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Region 4 Human Health Risk Assessment Supplemental Guidance

Contents

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Acronyms and Abbreviations

%	percent
ADAF	age-dependent adjustment factor
ALM	Adult Lead Methodology
ARAR	applicable or relevant and appropriate requirement
bgs	below ground surface
BRA	Baseline Risk Assessment
CalEPA	California Environmental Protection Agency
CERCLA	Comprehensive Environmental Response Compensation and Liability Act
COC	chemical of concern
COPCs	chemicals of potential concern
CSM	Conceptual Site Model
DQO	Data Quality Objectives
EFH	Exposure Factors Handbook
EPA	U.S. Environmental Protection Agency
EPC	exposure point concentration
ERA	ecological risk assessment
FI	fraction ingested
FS	Feasibility Study
ft	feet/foot
HHRA	Human Health Risk Assessment
HI	hazard index
HQ	hazard quotient
IC	institutional control
IEUBK	Integrated Exposure Uptake Biokinetic Model
IR	ingestion rate
IRIS	Integrated Risk Information System
ISM	Incremental Sampling Methodology
ITRC	Interstate Technology & Regulatory Council
IUR	Inhalation Unit Risk
kg	kilogram
K_{40}	potassium-40
MARSSIM	Multi-Agency Radiation Survey & Site Investigation Manual
MCL	Maximum Contaminant Level
µg/L	micrograms per liter

Acronyms and Abbreviations (continued)

$m^3/\mu g$	cubic meter per microgram
mg/kg	milligrams per kilogram
mg/kg/day	milligrams per kilogram per day
mg/m^3	milligrams per cubic meter
MMOA	mutagenic mode of action
NTU	Nephelometric Turbidity Unit
OSC	On-Scene Coordinator
OLEM	Office of Land and Emergency Management
OSWER	Office of Solid Waste and Emergency Response
PAH	polycyclic aromatic hydrocarbon
PCB	polychlorinated biphenyls
PCDD	polychlorinated dibenzodioxin
PCDF	polychlorinated dibenzofurans
PRG	Preliminary Remediation Goal
RAGS	Risk Assessment Guidance for Superfund
RCRA	Resource Conservation and Recovery Act
RfC	reference concentration
RfD	reference dose
RI	Remedial Investigation
RL	remediation level
ROD	Record of Decision
RPM	Remedial Project Manager
RSL	Regional Screening Level
SAP	Sampling and Analysis Plan
SESD	Science and Ecosystem Support Division
SSL	Soil Screening Level
SSRG	Site Specific Remedial Goal
SSS	Scientific Support Section
SFI	slope factors for inhalation
SOP	Standard Operating Procedure
TCDD	2,3,7,8-tetrachlorodibenzodioxin
TEF	Toxicity Equivalence Factor
TRW	Technical Review Workgroup
TSS	Technical Services Section

Acronyms and Abbreviations (continued)

UCL	upper confidence limit
VI	vapor intrusion
VOC	volatile organic compounds
WQC	Water Quality Criteria

1.0 Introduction

This guidance has been developed by the U.S. Environmental Protection Agency (EPA) Region 4 Superfund Division's Scientific Support Section (SSS), previously known as the Technical Services Section or TSS, risk assessment staff to update and replace all previous Region 4 Human Health Risk Assessment (HHRA) bulletins and to supplement the Agency guidance documents on site-specific HHRA: the Risk Assessment Guidance for Superfund (RAGS), Volumes I, II and III (EPA, 1989a, 1989b, 2001a). RAGS was developed as broad guidance, and the purpose of this Region 4 guidance document is to clarify and extend RAGS as interpreted and applied in Region 4 for Superfund and Resource Conservation and Recovery Act (RCRA) sites.

This supplemental guidance provides direction and does not constitute rulemaking by the Agency. The intent of this guidance is to aid in the development of high-quality risk assessments consistent with the expectations of the SSS in its oversight role.

2.0 Data Collection and Evaluation

One objective of the data collection and evaluation efforts at Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and Resource Conservation & Recovery Act (RCRA) sites is to produce data of sufficient and known quality for use in a HHRA. Each site is unique; therefore, data collection strategies for one site may not be appropriate for another site.

2.1 Data Collection

To ensure that Baseline Risk Assessment (BRA) data needs are met, those needs must be evaluated early in the site planning stage. The data necessary for conducting a defensible BRA, in many cases, is a subset of the data required for adequate characterization of a hazardous waste site. The following documents provide useful tools for developing the Sampling and Analysis Plan (SAP):

- Risk Assessment Guidance for Superfund (RAGS), Human Health Evaluation Manual: Part A (EPA, 1989a; Chapters 4 & 5).
- Guidance for Data Usability in Risk Assessment (EPA, 1992).
- Data Quality Objectives Process for Hazardous Waste Site Investigations (EPA, 2000a).
- Risk Assessment Guidance for Superfund (RAGS), Human Health Evaluation Manual: Part D, Section 2.2 (EPA, 2001b).
- Guidance for Choosing a Sampling Design for Environmental Data Collection (EPA, 2002a)
- Supplemental Soil Screening Guidance (EPA, 2002b)
- Metals Risk Assessment Guidance (EPA, 2007a)
- Field Branches Quality System and Technical Procedures (periodically updated)
- Incremental Sampling Methodology (Interstate Technology & Regulatory Council [ITRC], 2012)

2.2 Developing a Soil Sampling Strategy

The EPA Region 4 utilizes the Science and Ecosystem Support Division (SESD) Standard Operating Procedures (SOPs); Field Branches Quality System and Technical Procedures (and most recent procedural updates) to guide soil sampling strategies during a field investigation. The Region also supports the use of the Incremental Sampling Methodology (ISM) developed by the ITRC as a tool to investigate contaminated soils (Incremental

Sampling Methodology [IRTC 2012]). The table below represents the different types of soil sampling that may be appropriate for specific sites depending on your data quality objectives (DQOs).

