

Arizona Department of Health Services
Deterministic Risk Assessment Guidance



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PART B - DETERMINISTIC RISK ASSESSMENT GUIDANCE	24
1.0 INTRODUCTION	24
1.1 Organization.....	24
1.2 Overview and Objectives	24
1.2.1 Overview of the Site	24
1.2.2 Risk Assessment Objectives	25
1.3 Site Background.....	25
1.3.1 Site Description.....	25
1.3.2 Maps	25
1.3.3 History	25
1.4 Conceptual Site Model.....	25
1.5 Scope and Design of the Risk Assessment	26
1.5.1 Scope.....	26
1.5.2 Study Design.....	26
SITE ASSESSMENT.....	26
2.1 Detailed Rationale for Sampling Design	27
2.2 Sample Locations, Number, and Media.....	27
2.3 Definition of Modeling Parameters	27
2.4 Analytical Methods for Sampling and Analysis	27
2.5 Quality Assurance/Quality Control (QA/QC) Methods.....	27
2.6 Definition of Contaminant Boundaries.....	27
3.0 IDENTIFICATION OF CHEMICALS OF CONCERN	28
3.1 Evaluation of Chemical Data	28
3.2 Identification of Chemicals of Potential Concern.....	28
3.2.1 Soil.....	28
3.2.2 Soil Gas.....	28
3.2.3 Surface Water/Sediment	29
3.2.4 Air.....	29
3.2.5 Groundwater	29
3.3 Data Uncertainties.....	29
4.0 EXPOSURE ASSESSMENT	30
4.1 Characterization of Exposure Setting	30
4.1.1 Physical Setting	30
4.1.2 Characterization of Potentially Exposed Populations.....	30
4.1.2.1 Populations Relative to the Site	30
4.1.2.2 Current Land Use.....	31
4.1.2.3 Future Land Use	31
4.2 Exposure Pathways and Routes of Exposure.....	31
4.2.1 Source Identification.....	31
4.2.2 Fate and Transport Evaluation	32
4.2.3 Exposure Points and Routes	32
4.2.4 Synthesis into Complete Exposure Pathways.....	32
4.3 Quantification of Exposure Concentrations.....	33

4.3.1	Estimating Exposure Concentrations Under Current Conditions	34
4.3.2	Estimating Exposure Concentrations Under Future Conditions	35
4.3.3	Statistical Procedures	35
4.4	Estimation of Chemical Intakes for Each Exposure Pathway.....	26
4.4.1	Incidental Ingestion of Soils	36
4.4.2	Inhalation of Vapors and Particulates	38
4.4.3	Dermal Exposure Estimation Methods	41
4.5	Identification of Uncertainties	43
4.6	Summary of the Exposure Assessment.....	43
5.0	TOXICITY ASSESSMENT	44
5.1	Information for Noncarcinogenic Effects	44
5.2	Information for Carcinogenic Effects	44
5.3	Summary of Toxicity Information	45
5.4	Uncertainties Related to Toxicity Information	37
6.0	RISK CHARACTERIZATION	46
6.1	Current Land Use and Exposures38 6.1.1 Excess Lifetime Cancer Risk Under Current Conditions 38	
	6.1.2 Systemic (Noncarcinogenic) Effects Under Current Conditions	47
6.2	Potential Future Land Use and Exposures	48
	6.2.1 Excess Lifetime Cancer Risk Under Potential Future Conditions	48
	6.2.2 Systemic (Noncarcinogenic) Effects Under Potential Future Condition	48
6.3	Uncertainties	48
6.4	Summary Discussion and Tabulation of the Risk Characterization.....	49
	REFERENCES	51
	APPENDIX.....	55

PREFACE

This document provides guidance for parties using deterministic risk assessment to evaluate the potential health threat that may be posed by any property or site. This document essentially summarizes and streamlines risk assessment guidance developed by the United States Environmental Protection Agency (USEPA). The approach recommended here is modeled after guidance issued by the USEPA in 1989 in a document entitled *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A)* (USEPA, 1989) and elaborated upon in subsequent USEPA guidance documents.

The risk assessment procedures outlined in this document apply to all contamination situations except those arising from petroleum releases from underground storage tanks. Parties should consult the Arizona Department of Environmental Quality's (ADEQs) *Release Reporting and Corrective Action Guidance* (ADEQ, 2002) and the *Standard Guide for Risk-Based Corrective Action at Petroleum Release Sites, Designation E1739-95* developed by the American Society of Testing and Materials (ASTM, 1995a) for risk assessment guidance on petroleum releases.

