Term (June 1992). [http://www.epa.gov/oswer/riskassessment/pdf/1992\\_0622\\_concentrationterm.pdf](http://www.epa.gov/oswer/riskassessment/pdf/1992_0622_concentrationterm.pdf)
- Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites (December 2002). <http://www.epa.gov/oswer/riskassessment/pdf/ucl.pdf>
- Soil Screening Guidance: Technical Background Document (July 1996). <http://www.epa.gov/superfund/health/conmedia/soil/introtbd.htm>
- Soil Screening Guidance: User's Guide (July 1996). <http://www.epa.gov/superfund/health/conmedia/soil/index.htm#user>
- Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (November 2002). <http://epa.gov/wastes/hazard/correctiveaction/pdfs/f02052.pdf>
- EPA Guidance for Quality Assurance Project Plans (February 1998). <http://www.epa.gov/OUST/cat/epaqag5.pdf>
- Guidance on Choosing a Sampling Design for Environmental Data Collection (December 2002). <http://www.epa.gov/quality/qs-docs/g5s-final.pdf>
- Guidance on Systematic Planning using the Data Quality Objectives Process (February 2006). <http://www.epa.gov/quality/qs-docs/g4-final.pdf>

Data quality and data usability are important additional considerations in the use of analytical data for risk assessment purposes. Quality of analytical data should be assessed prior to use in the risk assessment using methods detailed in USEPA guidance for data usability including the collection and evaluation of appropriate

blank and duplicate data. The following USEPA guidance documents should be consulted for data usability guidance:

- Guidance for Data Useability in Risk Assessment (Part A; April 1992).  
<http://www.epa.gov/oswer/riskassessment/datause/parta.htm>
- Guidance for Data Useability in Risk Assessment (Part B; May 1992).  
<http://www.epa.gov/oswer/riskassessment/datause/partb.htm>
- Guidance for Data Useability in Risk Assessment: Quick Reference Fact Sheet (September 1990).  
<http://www.epa.gov/oswer/riskassessment/datause/pdf/index.pdf>.

One goal for data usability is to set analytical detection limits such that reporting limits are at least three-fold less than medium-specific screening criteria appropriate for selecting COPCs (see Section 4.1), as well as any applicable regulatory standards and guidelines. For highly toxic compounds with low screening criteria, this goal may not be achievable. In these cases, an analytical method should be selected that provides a reporting limit less than or as close as possible to the screening criteria.

In general, field screening data are not recommended for use in a quantitative risk assessment unless the chemical-specific results correlate well with fixed laboratory analysis conducted in parallel with the collection of field screening data. Data for tentatively identified compounds (TICs), if available, should be evaluated to determine the need for further chemical analysis, especially for those TICs estimated at a high concentration and/or displaying a high degree of chemical-specific toxicity.

#### **4.0 SELECTION OF CHEMICALS OF POTENTIAL CONCERN**

If the number of chemicals detected at a site is large, it may be appropriate to narrow the list of chemicals to be quantitatively evaluated in the risk assessment by selecting a subset of chemicals that are likely to pose the greatest risk and hazard. It is important to note that neither USEPA nor DEP/MeCDC permits the exclusion of inorganic or organic compounds from the human health risk assessment based on comparison to background levels. Compounds that may exist at background concentrations should be quantitatively evaluated in the risk assessment. In addition, chemicals should not be eliminated from the list of COPCs based on frequency of detection since one or a small number of detections could be indicative of a localized hot spot.

A chemical may be excluded from the risk assessment if it meets one of the following two requirements: 1) the maximum detected concentration of that chemical in a given medium is less than its risk-based concentration, or 2) the chemical is recognized by USEPA as an essential human nutrient, is present at low concentrations, and is toxic only at very high doses. USEPA (1989) recognizes magnesium, calcium, potassium, and sodium as

essential nutrients that may be evaluated and justified for exclusion from the quantitative risk assessment based on consideration of concentration and toxicity.

#### 4.1 Risk-Based Concentrations

Risk-based concentrations for use in selecting COPCs should reflect a cancer risk estimate of  $1 \times 10^{-6}$  and noncarcinogenic hazard quotient of 0.1. The use of risk-based concentrations at these target risk and hazard levels ensures that chemicals with the potential to contribute significantly to risk and hazard are included in the quantitative assessment. Because the intent of the COPC selection process is to generate a conservative list of chemicals requiring quantitative evaluation, recommended screening criteria are conservative so as not to omit chemicals that may contribute significantly toward cumulative site risk.

Regional Screening Levels (RSLs) developed by the Oak Ridge National Laboratory (ORNL) should be used as risk-based concentrations for COPC selection for soil, groundwater, and air. RSLs are conservative, risk-based concentrations for residential and industrial soil, tap water, and residential and industrial air (<http://epa-prgs.ornl.gov/chemicals/index.shtml>) for a wide variety of chemicals using the most current toxicity information available. RSLs are updated at least semi-annually. Should there be a problem with the ORNL website, RSLs are also posted on the Region III website ([http://www.epa.gov/reg3hwmd/risk/human/rb-concentration\\_table/Generic\\_Tables](http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/Generic_Tables)).