Typical soil sample methods used at lead-contaminated sites	
Discrete Samples	Discrete samples can be collected from biased or random sample locations. The samples are collected from a single location, and they are typically mixed in the field and placed into sample containers specified by the analytical method. The sample volume and additional sample processing can vary.
Composite Samples	A typical composite sample is assembled from a small number (e.g., five) of discrete samples that are combined in the field. The component discrete samples are typically collected in a quincunx pattern from samples that may or may not be of equivalent size/mass. The samples are typically mixed in the field and placed into sample containers specified by the analytical method. The sample volume and additional sample processing can vary.
Incremental Samples	Incremental samples (incremental composite, multi-increment) are structured samples that provide an unbiased, reproducible estimate of the mean of a given volume of soil (e.g., decision unit). An incremental sample is assembled from a large number (i.e., 30-100) of samples of equivalent size/mass (increments) collected from random/systematic random locations across the decision unit. The process typically yields large samples (> 1 kilogram [kg]). Additional sample processing (in the field or laboratory) and subsampling is usually required. Specialized sampling and subsampling tools are needed to properly sample and subsample soils.

OLEM Directive 9200.1-128, Recommendations for Sieving Soil and Dust Samples at Lead Sites for Assessment of Incidental Ingestion (EPA 2016), recommends sieving soils to <150 µm (#100 sieve). While this guidance is specifically for lead investigations, it's recommendations could be useful for investigations of sites with other metals contamination in soils. Sieving is not required for every sample, but at least a sub-set of samples should be sieved to determine if results differ after sieving is done.

Region 4 has also developed a Field Operations Guide (FOG) for using an XRF to collect high quality data for the investigation of lead and arsenic-contaminated sites. The Region supports the use of XRF for decision making at Superfund sites (including use in risk assessments), provided that the quality of the data can be adequately demonstrated. Use of

the Region 4 FOG or similar data quality demonstration procedures is recommended.

For radionuclides, the Multi-Agency Radiation Survey & Site Investigation Manual (MARSSIM, 2000) is the guidance used for surface soil sampling for characterization, remedial support surveys, and final status surveys.

2.2.1 Evaluation of Soil Pathways

As discussed in the Supplemental Soil Screening Guidance for Developing Soil Screening Levels for Superfund Sites (EPA, 2002b), exposure to contaminants in surface soils and subsurface soils is likely to occur via different mechanisms. Therefore, sampling plans for these two categories of soil should be designed to collect reliable, usable data appropriate for modeling exposure based on the Conceptual Site Model (CSM) and Data Quality Objectives (DQOs).

The depth to which samples need to be collected for adequate characterization of "surface soil" depends on the CSM and the contaminants of interest. The Supplemental Soil Screening Guidance (EPA, 2002b) states that surface soils "are located within two centimeters of the ground surface." Exhibit 1-1 of this document defines surface and *shallow sub-surface soils* as a pathway of concern for on-site residents and outdoor workers. For this reason, the Region generally considers soil from 0-12 inches as available for direct human contact for these exposure scenarios and refers to soil in this depth interval generically as "surface soil." If site-specific activities, such as gardening, suggest a potential for exposure to soil at depths greater than 0-12 inches for residential and outdoor worker scenarios, the definition of surface soil can be expanded to accommodate these considerations. However, the Region typically does not consider soil deeper than 2 feet below land surface to be "surface soil" for most residential or worker exposure scenarios. Residential and outdoor worker scenarios typically do not include direct exposure to subsurface soils.

Subsurface soil exposures at depths greater than those discussed above are defined as potential pathways of concern for construction workers in Exhibit 1-1 (EPA, 2002b). The Region typically considers soil from the bottom of the defined depth of surface soil up to 10 feet below land surface as "subsurface soil." Exposure to subsurface soil is evaluated via the construction and/or utility (excavation) worker scenario, which usually has a shorter exposure duration and/or exposure frequency but more contact intensive exposure to soils

than other exposure scenarios. A utility worker (usually lower exposure frequency than onsite worker) can also be evaluated for direct contact exposure to subsurface soil.

2.3 Detection Limits

Detection limits/quantitation limits should be reviewed before the SAP is completed to determine if any exceed levels of concern for human health. For chemicals, Region 4 SSS recommends using the most current version of EPA's Regional Screening Levels (RSLs) for Chemical Contaminants at Superfund Sites (EPA, 2017a [or the most recent update]) to evaluate whether analytical methods proposed in the SAP will be adequate for risk assessment purposes. If quantitation limits for any chemical(s) exceeds its screening value, SSS should be consulted before moving ahead with sampling/analysis. For radionuclides, use the Radionuclide Toxicity and Preliminary Remediation Goals (PRGs) for Superfund or the Soil Screening Guidance for Radionuclides (EPA, 2000b) and its associated calculation tool.

2.4 Turbidity in Groundwater

Low-flow/low stress sampling protocols, developed by EPA and others, should be used to minimize turbidity and to collect representative unfiltered groundwater samples for analysis. Samples with greater than 10 nephelometric turbidity units (NTUs) are not typically recommended for use in the BRA.