Part A of this document provides guidance for developing site-specific risk-based screening and initial remediation levels for soil, tap water, and air. The approach outlined in Part A uses simplified default equations while allowing flexibility to consider site-specific conditions at the site. This approach requires the preparation of a summary document but does not require the development of a complete human health risk assessment.

Part B and the **Appendix** of this document provide a summary of the steps and equations used in preparing a complete human health risk assessment.

This document has not been sanctioned for use by the USEPA or ADEQ. However, the concepts, equations, assumptions and narrative are consistent with USEPA risk assessment guidance, and are generally accepted in the scientific community as a reasonable approach in evaluating environmental health risks.

The Arizona Department of Health Services (ADHS) recognizes that alternative risk assessment methods that use Monte Carlo and other analytical methods may be used to more accurately quantify and evaluate health risks. The deterministic approach used in this guidance document is not intended to imply that the deterministic approach is the only acceptable method for evaluating human health risks from environmental contamination. Rather, it is intended to provide guidance for those who wish to use a deterministic approach to evaluate health risks.

PART A

SITE-SPECIFIC SCREENING AND REMEDIATION LEVELS

1.0 INTRODUCTION

1.1 Overview

Site-specific screening levels may be used as tools to identify contaminants and exposure areas of concern. The screening levels can be directly compared to environmental data collected at a site. Chemicals at concentrations above the screening levels are identified as chemicals of potential concern (COPCs) and are generally evaluated further in a quantitative risk assessment such as described in Part B of this document. Site-specific screening levels may be used as initial remediation goals and to establish final cleanup levels for a site. Other relevant factors such as protectiveness, community acceptance, implementability, and uncertainty must also be considered.

Specific websites are referenced throughout Part A. Two USEPA websites that provide links to a number of the guidance documents referenced in Part A are *Tools for Human Health Risk Assessment* at <http://www.epa.gov/superfund/programs/risk/toolthh.htm> (USEPA, 2002a) and *Tools of the Trade* at <http://www.epa.gov/superfund/programs/risk/tooltrad.htm> (USEPA, 2002b).

1.2 Screening and Remediation Standards and Guidelines

Site-specific screening/initial remediation goals may be calculated according to the guidance in Part A of this document. Site-specific background concentrations, chemical-specific federal or state standards, and generic risk-based screening/remediation levels may also be used as screening or remediation levels and should be considered in establishing site-specific risk-based screening/initial remediation levels.

Background Concentrations

Site background chemical concentrations may be either naturally occurring or from anthropogenic sources (human-made, off-site sources). Guidance for determining background contaminant concentrations is given in *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A)* (USEPA, 1989) at <http://www.epa.gov/superfund/programs/risk/ragsa/index.htm>. *Guidance for Characterizing Background Chemicals in Soil at Superfund Sites* (USEPA, 2001a) at <http://www.epa.gov/superfund/programs/risk/background.pdf> presents a guide to sampling and statistical analysis of background concentrations of chemicals in soil. Background issues are also discussed in *Role of Background in the CERCLA Cleanup Program* (USEPA, 2002c) at http://www.epa.gov/superfund/programs/risk/bkgpol_jan01.pdf.

Federal and State Standards

The applicable federal and state contaminant standards for soil, groundwater, tap water, and air in Arizona are respectively: the residential and non-residential Arizona Soil Remediation Levels (SRLs); the Arizona Aquifer Water Quality Standards (AAWQS); the Arizona (or Federal) Maximum Contaminant Levels (MCLs); and the National Ambient Air Quality Standards (NAAQS)

Generic Risk-Based Levels

The most frequently used generic risk-based screening/initial remediation levels for soil, tap water, and air are the USEPA Region 9 Preliminary Remediation Goals (PRGs) (USEPA, 2002d) at <http://www.epa.gov/region09/waste/sfund/prg/index.htm> and the USEPA Region 3 Risk Based Concentrations (RBCs) (USEPA, 2002e) at <http://www.epa.gov/reg3hwmd/risk/>. The USEPA Region 9 PRGs

table also includes California EPA PRGs (“CAL-Modified PRGs”) for specific chemicals where CAL-EPA screening values may be significantly more restrictive than the federal values. A national RBC/PRG table currently under development may eventually make the USEPA Region 3 table obsolete. Arizona Health-based Guidance Levels (HBGLs) for hazardous air pollutants (HAPs) may also be used as generic risk-based screening/initial remediation levels for HAPs in ambient air (Unpublished, ADHS, 1999). Parties should note that the PRGs, RBCs, and HBGLs should not be viewed as substitutes for site-specific assessments.