Soil RSLs address exposure through incidental ingestion, dermal contact, and inhalation of particulates and volatiles. Tap water RSLs address exposure through ingestion and inhalation of volatiles under a domestic water use scenario. Air RSLs address exposure through inhalation under a residential and industrial exposure scenario. Because RSLs reflect a target cancer risk of  $1 \times 10^{-6}$  and hazard quotient of 1, RSLs based on noncarcinogenic effects should be multiplied by 0.1 prior to use in selecting COPCs. It is DEP/MeCDC policy that residential screening criteria should be used to select soil COPCs, even for industrial sites. Note that some RSL values are based on soil saturation (“sat”) or a ceiling limit (“max”). In these cases, supporting tables provided by ORNL will need to be consulted to properly select risk-based concentrations set at the lower of a target cancer risk of  $1 \times 10^{-6}$  or hazard quotient of 0.1. For RSLs based on cancer but annotated with “\*\*\*”, meaning that the noncarcinogenic value is less than 10-fold greater than the value based on cancer, the noncarcinogenic value (provided in the supporting table), multiplied by 0.1, should be used as the screening value to properly select a risk-based concentration set at the lower of a target cancer risk of  $1 \times 10^{-6}$  or hazard quotient of 0.1.

For fish and shellfish data, ORNL provides a screening level calculator at <http://epa-prgs.ornl.gov/chemicals/index.shtml> for use in developing site-specific fish tissue RSLs. The ORNL calculator should be used with default assumptions provided in the calculator to develop site-specific fish tissue RSLs. As

previously described, default RSLs reflect a target cancer risk of  $1 \times 10^{-6}$  and hazard quotient of 1. Thus, RSLs based on noncancer effects should be multiplied by 0.1 to calculate risk-based concentrations for use in selecting COPCs, or the target hazard quotient should be changed from the default value of 1 to a value of 0.1 in the calculator. The lower of the cancer and noncancer values should be selected for use in selecting COPCs, with special regard to those compounds whose noncarcinogenic value is less than 10-fold greater than the value based on cancer (as described above). Alternatively, Region III risk-based concentrations (RBCs) may be used for selecting fish tissue COPCs. The USEPA Region III RBCs use the same assumptions as those used by the ORNL calculator in default mode. The most current USEPA Region III fish RBCs can be found at <http://www.epa.gov/reg3hwmd/risk/human/pdf/fish.pdf>.

For sediment, residential soil RSLs should be used for selecting COPCs. For surface water, tap water RSLs should be used in addition to National Recommended Water Quality Criteria for the human ingestion of organisms (<http://www.epa.gov/waterscience/criteria/wqctable/>) if the surface water body is a source of recreationally-caught fish or could directly impact a surface water body that is a source of edible fish.

If no risk-based concentration is available for a given chemical in a given medium, that chemical should be retained in the quantitative risk assessment, unless a risk-based concentration for a conservative surrogate compound is selected for screening and its maximum detected concentration is less than the conservative surrogate screening value. The use of surrogate screening values should be identified in footnotes on the COPC screening table. Recommended surrogate assignments include:

<b><u>Compound Lacking Screening Criteria</u></b>	<b><u>Conservative Surrogate Compound</u></b>
Alpha- and gamma-Chlordane	Chlordane
Total chromium	Chromium VI
2-Methylnaphthalene (air)	Naphthalene
Endrin aldehyde and Endrin ketone	Endrin
1-Methylnaphthalene (air)	Naphthalene
Acenaphthylene	Acenaphthene
Phenanthrene	Pyrene
Benzo(g,h,i)perylene	Pyrene
Bromochloromethane	Bromodichloromethane
cis- and trans-1,3-Dichloropropene	1,3-Dichloropropene
1,2,3-Trichlorobenzene	1,2,4-Trichlorobenzene
delta-Hexachlorocyclohexane	alpha-Hexachlorocyclohexane
Endosulfan I and Endosulfan II	Endosulfan
Endosulfan sulfate	Endosulfan

To account for the potential of compounds present in soil to impact groundwater, soil concentrations should also be compared to risk-based Soil Screening Levels presented on the ORNL Regional Screening Levels table (<http://epa-prgs.ornl.gov/chemicals/index.shtml>) or to leaching-based soil values developed by the DEP. The list of soil contaminants with the potential to impact groundwater is not further evaluated in the quantitative risk assessment, but should be used to identify the need for additional consideration of this fate and transport pathway during the remedial decision-making process.

#### **4.2 COPC Selection for Dermal Exposure to Contaminants in Water**

In RAGS Part E, USEPA screened a large number of chemicals to determine whether dermal uptake of the chemical in a domestic water supply would contribute a significant dose relative to oral exposure. USEPA defined “significant” intake when the dermal intake was predicted to be greater than 10% of the oral intake using conservative exposure parameters. The screening assessment is included in Exhibit B of RAGS Part E ([http://www.epa.gov/oswer/riskassessment/ragse/pdf/appendix\\_b.pdf](http://www.epa.gov/oswer/riskassessment/ragse/pdf/appendix_b.pdf)).

Currently, ORNL does not include dermal uptake in the calculation of tap water RSLs. As a result, it is not possible to use tap water RSLs to select COPCs for this exposure pathway. Therefore, if USEPA’s screening assessment showed significant dermal intake of a given chemical using a residential water scenario (i.e., labeled “Y” in Exhibit B-3), DEP/MeCDC require that this chemical be selected as a COPC for the household water use pathway and oral, dermal, and inhalation risks and hazards from water exposure to that chemical be calculated, as appropriate.