2.5 Data Evaluation

Chapter 5 of RAGS Part A (EPA, 1989a) includes a discussion on the data evaluation process and should be consulted during the development of the SAP as well as the BRA. The data evaluation process includes screening detected contaminants against risk-based screening levels to identify Chemicals of Potential Concern (COPCs), which are then carried through the risk assessment process.

2.6 COPC Selection Process

SSS recommends the following basic process to identify COPCs: All concentrations of each chemical detected in a site sample/media should be compared to the appropriate screening level. For chemicals, SSS recommends using the most current version of EPA's Regional Screening Levels (RSLs) for Chemical Contaminants at Superfund Sites (EPA, 2017a [or most recent update]) for selecting COPCs. For radionuclides, use the Radionuclide Toxicity and Preliminary Remediation Goals (PRGs) for Superfund (EPA, 2018 [or most recent update]).

For screening purposes, it is Region 4 policy to use screening values based on the lower of the $1x10E^{-6}$ or a Hazard Quotient (HQ) of 0.1.

- The data for each chemical should be sorted by medium. For this purpose, surface soil and subsurface soil should be considered as separate media.
- For any data which have qualifiers, decide if the qualified data should be retained. Do not eliminate data based on "J" qualifiers.
- Present a table with all detected chemicals similar in content to the format of the RAGS Part D (EPA, 2001b) example tables 2.

2.6.1 Basis for Retaining or Eliminating a Chemical as a COPC

- **The chemical is naturally occurring and detected in background samples.** For naturally occurring inorganics and radionuclides, Region 4 has traditionally recommended comparing the on-site maximum detected concentration to 2 times the average site-specific background concentration. The chemical can be eliminated as a COPC if it is less than 2 times the average background level. The number of appropriate background samples should be determined on a site-specific basis. This process is a policy-based screening that recognizes that statistically-based background data sets may not be available.

  The Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites recommends statistical methods for characterizing background concentrations of chemicals in soil (EPA, 2002c). This guidance can be applied on a site-specific basis where background samples have been collected using a statistically valid approach.

- **The chemical is also detected in blank samples.** Current Region 4 policy is that COPCs may be eliminated based on comparison to blanks as described in RAGS Part A (EPA, 1989a). Please note that there may be special circumstances that RAGS Part A does not address, such as comparing a blank of one matrix to samples of another (e.g., a water equipment blank which relates to a group of soil samples). EPA should be consulted regarding such special circumstances.

- **The maximum detected concentration of the chemical is below the screening level.**

Surface Soil. Compare maximum detected concentrations in surface soils to the residential screening values for soil contact determined at a risk level of $1x10^{-6}$ or HQ level of 0.1. Eliminate the chemical as a COPC for human exposures if the concentration is less than the screening level.

Subsurface Soil. Compare maximum detected concentrations in subsurface soils to industrial screening values for soil determined at a risk level of $1x10^{-6}$ or HQ level of 0.1, assuming the CSM reflects current/future potential exposure to utility/construction worker only. Eliminate the chemical as a COPC for direct contact human exposures if the concentration is less than the screening level. For protection of groundwater, subsurface soil concentrations should be evaluated against leachability-based screening levels. This evaluation should be provided in the fate and transport portion of the Remedial Investigation (RI)/Feasibility Study (FS).

Groundwater. Compare maximum detected concentrations in groundwater to the tap water values determined at a risk level of $1x10^{-6}$ or HQ level of 0.1. Eliminate the chemical as a COPC for human exposures if the concentration is less than the screening level. Drinking Water Maximum Contaminant Levels (MCLs) are not an appropriate basis for eliminating COPCs from the risk assessment, but a chemical should be kept as a COPC if its MCL is exceeded.

Surface Water. Compare maximum detected concentrations in surface water to the Water Quality Criteria (WQC) for human health (consumption of water & organisms; EPA, 2015 [or most recent update]). Eliminate the chemical as a COPC for human exposures if the concentration is less than the screening level. If a WQC is not available for a chemical, use the RSLs for tap water or an appropriate health-based state value as the screening level value.

Sediment. Compare maximum detected concentrations in sediments to the residential screening values for soil ingestion determined at a risk level of $1x10^{-6}$ or HQ level of 0.1. Eliminate the chemical as a COPC for human exposures if the concentration is less than the screening level. Section 4 of this document should be consulted regarding the appropriateness of sediment exposure assessment relative to selection of COPCs for sediments.

Air. Compare maximum detected concentrations in air to the residential air screening level determined at a risk level of $1x10^{-6}$ or HQ of 0.1. The industrial air screening values should be used for comparison to the air levels for worker scenarios.

Soil Gas. For more detailed information on EPA's vapor intrusion (VI) analysis, see Section 4.8 of this document.

Radionuclides. Radionuclides should be screened against the appropriate media-specific values contained in the PRGs for Radionuclides.

- **The chemical is an essential nutrient.** Screening for non-site related essential nutrients in all media should be based on professional judgment. The only chemicals which may be eliminated based on essential nutrients are calcium, chloride, iodine, magnesium, phosphorus, potassium, and sodium. However, these chemicals may pose a risk if present at high concentrations. If this is the case, consultation with SSS staff is advised before elimination of these chemicals.

- **Review the list of eliminated chemicals.** Evaluate if any previously eliminated chemical or medium should be included due to other considerations (e.g., potential break-down products, chemicals previously eliminated based on blank comparisons, chemicals with detection limits above health-based levels).

For each medium, determine whether there are any COPCs remaining. If no COPCs remain, drop the medium from further consideration in the risk assessment. The chemicals selected by this process are retained for further risk evaluation in the BRA. A table should be provided for summarizing these COPCs.