1.3 Summary Report Requirement

Parties developing site-specific screening/initial remediation levels should prepare a summary document for submittal to the reviewing agency that presents the methodology used to develop the proposed site-specific screening/remediation levels. The document should include the following elements:

- A conceptual site model (CSM) that identifies the sources of contamination, the types and concentrations of chemicals detected in various media, COPCs, potential exposure pathways and exposure points;
- An exposure component that quantifies the magnitude of exposure from each complete pathway and provides documentation to support the decision to eliminate any exposure pathway;
- A toxicity component that discusses the reference doses, cancer slope factors, and weight-of-evidence (WoE) classifications for the COPCs;
- An uncertainty analysis; and
- A narrative summary, tables, and/or appendices displaying the equations, default and site-specific exposure factors, calculations, proposed final site-specific screening/initial remediation levels, and relevant factors. All equations and default or site-specific exposure factors from this or any other source should be referenced.

2.0 CONCEPTUAL SITE MODEL DEVELOPMENT

A CSM should be completed before developing site-specific screening/initial remediation levels. The CSM is a representation of the connections between contaminant sources, release mechanisms, exposure pathways and routes, and receptors. The complexity of the CSM should be consistent with the complexity of the specific site and available information.

A CSM is developed by conducting an extensive record search and site visit, and by compiling all of the existing data including site sampling data, historical records, aerial photographs, hydrogeologic information and population locations. Once this information is organized, the source(s) of contamination, types and concentrations of chemicals in various media, and the potential exposure pathways and exposure points are identified.

The development of a CSM is usually interactive. CSM development should begin as early in the site investigation process as possible to identify data gaps and determine data needs. The preliminary model should be revised following additional data collection efforts to refine the potential sources, transport media,

exposure pathways, and identified receptors. The ASTM Standard E 1689-95: *Guide for Developing Conceptual Site Models for Contaminated Sites* (ASTM 1995b) provides additional information on developing a CSM. Information on this standard can be found at <http://www.astm.org>.

3.0 EXPOSURE ASSESSMENT

General

Site-specific screening/initial remediation levels for soil, tap water, and air are calculated using a combination of standard default equations, standard default or site-specific exposure factors, and toxicity criteria (reference doses or cancer slope factors).

The standard default equations for calculating site-specific screening/initial remediation levels for soil, tap water, and air are presented in Part A, Equations 1-10 and discussed in Part A, Section 3.1. Default equations for calculating volatilization factors (VFs) and particulate emission factors (PEFs) used in the above equations are presented in Equations 11-15 of Part A. Default equations for calculating site-specific age-adjusted factors are presented in Equation 16-18. Default exposure factors for soil, tap water, and air are discussed in Section 3.2 and shown in Table 1. Toxicity factors are discussed in Section 3.3 of Part A.

Not all exposure pathways are addressed by the above standard default equations. The pathways not addressed are: migration of contaminants to an underlying aquifer; inhalation of volatiles that have migrated into an enclosed space (see Section 3.1.1. of Part A); ingestion via plant uptake; ingestion via meat, dairy products, human milk; and ecological pathways. A list of suggested websites containing further information on these pathways is given in the USEPA Region 9 PRG Update at <http://www.epa.gov/region09/waste/sfund/prg/index.htm> (USEPA, 2002d).

In conducting a screening evaluation, parties should compare both the arithmetic average and the reasonable maximum exposure (RME) concentrations of the environmental data collected at the site to the calculated site-specific screening level. The arithmetic average is regarded as a reasonable estimate of the concentrations likely to be contacted over time. The RME is defined as the maximum exposure which is reasonably expected to occur at a site. The RME is frequently considered to be the 95% Upper Confidence Limit (UCL) on the arithmetic average of the data. Before performing any calculations, parties should determine whether the data is normally or lognormally distributed. For more information on calculating the UCL for normal and lognormal data, USEPA's *Supplemental Guidance to RAGS: Calculating the Concentration Term* (USEPA, 1992b) should be consulted.