#### **5.0 RECOMMENDED EXPOSURE SCENARIOS AND EXPOSURE ASSUMPTIONS**

DEP/MeCDC require that the baseline risk assessment consider all current and future land uses at each site through the evaluation of potentially complete exposure pathways. Figure 1 depicts standard default exposure pathways of concern by land use and receptor. Applicable receptors and exposure pathways should be identified and justified as part of the CSM prepared for the site. The elimination of any receptor or exposure pathway from quantitative evaluation in the risk assessment should be justified and based on site-specific information.

Based on site-specific information, receptors and exposure pathways in addition to those identified in Figure 1 may be of concern at a site and may require evaluation on a case-by-case basis. Some additional pathways and/or receptors that may require consideration for evaluation include:

- Ingestion of homegrown meat and dairy products for a home farm scenario
- Ingestion of game and waterfowl for hunters and their families

- Inhalation of volatiles from surface water
- Inhalation of particulates by dirt biking trespassers, residents, or recreational users
- [Ingestion of fish and shellfish as part of a regular subsistence diet for certain populations \(e.g., Native American, off-shore island families\)](#)

To evaluate the subsurface migration of volatile compounds to indoor air, DEP has developed Vapor Intrusion Guidance that should be followed to determine whether impacts to indoor air require investigation as well as the methods and procedures to be followed in cases where further investigation of this pathway is warranted.

DEP's Vapor Intrusion Guidance can be found at:

<http://www.maine.gov/dep/rwm/publications/guidance/index.htm>.

In the vast majority of cases, DEP requires that a future residential scenario for each site be included in the risk assessment. The rationale for requiring a residential scenario is that it affords the Department more flexibility in determining the degree of cleanup and the nature of institutional controls when they are deemed necessary. DEP recognizes that some sites, because of their location, local zoning, or inherent characteristics, will likely be used for non-residential uses. However, by evaluating a future residential scenario for such sites, DEP is able to determine if unrestricted cleanup is possible and if not, which parts of a site may require institutional controls as well as how stringent such controls need to be.

The selection of exposure assumptions to be used in Maine risk assessment should be consistent with the intent of a Reasonable Maximum Exposure (RME) scenario, defined by USEPA as the highest exposure that is reasonably anticipated to occur at a site. Exposure parameters that are specific to the standard default exposure pathways (Figure 1) for the state of Maine are listed in Table 1. Deviation from these recommended values should be based on well-documented site-specific justification. The following USEPA guidance documents served as sources of many of the exposure parameters provided in Table 1:

- Risk Assessment Guidance for Superfund, Volume I Part A (1989). <http://www.epa.gov/oswer/riskassessment/ragsa/index.htm>  
Part E (2000). <http://www.epa.gov/oswer/riskassessment/ragse/index.htm>
- Exposure Factors Handbook. Volumes I, II, and III (1997). <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12464>
- Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites (2002). [http://www.epa.gov/superfund/health/conmedia/soil/pdfs/ssg\\_main.pdf](http://www.epa.gov/superfund/health/conmedia/soil/pdfs/ssg_main.pdf)

Dermal exposure to COPCs in soil and groundwater should be assessed following USEPA guidance for dermal risk assessment (<http://www.epa.gov/oswer/riskassessment/ragse/index.htm>). For soil, dermal exposures should only be quantified for those compounds listed on Exhibit 3-4 of USEPA's dermal guidance. The lack of

quantification of this pathway for compounds not listed on Exhibit 3-4 should be discussed in the uncertainty section of the report.

## **6.0 CALCULATION OF EXPOSURE POINT CONCENTRATIONS**

### **6.1 Exposure Points**

An exposure point is the site area in which a receptor could reasonably be exposed. In the quantitative risk assessment, data are grouped by exposure points for the purpose of calculating exposure point concentrations. Data should be grouped into appropriate exposure points for the purpose of estimating risks and hazards from exposure to soils, unless chemical concentrations are uniformly and homogeneously distributed across a larger portion of the site. The risk assessor should use available site-specific information to propose and justify exposure points for review and approval by DEP.

At sites where chemical contamination is distributed in small “pockets” or localized areas of contamination, consideration should be given to selecting exposure points that focus on the areas of contamination. As USEPA (1996) notes, “exposure areas should not be laid out in such a way that they unnecessarily combine areas of high and low contamination”. In addition, portions of the site documented as beyond the area of impact may not be appropriate for inclusion in an exposure point. Instead, these areas may be useful in identifying site-specific background conditions for the site, potentially necessary information for the risk management process.

Individual public and private wells should be considered unique exposure points. Applicable exposure points for monitoring wells, installed to characterize the distribution of contamination in groundwater at a site, should be proposed on a site-specific basis for DEP review and approval. Similarly, exposure points for sediment and surface water (e.g., rivers, ponds, lakes, estuaries, coastal, and wetland environments) should be proposed on a site-specific basis, giving consideration to the distribution of contamination in depositional areas, tidal influence, and known human exposure patterns in the area.