Frequency of detection should not be used as a criterion for eliminating chemicals from the BRA without EPA Region 4 approval.

For radionuclides, potassium-40 (K_{40}) is often a naturally occurring radionuclide, and is not often site-related. K_{40} can always be dropped from COPCs. Other naturally occurring radionuclides may be dropped on a site-by-site basis.

3.0 Toxicity Assessment/Chemical-Specific Issues

The toxicity assessment presents and discusses chemical-specific quantitative dose-response data for the COPCs. Toxicity values for use in a HHRA should be selected based upon the hierarchy provided in Office of Solid Waste and Emergency Response (OSWER) Directive 9285.7-53 (EPA, 2003a). Additional assistance with selecting Tier 3 toxicity values is provided in the Tier 3 Toxicity Value White Paper (EPA, 2013a).

There may be cases where a toxicity value is not available in any of the sources discussed above. When a chemical does not have a toxicity value, the value of a chemical that is related both chemically and toxicologically (i.e., structure-activity relationship), may sometimes be appropriate to use as a surrogate. Any surrogates should be approved by EPA prior to BRA submission.

There are chemicals for which chronic toxicity values or surrogate values are not available. Such a chemical may come to be considered a potential risk driver at a site based on its relatively high acute toxicity. Although a quantitative risk estimate cannot be made for chemicals without toxicity values, the chemical should not be excluded as COPCs on this basis. Instead, the implications of the presence of chemicals without toxicity values should be discussed in the Uncertainty Section of the BRA.

3.1 Presentation of Toxicity Values

Toxicity values used in the risk assessment are best presented in a table. Example tables can be found in RAGS Part D Tables 5 and 6 (EPA, 2001b). Screening Levels Tables [e.g., RSLs, PRGs, etc.] should not be cited as a source of toxicity values. The original source of each toxicity value should be cited.

A short description of all known toxic effects of each COPC in non-technical language should be included in the toxicity assessment. For non-carcinogens, this description should identify the critical effect and the dose or concentration at which adverse effects in humans are not expected. For carcinogens, the description should discuss the range of tumor types observed. For both cancer and non-cancer endpoints, the discussion should include whether the toxicity value was derived from human or animal data.

3.1.1 Inhalation Toxicity Values

Oral/Inhalation Route-to-Route Extrapolation

Previous versions of regional screening tables did contain some route-to-route extrapolation, because of the scarcity of inhalation toxicity factors. With the now standard approach for derivation of reference concentrations (RfCs), routine route-to-route extrapolation has been discontinued.

Reference Concentrations (RfCs) and Inhalation Unit Risks (IURs)

In the past, some regional tables converted RfCs to reference doses (RfDs) and IURs to slope factors for inhalation (SFIs). This was initially done because risk equations once relied upon RfDs and SFIs in units of milligrams per kilograms per day (mg/kg/day) and 1/mg/kg/day, respectively. However, as the inhalation guidance has evolved, RfCs and IURs, in units of milligrams per cubic meter (mg/m^3) and cubic meter per microgram ($m^3/\mu g$) respectively have become the recommended toxicity factors. RAGS Part F-*Supplemental Guidance for Inhalation Risk Assessment* (EPA, 2009) has further discussion on this issue.

3.1.2 Dermal Toxicity Values

The Office of Land and Emergency Management's (OLEM) approach to quantifying the risk posed by exposure to contaminants via the dermal route is presented in RAGS Part E, Supplemental Guidance for Dermal Risk Assessment (EPA, 2004).

3.2 Toxicity of Special Chemicals

3.2.1 Dioxins and Furans

Dioxin is the "shorthand" name for 2,3,7,8-tetrachlorodibenzodioxin (TCDD). This is the most potent of a series of related polychlorinated dibenzodioxin (PCDDs) and polychlorinated dibenzofurans (PCDFs). This compound and its related congeners are often of special concern to EPA because dioxin has been shown in human epidemiological studies to be toxic at relatively low doses, and may also be a potent carcinogen (the EPA currently has no cancer slope factor for dioxin on the Integrated Risk Information System [IRIS]; California EPA [CalEPA] has cancer potency values [tier 3] for ingested and inhaled dioxin/furan). In general, the quantitative toxicity of the different PCDD and PCDF congeners depends on the number and arrangement of the chlorine atoms on the dibenzodioxin or dibenzofuran ring structures. For more information, see Use of Dioxin Toxicity Equivalence Factors (TEFs) in calculating Dioxin TEQs at CERCLA and RCRA Sites (EPA, 2013b).

EPA has developed several tools to help risk assessors and risk managers evaluate whether it is necessary to perform a detailed investigation of dioxins in site media. For more information, visit the EPA dioxin toolbox and the Fact Sheet on the Management of Dioxin Contaminated Soils (EPA, 2011a).

3.2.2 Approach to Sampling, Analysis, and Evaluation of Polychlorinated Biphenyls (PCBs)

An Issue Paper was developed by Region 4's SSS to provide Project Managers, On-Scene Coordinators (OSCs) and technical staff with a recommended approach for evaluating and characterizing PCBs in groundwater, soil and sediment to inform remedy selection. To learn more, please visit our website: EPA Region 4 Technical Services Section Issue Paper for PCBs Characterization at Region 4 Superfund and RCRA Sites.

3.2.3 Approach to Sampling, Analysis, and Evaluation of Toxaphene

The pesticide toxaphene is similar to PCBs in that it is a commercial mixture of many chemically similar compounds. If toxaphene is a potential chemical of interest at your site, contact a Region 4 risk assessor to discuss the latest methods for sampling, analysis, and evaluation.