### **6.2 Estimating Exposure Point Concentrations**

Consistent with USEPA guidance

([http://www.epa.gov/oswer/riskassessment/pdf/1992\\_0622\\_concentrationterm.pdf](http://www.epa.gov/oswer/riskassessment/pdf/1992_0622_concentrationterm.pdf); <http://www.epa.gov/oswer/riskassessment/pdf/ucl.pdf>), the upper confidence limit (UCL) on the arithmetic mean concentrations are generally recommended for use as EPCs for soil, sediment, and surface water exposure points. Total surface water analytical results rather than filtered results are recommended for use in EPC estimation. Prior to EPC estimation, duplicate sample results should be averaged. The risk assessment work

plan or interim deliverable should specify the method(s) used to calculate the UCL on the arithmetic mean for each COPC at each exposure point. The following should be specified for each data set:

- How the underlying data distribution was identified;
- The chosen upper confidence limit (UCL) on the arithmetic mean;
- Reasons this method is appropriate for the site data; and
- Assumptions inherent in the method used to calculate the UCL on the arithmetic mean.

Data tables showing all the inputs to UCL on the arithmetic mean calculation (e.g., mean, standard deviation, number of samples, etc.) should be presented. Estimated values (e.g., “J” qualified results) should be used without adjustment. The most current ProUCL calculation software developed by EPA (<http://www.epa.gov/esd/tsc/images/proucl-4-0-02-user.pdf>) should be used to calculate each UCL on the arithmetic mean. Non-detects in the dataset should be treated as recommended in the ProUCL User’s Guide. The most current ProUCL version recommends a minimum of eight samples in order to calculate a reliable UCL on the arithmetic mean for an exposure point. Therefore, data sets with less than 8 data points may require the use of maximum detected COPC concentrations as EPCs (this approach is not recommended; see first bullet point below). It is the policy of DEP to use no less than the 95% UCL on the arithmetic mean as the EPC. In cases where ProUCL recommends a UCL on the arithmetic mean that exceeds the maximum detected concentration in the dataset, a lower percentile UCL, not less than the 95% UCL, or the maximum detected concentration should be used as the EPC.

The following provides minimum guidance on the calculation of soil EPCs:

- For exposure points with less than eight samples, EPCs are not recommended for calculation. Instead, if limited sampling suggests site-related chemical contamination, then additional samples should be collected to properly define the limits of contamination and provide adequate randomly collected data for risk assessment purposes prior to the calculation of EPCs.
- For exposure points with more than eight randomly collected samples, ProUCL may be used to calculate the UCL on the arithmetic mean for use as EPCs. It should be noted that the reliability of the estimated EPC increases as the sample size increases with eight samples per exposure point representing the minimum number of samples necessary for EPC estimation.
- For biased data with more than eight samples, treat the data as if they represent simple random sampling, and use ProUCL to estimate EPCs. Again, the reliability of the estimated EPC increases as sample size increases with eight samples per exposure point representing the minimum number of samples necessary for EPC estimation. The use of biased data likely results in the overestimation of

EPCs. Should ProUCL select the Bootstrap Method as the most appropriate statistical method for the biased data set, ten to fifteen samples are recommended to calculate a reliable EPC.

For monitoring well data being evaluated for the household water use pathway, the groundwater EPC should be the maximum detected concentration for each COPC, across all wells in the exposure point. This is consistent with USEPA Region I guidance (<http://www.epa.gov/region01/superfund/resource/risk5.pdf>). For direct contact with groundwater by an excavation worker, it may be appropriate to use UCLs for groundwater COPCs for each exposure point with appropriate justification provided. In both cases, groundwater data selected for use should be representative of current site conditions. Unfiltered (i.e., total) sample data are recommended for use over filtered (i.e., dissolved) sample data since there is no guarantee that homeowners will filter drinking water prior to ingestion and workers directly contact shallow exposed groundwater in an unfiltered state. For sites with multiple rounds of groundwater data, temporal averaging may be used prior to the identification of maximum concentrations as long as enough data have been collected to adequately characterize seasonal variability (e.g., quarterly sampling in spring, summer, winter, and fall).

For chlorinated dibenzo-*p*-dioxin, chlorinated dibenzofuran and co-planar polychlorinated biphenyl (PCB) data, the relative potencies of the isomers and congeners should be addressed through the use of toxicity equivalency factors (TEFs) re-evaluated by the World Health Organization and published in 2005 ([www.who.int/ipcs/assessment/tef\\_values.pdf](http://www.who.int/ipcs/assessment/tef_values.pdf)). The raw analytical data should be adjusted using the TEFs prior to the estimation of EPCs. EPCs should be expressed as Toxicity Equivalents (TEQs) and evaluated as 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (2,3,7,8-TCDD or TCDD).

### **6.3 Exposure Modeling**

DEP/MeCDC recommend the use of monitoring data rather than modeled results, where possible, to estimate EPCs. For example, reported concentrations in indoor air are preferable to concentrations estimated by modeling subsurface migration and dilution into indoor air. However, when the use of monitoring data is not feasible (e.g., determining the contribution of subsurface migration of solvents to indoor air concentrations in a facility that actively uses solvents), conservative application of the model within its limitations to derive EPCs is acceptable.

Specific models together with parameters and assumptions to be used with the models should be submitted for DEP review and approval. Modeling of other medium-specific environmental contaminant concentrations (e.g., contaminant uptake into edible fish or game) or the use of other available models must be proposed on a site-specific basis and likewise be submitted for DEP review and approval before completion of the risk assessment.

The following provides general guidance relative to the use of specific models to estimate EPCs:

- USEPA's Johnson & Ettinger model is used to model indoor air concentrations from groundwater, soil, or soil gas concentrations ([http://www.epa.gov/oswer/riskassessment/airmodel/johnson\\_ettinger.htm](http://www.epa.gov/oswer/riskassessment/airmodel/johnson_ettinger.htm); [http://www.epa.gov/oswer/riskassessment/airmodel/pdf/2004\\_0222\\_3phase\\_users\\_guide.pdf](http://www.epa.gov/oswer/riskassessment/airmodel/pdf/2004_0222_3phase_users_guide.pdf)). To select indoor air COPCs, maximum soil, groundwater or soil gas results should be used to generate maximum modeled air concentrations which can be compared to RSLs for residential air, adjusted to a hazard quotient of 0.1. Once COPCs are selected, soil, groundwater, and soil gas EPCs (e.g., 95% UCLs on the arithmetic mean concentration) for the COPCs can be used to model indoor air EPCs, resulting in modeled air EPCs that approximate UCL on the arithmetic mean concentrations.
- The Foster and Chrostowski shower model (1987) is used to generate air concentrations in a bathroom during showering and bathing if groundwater contains volatile organic compounds. The Massachusetts Department of Environmental Protection (MassDEP) provides the model equations and standard inputs for the model in their Residential Drinking Water Shortform (file sf06rw.xls located within the Shortforms Method 3 Human Health Risk Assessment zip file at <http://www.mass.gov/dep/service/compliance/riskasmt.htm>). The modeled EPCs should be evaluated using exposure assumptions provided in Table 1 for showering and bathing.
- The Virginia Department of Environmental Quality (VDEQ) trench air models are used to assess the inhalation pathway for workers in an excavation trench impacted by volatiles in groundwater (<http://www.deq.virginia.gov/vrprisk/raguide.html>). Two distinct models have been developed by VDEQ for groundwater greater than 15 feet below ground surface and groundwater less than 15 feet below ground surface. Again, maximum groundwater concentrations should be used to model trench air concentrations for COPC selection. Once COPCs are selected, groundwater EPCs (e.g., 95% UCLs) may be used to generate trench air EPCs. Should volatile compounds be present in soil above the water table, their impact on outdoor air concentrations may be assessed using compound-specific volatilization factors (VFs), as presented by USEPA ([http://www.epa.gov/superfund/health/conmedia/soil/pdfs/ssg\\_main.pdf](http://www.epa.gov/superfund/health/conmedia/soil/pdfs/ssg_main.pdf)). Compound-specific default VFs have been calculated by USEPA and are provided on the ORNL residential soil screening level supporting table ([http://www.epa.gov/reg3hwmd/risk/human/rb-concentration\\_table/Generic\\_Tables](http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/Generic_Tables)).
- Modeling of fugitive dust EPCs for outdoor air is done using particulate emission factors (PEFs; Table 1) presented by USEPA ([http://www.epa.gov/superfund/health/conmedia/soil/pdfs/ssg\\_main.pdf](http://www.epa.gov/superfund/health/conmedia/soil/pdfs/ssg_main.pdf)). Similarly, the modeling of volatile compounds released from soil to outdoor air may be done using volatilization factors (VFs) presented in the same source.

- Modeling of EPCs for homegrown fruits and vegetables grown in impacted soil is done using soil/plant uptake factors (i.e., bioconcentration factors) developed by USEPA for metals ([http://www.epa.gov/superfund/health/conmedia/soil/pdfs/appd\\_g.pdf](http://www.epa.gov/superfund/health/conmedia/soil/pdfs/appd_g.pdf)). Geometric mean bioconcentration factors for leafy vegetables should be used in the modeling of contaminant concentrations in exposed fruits and vegetables. Geometric mean bioconcentration factors for root vegetables should be used to model contaminant concentrations in root vegetables. The modeled EPCs should be used in conjunction with intake rates for exposed fruits, exposed vegetables and root vegetables and exposure durations provided in Table 1 to estimate risks and hazards associated with the homegrown produce consumption pathway. Because intake rates for fruits and vegetables are provided in units of g/kg-day, no body weight factor is to be used in the average daily dose calculation and a 30-year residential exposure duration should be used. Due to the uncertainty associated with modeling plant uptake for organic compounds, the plant uptake pathway for organic compounds should not be quantified but instead, discussed in the uncertainty section.

## 7.0 SELECTION OF TOXICITY VALUES

Toxicity values of interest include reference doses (RfDs) and slope factors (SFs), applicable to the oral route of exposure, and reference concentrations (RfCs) and unit risks (URs), applicable to the inhalation route of exposure. DEP/MeCDC recommends that inhalation pathways be evaluated using airborne concentrations as EPCs ( $\mu\text{g}/\text{m}^3$  or  $\text{mg}/\text{m}^3$ ) and inhalation toxicity values in compatible units of airborne concentrations (RfCs in units of  $\mu\text{g}/\text{m}^3$  or  $\text{mg}/\text{m}^3$ ; URs in units of  $(\mu\text{g}/\text{m}^3)^{-1}$  or  $(\text{mg}/\text{m}^3)^{-1}$ ). Toxicity values used to evaluate inhalation pathways should not be in units of dose ( $\text{mg}/\text{kg}\text{-day}$  or  $(\text{mg}/\text{kg}\text{-day})^{-1}$ ). Further information concerning the evaluation of the inhalation pathway is provided in USEPA's Risk Assessment Guidance for Superfund, Volume 1: Part F (<http://www.epa.gov/oswer/riskassessment/ragsf/>).