3.2.4 Asbestos

The Framework for Investigating Asbestos-Contaminated Superfund Sites (EPA, 2008) provides details for collecting data and conducting a risk assessment at sites contaminated with asbestos. These methods may be different from the sampling and analytical methods used by other EPA programs. Consultation with Regional staff familiar with the Framework is recommended prior to conducting investigations at asbestos contaminated sites. When conducing a Five-Year Review of a site that may contain asbestos contamination, the recommendations provided in the memorandum Assessing Protectiveness for Asbestos Sites: Supplemental Guidance to Comprehensive Five-Year Review Guidance (EPA, 2009d) should be consulted and followed.

3.3 Bioavailability Factors

The actual bioavailability of environmental chemicals is usually not determined in the risk assessment process. Health-based toxicity values are typically developed using intake levels (i.e. administered doses in controlled animal studies). The portion that is actually absorbed by the receptor, therefore bioavailable, is not necessarily determined in these studies. Hence, the actual bioavailability is irrelevant as long as risk conclusions are based on comparisons between calculated human intakes and toxicity values developed from

administered doses (i.e., equivalent and appropriate dose-response comparisons).

A default assumption of 100 percent (%) bioavailability (relative to that of the toxicity study), with the exception of arsenic and lead, is to be used unless a consultation with Region 4 SSS determines otherwise.

EPA has developed some medium-specific default values for the bioavailability of metals which are included in the Guidance for Evaluating the Bioavailability of Metals in Soils for Use in HHRAs (EPA, 2007c). In addition, EPA has an OSWER directive (9200.1-113) which provides Recommendations for Default Value for Relative Bioavailability of Arsenic in Soil (EPA, 2012a). Where applicable, collecting site-specific bioavailability data for lead and arsenic is recommended.

3.4 Assessment of Lead

In the case of lead, human exposure and risk are characterized using a different approach than other chemicals. This is because lead exposure is evaluated using a biokinetic model and risk is interpreted in terms of predicted blood lead concentration rather than a HQ. EPA's Technical Review Workgroup (TRW) for lead has developed extensive guidance on how to evaluate risks from lead, and all of this information is available at the TRW website.

The health-based screening level for lead in residential soil, please refer to the Regional Screening Level tables and the health-based action level for lead in drinking water is 15 micrograms per liter (µg/L). If either of these levels is exceeded, the Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children (EPA, 2009b) or most recent version, and the Adult Lead Methodology (ALM; EPA, 2017b) can be used as appropriate to assess the site-specific risks and to help set remedial levels. Additional EPA guidance is available at the following website: https://www.epa.gov/superfund/lead-superfund-sites-guidance and
https://semspub.epa.gov/work/08/1884204.pdf

3.4.1 Use of IEUBK Model to Assess Risks to Children

In residential locations and other areas where young children are exposed to lead, EPA recommends the use of the IEUBK Model for Lead in Children to evaluate exposures from lead-contaminated media and to derive predicted blood lead levels.

3.4.2 Use of the Adult Lead Methodology

When young children are not expected to be present at a site (e.g., a workplace), the population of concern is the adult (e.g., a worker). While both males and females are susceptible to adverse effects from excess lead exposure, the female of child-bearing age is the sub-population of chief concern, since exposure of the pregnant female can result in exposure of the fetus *in utero*. The EPA has developed the ALM for evaluating the potential risks from lead in pregnant females.

3.5 Approach for Potential Mutagenic Effects

For COPCs that act via a mutagenic mode of action (MMOA), cancer risks should be estimated using age-dependent adjustment factors (ADAFs), that are consistent with cancer guidelines and supplemental guidance (EPA, 2005a; 2005b). The default ADAFs used to adjust the CSFs are 10 for 0-2 year olds, 3 for 2 to <16 year olds, and 1 (i.e., no adjustment) for receptors 16 years of age or older.

4.0 Exposure Assessment

The objective of the exposure assessment is to estimate the type and magnitude of exposures to chemicals of potential concern present at or migrating from a site. The exposure assessment should include the following sections.

- Characterization of Exposure Setting
- Identification of Exposure Pathways
- Quantification of Exposure

Unless site-specific exposure inputs are appropriate, the latest national Superfund default exposure assumptions should be used. The current recommended values can be found as Standard Default Exposure Factors.

4.1 Characterization of Exposure Setting

The general physical characteristics of the site and of the populations on and near the site should be presented in this section. Populations should be addressed relative to those characteristics that influence exposure, such as location and activity patterns. In addition, the presence of sensitive subpopulations should be discussed, e.g., children, women of child-bearing age, etc. Current receptors as well as potential future receptors should be considered.

4.2 Identification of Exposure Pathways

This section should identify the pathways by which the identified populations may be exposed. A CSM should be developed for each site. The CSM should include known and suspected sources of contamination, types of contaminants and affected media, known and potential routes of migration, and known or potential human and environmental receptors. In addition to the narrative discussion of pathways, a figure following the format of the example presented in Chapter 2 (Figure 2-2) of the *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (EPA, 1988) should be presented. Institutional controls ([ICs] e.g., fences or guards) should not be used as the justification for elimination of a pathway in the BRA for current or future scenarios. However, ICs may be used in the determination of exposure frequency for current exposure. The following scenarios should be used as appropriate.