For the dermal route of exposure, oral toxicity values (expressed as administered doses) should be adjusted to absorbed doses using methodology and gastrointestinal absorption values ( $\text{ABS}_{\text{GI}}$ ) provided by USEPA (Exhibit 4-1; <http://www.epa.gov/oswer/riskassessment/ragse/pdf/chapter4.pdf>). For chemicals with an  $\text{ABS}_{\text{GI}}$  of greater than 50%, an  $\text{ABS}_{\text{GI}}$  value of 100% should be assumed, as recommended by USEPA. The adjusted toxicity value should then be used with systemically absorbed doses for dermal contact with COPCs in soil, sediment, and water (<http://www.epa.gov/oswer/riskassessment/ragse/pdf/chapter3.pdf>).

Relative potency factors (RPFs) developed by USEPA should be applied to the cancer potency factor for benzo(a)pyrene when evaluating polycyclic aromatic hydrocarbon (PAH) carcinogenicity ([www.epa.gov/oswer/riskassessment/pdf/1993\\_epa\\_600\\_r-93\\_c89.pdf](http://www.epa.gov/oswer/riskassessment/pdf/1993_epa_600_r-93_c89.pdf)).

For lead which has no noncarcinogenic toxicity values, biokinetic models developed by USEPA should be used. For young children, the Integrated Exposure Uptake Biokinetic (IEUBK) Model should be used while the Adult Lead Methodology should be used for older children and adults

(<http://www.epa.gov/superfund/lead/products.htm>). In instances where lead exposures are occurring intermittently (e.g., at a summer camp), USEPA methodology for assessing intermittent or variable exposures to lead should be considered (<http://www.epa.gov/superfund/lead/guidance.htm#leadsites>).

For compounds with a mutagenic mode of action, identified on the Regional Screening Levels table (e.g., vinyl chloride and carcinogenic PAHs), USEPA methodology for assessing early-life exposures to carcinogens should be applied (<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=160003>). USEPA currently recommends a screening approach for carcinogenic PAHs and a specific more-detailed approach for vinyl chloride (<http://www.epa.gov/ncea/iris/toxreviews/1001-tr.pdf>).

The following sections describe hierarchical approaches for selecting chronic and subchronic toxicity values, which recognizes that values from historically reliable sources are aging and may not represent the best-available science. The overall goal is to obtain the most scientifically defensible toxicity values for use in the risk assessment. To this end, the following hierarchy approach and supplemental evaluations were used by DEP/MeCDC in the 2009 update of the Remedial Action Guidelines for soil. The chronic and subchronic toxicity values in Table 1 of the updated Remedial Action Guidelines<sup>1</sup> should be used for those chemicals for which Remedial Action Guidelines have been developed. Toxicity values for additional chemicals may be selected using the rationale described below or requested on a case-by-case basis through DEP.

Chemicals lacking toxicity values from the sources in the hierarchies described below should be retained in the quantitative risk assessment (i.e., exposure should be estimated although risk/hazard cannot be estimated). The uncertainty section of the risk assessment should include a discussion of these chemicals and their apparent health effects.

## **7.1 Hierarchy of Chronic Toxicity Values**

The following hierarchy of preference should be used to identify chronic toxicity values for COPCs. This hierarchy is based on the revised recommended human health toxicity value hierarchy published by USEPA (<http://www.epa.gov/oswer/riskassessment/pdf/hhmemo.pdf>) for use when performing human health risk assessments at Superfund sites. However, the hierarchy listed below modifies the USEPA hierarchy due to the

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<sup>1</sup> “Implementation Manual for Remedial Action Guidelines for Soil – July 10, 2009 draft Table” Document No DEP-BRWM 4A 2009, are available from the Remediation Division, Bureau of Remediation and Waste Management, Maine DEP, 17 SHS, Augusta ME 04333 and from the Maine DEP website at: [Remediation and Waste Management Guidance/Guidelines, Bureau of Remediation and Waste Management, Maine Department of Environmental Protection](#)

limited availability of certain toxicity values for non-Superfund purposes and recognizes that, due to the age of some of the toxicity values, consultation of additional sources of information may be necessary to select the most appropriate of the available toxicity values for a specific COPC:

1. Tier I: USEPA's Integrated Risk Information System (IRIS) provides peer-reviewed chronic cancer and noncancer toxicity values. This database should be the first consulted for chronic toxicity values (<http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showSubstanceList>). In reviewing the information contained in IRIS for a particular COPC, Tier II through Tier V sources of toxicity values should be consulted if the date of the last IRIS revision is greater than 5 years old or the IRIS record indicates a screening-level literature review has been conducted that identified the availability of one or more significant new studies. Because other sources of toxicity values may have incorporated the more recent toxicity information into their toxicity evaluation, Tier II through Tier V sources should be consulted for more current and technically-defensible values. Should a more current toxicity value be unavailable, then the IRIS value should be used.
2. Tier II: If IRIS does not provide a toxicity value for a given chemical or the IRIS value is outdated, California's Office of Environmental Health Hazard Assessment (CA-OEHHA) Toxicity Criteria Database should be consulted (<http://www.oehha.ca.gov/risk/ChemicalDB/>). CA-OEHHA derives chronic noncancer Reference Exposure Levels (RELs) that parallel USEPA's RfCs, as well as URs that are appropriate substitutes for USEPA UR estimates. A listing of current RELs can be found at <http://www.oehha.ca.gov/air/allrels.html>. CA-OEHHA also derives oral cancer SFs that are appropriate substitutes for USEPA SFs. Because CA-OEHHA values may also be outdated, additional sources of toxicity values based on more recent toxicity studies should be consulted prior to selecting a CA-OEHHA value.
3. Tier III: For noncancer endpoints, in the absence of IRIS and CA-OEHHA values or if the IRIS/CA-OEHHA value is outdated, risk assessors may use ATSDR chronic Minimal Risk Levels (MRLs; <http://www.atsdr.cdc.gov/mrls/index.html>). Draft ATSDR values are not recommended for use. CA-OEHHA values are recommended before ATSDR values in the hierarchy due to the methodological similarities between the development of IRIS and CA-OEHHA values and the degree of peer review performed for CA-OEHHA toxicity assessments. As noted with IRIS and CA-OEHHA values, ATSDR values may be outdated requiring further consideration of other sources of information prior to finalizing the selection of a toxicity value.
4. Tier IV: In the absence of a chronic toxicity value for a particular chemical from above sources or in cases where the IRIS/CA-OEHHA/ATSDR record is outdated, USEPA Provisional Peer-Reviewed Toxicity Values (PPRTVs) should be consulted. PPRTVs are available through the Risk Assessment Information

System (RAIS) database ([http://rais.ornl.gov/homepage/rap\\_tool.shtml](http://rais.ornl.gov/homepage/rap_tool.shtml)). PPRTVs are developed using USEPA methodology, but do not undergo the degree of peer review performed for the IRIS process. Full documentation of the values from this database needs to be requested on a chemical-specific basis through USEPA Region 1. Please note that values not currently endorsed by the Superfund Technical Support Center (STSC) (e.g., withdrawn values) should not be used in Maine risk assessments.

5. Tier V: The Health Effects Assessment Summary Table (HEAST) is an alternative source of toxicity values from USEPA. This table of toxicity values was most recently updated in 1997, but may be consulted for toxicity values should values not be available from more current sources, including IRIS. Before a HEAST value is used, risk assessors must verify that the value to be used has not been withdrawn by USEPA or that the use of a withdrawn value is appropriate. Before selecting a HEAST value or if no HEAST value is available, an additional source of toxicity values to consult is the International Toxicity Estimates for Risk (ITER) database (<http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?iter>) which contains supplemental information from international sources (e.g., Health Canada). In general, HEAST values are preferred over values from international sources because the methods used to develop the international toxicity value may not be consistent with USEPA methods. However, an alternate value from the ITER database may be selected if it is based on more current information than the HEAST value.

Prior to finalizing the list of chronic toxicity values, risk assessors are encouraged to cross check the chronic values against subchronic values. In the event that a subchronic value derived from IRIS, ATSDR, or PPRTV is based on more recent toxicity information, the risk assessor should review the derivation of both toxicity values and determine whether it is appropriate to adopt the subchronic value as the chronic value, either with or without a 10-fold downward adjustment to account for uncertainties associated with the less-than-lifetime study duration. If a substitution or other deviation from the hierarchy is made, the rationale should be documented in the risk assessment report.

## **7.2 Hierarchy of Subchronic Toxicity Values**

The major scenario classified as a subchronic exposure is the construction worker scenario, with exposures anticipated to occur over six months or less. This hierarchy applies to the selection of subchronic RfDs and subchronic RfCs only. Chronic SFs and URs should be used to evaluate carcinogenic effects for subchronic exposure scenarios.

The following hierarchy of preference should be used to identify subchronic noncarcinogenic toxicity values for COPCs. This hierarchy is consistent with the hierarchy provided for chronic toxicity values, but removes sources which do not provide subchronic values (e.g., CA-OEHHA):