4.2.1 Residential Scenario

A residential scenario (current or future) should be included in the BRA. There are cases where future residential land use is unlikely (e.g., an industrial area expected to remain industrial or a wetland). In those cases, the risk calculated for a residential scenario is used to establish the need for land use controls at the site to prevent future residential development. Thus, if a future residential scenario is not included in the risk assessment, a justification should be presented and prior approval from the Remedial Project Manager (RPM) should be obtained.

If the groundwater is considered to be potentially potable according to state regulations, the future consumption of groundwater for residential purposes must be evaluated regardless of its current use. Inhalation of chemicals volatilized from groundwater (vapor intrusion) into homes and ambient air should also be considered.

4.2.2 Trespasser Scenario

The evaluation of current exposure scenarios at most sites should include the trespasser or visitor scenario. Region 4 considers the typical trespasser to be an adolescent aged 7-16 (10-year exposure duration) with a body weight of 45 kg as representative of this age range. Trespasser exposure frequency should consider site-specific factors such as distance from the site to residences and the attractiveness of the site to the trespasser.

4.2.3 Excavation or Construction Worker Scenario

It may be useful to include an excavation/construction worker as a future scenario in the BRA. Typically, the construction worker represents an excavation worker or other worker who may have intensive contact with subsurface soil up to 10 feet (ft) below ground surface (bgs) through digging for a relatively short duration. Alternatively, a utility worker may be exposed to subsurface soil for a lower exposure frequency, but for a higher exposure duration (e.g. 25 years). Site-specific considerations, such as a shallow water table or known construction plans, should be considered in establishing the applicable soil profile for potential exposure. For scenarios with sub-chronic durations, sub-chronic toxicity values should be used, if available.

4.2.4 Commercial/Industrial Scenario

The commercial or industrial worker is typically evaluated as a current scenario or in anticipation that at some point in the future the site will be redeveloped. The parameters

used for the commercial/industrial worker can be considered site-specific factors, if available, pending EPA concurrence.

4.3 Quantification of Exposure

Chemical-specific exposure for most complete exposure pathways should be presented in terms of the mass of substance in contact with the body per unit/body weight per unit time - most often as mg chemical per kg body weight per day or mg/kg/day. These exposure estimates are termed "intakes." Standard intake equations are presented in Chapter 6 of RAGS Part A (EPA, 1989a).

The "exposure unit" concept should be considered in the development of the exposure assessment. An exposure unit denotes a real extent of a receptor's movements during the time period of interest - analogous to the idea of a home range used in an ecological risk assessment (ERA). For example, a young child under the age of 6 will probably range over the area of a typical residential lot (less than an acre) where a maintenance worker at a large industrial facility may move about the entire facility. This concept is important in determining which samples should be included in the calculation of the exposure point concentration (EPC).

EPA has established default assumptions for many parameters in an effort to establish consistency (See OSWER Directive 9200.1-20. Also, Table 1 of the RSL website's User's Guide (EPA, 2016) can be consulted for default versus site-specific values. Site-specific values are allowed to be used to evaluate current exposures or other site-specific considerations, but prior approval of the RPM and/or Region 4 risk assessor is recommended.

4.4 Concentration Term

The concentration term in the intake equation is an estimate of the arithmetic average concentration for a chemical contacted by a receptor within an exposure unit over a time scale appropriate for the toxic effect of the chemical. Ideally the EPC should be the true average concentration within the exposure unit. However, because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent upper confidence limit (UCL) of the arithmetic mean should be used as the concentration term. The EPA has developed software (ProUCL) that computes the UCL for a given data set by a variety of statistical approaches (including several approaches that do not require the assumption of normality or lognormality) and then recommends specific UCL values as

being the most appropriate for that particular data set. The software and User's Guide for ProUCL may be obtained at the following.

> Note: There is a substitution method for replacing non-detect concentrations with a value of half the detection limit for non-detected concentrations samples in accordance with EPA guidance (EPA, 1992). For a variety of reasons, however, detection limits may be elevated for a given sample and/or may vary between samples. For these and other considerations, alternative methods of accounting for non-detects (such as Maximum Likelihood Estimation, Kaplan-Meier, and other statistical methods) in data sets should be considered.

4.4.1 Concentration Term in Groundwater

Region 4 recommends that the groundwater exposure point concentration should be calculated in accordance with *Determining Groundwater Exposure Point Concentrations*, OSWER Directive 9283.1-42.

Chemical degradation or attenuation should not be considered in the BRA unless site and chemical-specific data are available and prior approval from the RPM and SSS is obtained.

4.5 Ingestion

Default soil and water ingestion rates (IRs) can be found in the OLEM Directive, Update of Standard Default Exposure Factors (2014).

Sediments in an intermittent stream should be considered as surface soil for the portion of the year the stream is without water. In most cases it is unnecessary to evaluate human exposures to sediments that are always covered by surface water. Worker exposure to potable water can be assessed based on a current or potential future scenario. However, for the purposes of establishing risk-based remedial goals, drinking water should also be assessed using residential use assumptions.

Fish ingestion is highly variable and site-specific intake assumptions are most desirable. When site-specific data are not available, EPA's Exposure Factor's Handbook: 2011 Version (EPA, 2011b) provides default fish IRs for: the general population, recreational marine and freshwater anglers and Native American subsistence fish populations. The Office of Water has a default IRs for recreationally caught fish that is used to derive the human health based water quality criteria (EPA 2015). This value can be used in Superfund human health risk assessments. For specific guidance on inputs, a site-specific consultation

with regional risk assessors is recommended.

4.6 Dermal Contact

The areas of the body receiving exposure to the specific media should be considered and summed to obtain the skin surface area. The RAGS Part E, Supplemental Guidance for Dermal Risk Assessment provides methods to determine the surface area of each portion of the body which is exposed (EPA, 2004). Surface area inputs to the model should be based on data in the Exposure Factors Handbook (EFH) 2011. Default assumptions can be found in Update of Standard Default Exposure Factors.

The dermal pathway is not used for evaluation of radionuclides.

4.7 Inhalation

Inhalation rates are no longer needed for risk assessment calculations. (See RAGS Part F for more information.)

4.8 Vapor Intrusion (VI)

VI is the general term given to migration of hazardous vapors from any subsurface contaminant source, such as contaminated soil or groundwater, through the vadose zone and into indoor air. The route volatile organic compounds (VOCs) take from a subsurface source to the air inside a building is referred to as the VI pathway. When VOCs present in soil gas migrate to the interior of a building and reach concentrations that could pose a potentially unacceptable health risk, the pathway is considered "complete." For sites where soil or groundwater concentrations result in the potential for migration of vapors to indoor air, additional tools and methodologies may be considered on a site-specific basis and implemented as appropriate. If trichloroethylene is a known or suspected COPC, it may be necessary to take prompt actions if women of child-bearing age are or could be present at the site. The Region 4 SSS should be contacted regarding approval of all site specific approaches and specific sampling strategies.

4.8.1 Risk Assessment for Vapor Intrusion (VI)

OSWER's Technical Guide for Assessing and Mitigating the VI Pathway from Subsurface Vapor Sources to Indoor Air (2015) provides technical and policy recommendations on determining if the VI pathway poses an unacceptable risk to human health at cleanup sites. We recommend collecting indoor air, ambient air, and sub-slab/crawlspace samples. This data should be screened against the appropriate Regional Screening Level/Vapor Intrusion

Screening Level (VISL). If RSLs/VISLs are exceeded, site-specific determinations are needed. Consult with your project manager and/or SSS.
At sites where environmental concentrations fall below screening levels, no further action or study may be warranted if supported by multiple lines of evidence, including: (EPA 2015)

- site-specific data verify that the subject property reflects the conditions and assumptions of the generic model underlying the VISLs
- hydrogeologic information (in addition to sampling data) support assessments of the vapor intrusion pathway
- Multiple rounds of groundwater (or soil gas) sampling results support conclusions that a specific vapor source is stable or shrinking and/or is not expected to pose a vapor intrusion concern under reasonably expected future, as well as current, conditions.

But in most cases, at least two rounds of VI data is needed. EPA generally recommends that a human health risk assessment should be conducted to determine whether the potential human health risk posed to building occupants by a complete or potentially complete vapor intrusion pathway are within or exceed acceptable levels, consistent with applicable statutes and considering EPA guidance. The primary purpose of this risk assessment is to provide risk managers with an understanding of the actual and potential risks to human health posed by vapor intrusion under current and reasonably expected future conditions. Depending on building-and site-specific circumstances, an early action may be needed. See Sections 3.3 and 7.8 of OSWER Publication 9200.2-154 for additional information on when it may be appropriate to implement mitigation of the vapor intrusion pathway as an early action even though all pertinent lines of evidence have not yet been completely developed.

4.8.2 Technical Support Documents for Vapor Intrusion (VI)

EPA's technical information pertaining to VI approaches and policy recommendations include:

- VI Screening Level Calculator
- Frequently Asked Questions about VI (EPA, 2015)
- Background Indoor Air Concentrations of Volatile Organic Compounds in North American Residences (1990-2005) (EPA, 2011c)
- EPA's VI Database: Evaluation and Characterization of Attenuation Factors for Chlorinated Volatile Organic Compounds and Residential Buildings (EPA, 2012b)

- Conceptual Model Scenarios for the VI Pathway (EPA, 2012c)

4.9 Exposure to Volatile Organic Chemicals (VOCs) During Showering

Region 4 accepts the default assumption that inhalation and dermal exposure from showering is equivalent to exposure from the daily ingestion of contaminated water per day (EPA, 1991a; Jo *et al.* 1990). In addition, shower/bath models can be used with EPA Region 4 approval. For example, Region 4 has approved the use of the Foster & Chrostowski model (2003) for this pathway. Other approaches for assessing the shower/bath pathway should be approved by regional risk assessors during document scoping.

4.10 Exposure Frequency

Default exposure frequency factors are highlighted for key exposure scenarios in Update of Standard Default Exposure Factors. Current exposure assumptions should represent a conservative estimate of actual occurrences as accurately as possible. As a default, Region 4 believes swimming frequency in the southeast should be at least 45 days/year. However, for backyard swimming pools, in the southern portion of the region, a substantial increase in exposure frequency over the 45 days/year should be considered based on site specific information. Region 4 recommends that a backyard swimming pool or coastal areas use an exposure frequency of 90 days/year.

4.11 Exposure Duration

Exposure duration default assumptions are included in Update of Standard Default Exposure Factors for typical exposure scenarios. Please refer to RAGS, Part A (2010), Chapters 7 and 8 where it states *"chronic RfDs… pertain to lifetime or other long-term exposures and may be overly protective if used to evaluate the potential for adverse health resulting from substantially less-than-lifetime exposure."* Section 8.2.1 defines chronic exposure and sub-chronic exposure.

4.12 Use of the Fraction Ingested (FI) Term

Region 4 SSS should be consulted regarding the use of a fraction ingested (FI) term less than 100 percent. A FI of 100% should be used except in assessments of highly contaminated areas significantly smaller than the exposure unit and in the evaluation of exposures to intermittent streams.