1. Tier I: USEPA's Integrated Risk Information System (IRIS) provides peer-reviewed subchronic toxicity values for a small number of chemicals (e.g., 1,1,1-trichloroethane). This database should be the first consulted for subchronic toxicity values (<http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showSubstanceList>). Subchronic values posted in IRIS are only found in records less than a few years old and therefore, reflect current toxicity information and methodology.
2. Tier II: In the absence of IRIS values, risk assessors may use ATSDR intermediate Minimal Risk Levels (<http://www.atsdr.cdc.gov/mrls/index.html>), developed for oral and inhalation pathways. These values are applicable to exposure scenarios where the subchronic exposure duration is assumed to be less than 365 days since intermediate MRLs are defined for exposure durations between 14 days and 364 days. The construction worker scenario is one where MRLs may be useful.
3. Tier III: In the absence of a subchronic toxicity value for a particular chemical from above sources, USEPA PPRTVs should be consulted through the RAIS database ([http://rais.ornl.gov/homepage/rap\\_tool.shtml](http://rais.ornl.gov/homepage/rap_tool.shtml)). Full documentation of the values from this database needs to be requested on a chemical-specific basis through USEPA Region 1. Please note that values not currently endorsed by the Superfund Technical Support Center (STSC) (e.g., withdrawn values) should not be used in Maine risk assessments.
4. Tier IV: For chemicals with no IRIS, ATSDR, or PPRTV subchronic values, assessors may consult HEAST. Caution should be exercised when using values from HEAST, which has not been updated since 1997. Before a HEAST value is used, risk assessors must verify that the value to be used has not been withdrawn or that the use of a withdrawn value is appropriate.
5. Tier V: In the absence of appropriate values from the above sources, subchronic toxicity values may be calculated from chronic toxicity values based on subchronic toxicity data. When the toxicological database for a given chemical is limited, USEPA may derive chronic RfDs and RfCs based on studies where the exposure is not of chronic duration (e.g., not >10% of the animal's predicted lifespan). In these cases, USEPA applies an uncertainty factor to extrapolate from toxicity after subchronic exposure to toxicity after chronic exposure. This uncertainty factor generally ranges from 3 to 10 in magnitude. A subchronic toxicity value can be calculated from a chronic value derived under these circumstances by multiplying the chronic toxicity value by the corresponding uncertainty factor.
6. Tier VI: Alternatively, a chronic toxicity value may be used as a surrogate for the subchronic value. USEPA guidance (1989, RAGS Part A) recommends the use of chronic toxicity values when subchronic values are missing. DEP and MeCDC strongly recommend that risk assessors evaluate and

justify the relative merits of HEAST value and chronic toxicity values when choosing between these options.

Prior to finalizing the list of subchronic toxicity values, risk assessors are encouraged to cross check the subchronic values against the chronic values. In the event that a subchronic value derived from IRIS, ATSDR, PPRTV, or HEAST is more conservative than a more recent chronic toxicity value, the risk assessor should review the derivation of both toxicity values and determine whether it is appropriate to substitute the chronic value. If a substitution or other deviation from the hierarchy is made, the rationale should be documented in the risk assessment report. Finally, if the risk calculations suggest that a subchronic exposure scenario may be driving risks and remediation decisions, the toxicity values used to generate the risk estimates should be thoroughly reviewed to ensure their appropriateness. The absence of a centralized, peer-reviewed database for subchronic toxicity values means that there is greater uncertainty in the scientific basis for some subchronic values. As a result, closer examination of the subchronic toxicity values is warranted if they become important to the risk assessment results.

### **7.3 Acute Toxicity Values**

A utility worker scenario may be appropriate for evaluation for acute noncarcinogenic health effects. At a minimum, any COPC whose primary health effect is irritation, developmental or reproductive toxicity, or teratogenicity should also be considered for evaluation of acute effects. As with subchronic toxicity values, there is no centralized database for acute toxicity values. ATSDR develops MRLs for acute exposures ranging from 1 to 14 days in duration (<http://www.atsdr.cdc.gov/mrls/index.html>). For inhalation exposures, USEPA maintains a website (<http://www.epa.gov/ttn/atw/toxsource/summary.html>) with acute toxicity values from a variety of sources and for a variety of exposure durations (generally ranging from 1 hour to 8 hour exposures). In addition, CA-OEHHA develops acute RELs for certain chemicals, applicable to short-term inhalation exposures ([http://www.oehha.ca.gov/air/acute\\_rels/index.html](http://www.oehha.ca.gov/air/acute_rels/index.html); <http://www.oehha.ca.gov/risk/ChemicalDB/>). These sources are not prioritized because the values are not comparable. Risk assessors are encouraged to work closely with a DEP or MeCDC toxicologist to select acute toxicity values most applicable to the exposure scenario of interest. However, use of Acute Exposure Guideline Levels (AEGLs) is inappropriate for assessing acute air exposure risk at remediation sites since AEGLs were developed to assess the risk resulting from a once-in-a-lifetime exposure to airborne chemicals from catastrophic events,

## **8.0 RISK CHARACTERIZATION**

For each receptor, cancer risks and hazard quotients should be summed across all contaminants and media of concern in order to estimate a cumulative cancer risk and hazard index for that receptor. Cancer risk should additionally be summed across age groups (e.g., adult plus child resident cancer risks) to generate a total

receptor cancer risk, as applicable. DEP and MeCDC use a benchmark Incremental Lifetime Cancer Risk (ILCR) level of  $1 \times 10^{-5}$  and a benchmark Hazard Index (HI) of 1. These benchmarks are compared with the cumulative (added across all contaminants and media of concern) HI for each receptor and the total receptor ILCR as an initial step in risk management determinations. For instances where the cumulative HI exceeds 1, consideration may be given to providing a defensible target organ segregation rationale to demonstrate that the COPCs contributing to the HI in excess of 1 act through distinct mechanisms of actions and on different target organs, thereby calculating target organ-specific hazards which can be compared to the benchmark of Hazard Index of 1. Recommendations concerning methodology to use in the evaluation of acute hazards can be found at [http://www.epa.gov/oswer/riskassessment/superfund\\_acute.htm](http://www.epa.gov/oswer/riskassessment/superfund_acute.htm). If cleanup is warranted, site-specific target cleanup levels should be derived to ensure that the cumulative ILCR and HI for each receptor do not exceed the DEP/MeCDC benchmarks.

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