5.0 Risk Characterization

Risk Characterization is the final step of the risk assessment process. It should be developed with thought to communicating risk information to risk managers who may have minimal training in risk assessment and the biological sciences. Chapter 8 of RAGS, Part A, should be followed in developing the human health risk conclusions (EPA, 1989a).

The risk characterization section brings the toxicity/potency data and the exposure data together in an expression of quantitative risk estimates for all receptors considered in the BRA. Appropriate tabulation of this information is extremely important for clear communication to the reader.

Cancer risk values and hazard index (HI) values may express more than one significant figure, but for decision-making purposes one significant figure should be used.

As important as these numbers are in the remedial decision, this section of the risk assessment is incomplete without adequate discussion of uncertainty and the qualitative aspects of the assessment. The text should flow as a logical discussion of science and policy assumptions that led to the risk conclusions for all COPCs and/or COCs whether or not quantitative values could be derived.

6.0 Chemicals of Concern and Remedial Goals

Throughout the process of remediating a hazardous waste site, a risk manager uses a progression of increasingly site-specific acceptable media levels, so called "cleanup levels," for the consideration of remedial alternatives. Region 4 SSS suggests that a range of Site-Specific Remediation Goals (SSRGs) be presented for the risk manager's use as the last component of the risk assessment. From the SSRGs, the risk manager chooses remediation levels for the Chemicals of Concern (COCs), and these numbers are addressed in the FS and are included in the Proposed Plan and the Record of Decision (ROD).

This bulletin details the development of SSRGs and acceptable media levels that will ultimately become remediation levels (RLs), aka cleanup goals, for the COCs.

6.1 Preliminary Remediation Goals (PRGs)

PRGs are either risk-based levels of hazardous chemicals in various environmental media, or applicable or relevant and appropriate requirement (ARARs). PRGs may be established early in the RI process, usually at scoping, and serve as the basis for the RI SAP. Region 4 recommends the use of the RSLs (based on carcinogenic risk of $1x10^{-6}$ or HQ of 1) for risk-based PRGs. Use of PRGs will determine if (1) proposed analytical methods will have adequate quantitation limits to achieve these risk-based levels; (2) the site will be adequately characterized; and (3) the remedial alternatives being considered can achieve risk-based levels.

PRGs based on ARARs (e.g., drinking water MCLs) should be clearly identified. RSLs should be used as risk-based PRGs, but they are not intended to be default remediation levels.

6.2 Chemicals of Concern

COCs are the COPCs that significantly contribute to an exposure pathway for a receptor (e.g. hypothetical future child resident, current youth trespasser, current adult construction worker, etc.) that either (a) exceeds a $1x10^{-4}$ cumulative site cancer risk; or (b) exceeds a non-carcinogenic HI of 1. Note: generally, a cumulative site risk level exceeding $1x10^{-4}$ and target organ HIs exceeding 1 are used as the remediation "triggers." The carcinogen "trigger" represents the summed risks to a receptor considering all exposure pathways and environmental media. The HI represents the total of the HQs of all COPCs in all pathways, media, and routes to which the receptor is exposed. If the total receptor HI exceeds 1, then

more precise HIs should be developed for each target organ and/or toxic effect. These target organ-based HIs should form the basis for the COC selection.

Chemicals are not considered as significant contributors to risk and therefore are not included as COCs if their individual carcinogenic risk contribution is less than $1x10^{-6}$ and their non-carcinogenic HQ is less than 0.1 (See Sections 2.5 and 2.6 for more on COPCs).

6.3 Site-Specific Remedial Goals

The BRA should include a section that outlines the SSRGs for the chemicals and media of concern. This section should include both identified ARARs (e.g. MCLs) and human health-based cleanup goals for all media considered.

The SSRGs section should contain a table of media-specific cleanup levels for each COC in each land use scenario evaluated in the BRA. The table should include potential cleanup levels for $1x10^{-6}$, $1x10^{-5}$ and $1x10^{-4}$ cancer risk levels for each carcinogenic COC. The table should also include potential cleanup levels for each non-carcinogenic COC at HQ levels of 0.1, 1 and 3.

Region 4 has adopted the HQ range of 0.1 to 3 to span the uncertainty, perhaps an order of magnitude or greater, inherent in the reference dose (RfD) (RAGS, p. 7-5). The range of cleanup levels is provided to address specific chemicals for which the use of an HQ greater or less than 1 may be justified.

These potential SSRGs should be presented for each COC in each medium and use scenario. The table should also contain any chemical-specific, health-based ARARs (state and Federal), appropriate groundwater protection levels, state guidance concentrations and any other cleanup numbers that may pertain.

This table permits the risk manager to view the potential cleanup goals in a relatively condensed way. The purpose is to provide the risk manager with a range of risk-related media levels as a basis for developing remediation aspects of the FS and Proposed Plan or the Corrective Measures Study.
RAGS, Part B (EPA, 1991b) PRG calculations and RSLs are not appropriate for the development of SSRGs because they do not consider site-specific exposure information.

6.4 Remediation Levels

Remediation levels (RLs) are chosen by the risk manager for COCs and are included in the Proposed Plan and the ROD. These values, derived from SSRGs or chemical specific ARARs, are considered the levels the remedial action needs to achieve in order to be protective of human health risks. If a chemical specific risk-based value other than $1x10^{-6}$ for carcinogens or HQ of 1 is recommended and/or selected as the RL, the FS, Proposed Plan, and ROD should provide a justification.

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