Finally, if both a carcinogenic and noncarcinogenic risk-based screening/initial remediation level are calculated for a particular contaminant, the lower of the two values is considered the appropriate risk-based value for the contaminant.

3.1 Site Specific Equations

3.1.1 Soils

General

Screening/initial remediation levels are calculated separately for residential and nonresidential sites for soils but not for tap water or air.

Current and future land use (residential or nonresidential) must be determined so that the most appropriate equations, exposure pathways, and default exposure factors can be selected to calculate the screening/initial remediation levels. Identification of future land use for soil evaluations goes beyond making assumptions about categories of use. It involves identifying the kinds of human receptors that may be present and the types of activities they are likely to engage in. If future land use is uncertain, the USEPA

recommends assuming residential land use which generally leads to more conservative risk-based levels. More information on land use determination, including definitions of “nonresidential”, “commercial/industrial”, “outdoor worker”, and “indoor worker”, is given in *Supplemental Guidance for Developing Soil Screening Levels for Superfund Site* (USEPA, 2001b) at <http://www.epa.gov/superfund/resources/soil/ssgmarch01.pdf>.

If the CSM determines that a soil exposure pathway is not complete (i.e. ingestion, inhalation, dermal contact), then the default equation may be modified by eliminating the applicable exposure component in the denominator of Equations 1-4.

Residential and Commercial/Industrial

Site-specific screening/initial remediation levels for residential and commercial/industrial soils may be calculated using Equations 1-4 in Part A by substituting soil properties at the site for the default parameters and/or by calculating site-specific VFs and PEFs and substituting these values in the default equations.

Construction

Equations for calculating risk-based screening/initial remediation levels for construction activities can be found in *Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites* (USEPA, 2001b) at <http://www.epa.gov/superfund/resources/soil/ssgmarch01.pdf>. in which screening level equations are presented for the ingestion, dermal, and inhalation pathways for on-site construction workers and the inhalation pathway for off-site residents. Alternative equations for calculating PEFs, VFs, and dispersion factors (Q/Cs) for the construction scenario are also presented.

Because of the difficulty of developing standardized default exposure factors and other parameters for construction scenarios, the USEPA has not established generic soil screening/remediation levels for construction similar to the USEPA PRGs and RBCs for residential and commercial/industrial land uses.

3.1.1.1 Alternatives for Quantifying Inhalation Exposure Concentrations

The approaches for evaluating inhalation exposure in Equations 1-4 for residential and commercial/industrial sites include the use of default or site-specific PEFs for semi-volatile and nonvolatile compounds and default or site-specific VFs for volatile compounds. The default PEF value is 1.396×10^9 m³/kg as shown in Table 1. Default VFs for individual chemicals can be found in the USEPA Region 9 Phys-Chem Tables (USEPA, 2002d) at <http://www.epa.gov/region09/waste/sfund/prg/index.htm>. Volatile compounds are defined as chemicals that meet all of the following volatility criteria: 1) a Henry’s Law constant greater than 10^{-5} (atm·m³/mol), 2) a molecular weight of less than 200 g/mole, and 3) a melting point of less than 25°C. PEFs should be used in Equations 1-4 for semi-volatiles, nonvolatiles, and other chemicals that do not meet these criteria.

Default Exposure Equations

Equation 13 displays the default equation for the soil-to-air PEF for semi-volatiles and nonvolatiles. The equation calculates an annual average emission rate that is based on wind erosion, but it is not appropriate for calculating more acute exposures such as from construction operations, unpaved roads, agricultural activities, or other forms of mechanical disturbance. Site-specific properties for vegetative cover and average windspeed may be substituted for the default assumptions. The resulting site-specific PEF may then be substituted for the default PEF in Equations 1-4.

Equation 11 displays the default equation for calculating the soil-to-air VF. Equation 11 assumes an infinite contaminant source. Site soil properties for porosity, bulk density, and organic carbon content may be substituted for the default assumptions. The resulting site-specific VF may then be substituted for the default VF in Equations 1 through 4. Equation 11, the alternative Mass-limit Equation (Equation 14), and the Finite Source Model for Volatiles (Equation 15) discussed below are applicable only when the contaminant concentration in soil is at or below saturation (i.e. there is no nonaqueous phase liquid (NAPL) present).

Above this level an accurate VF cannot be predicted. Equation 12 may be used to calculate soil saturation (“sat”) for volatile contaminants.

Mass-limit Equation for Volatiles

In situations where information about the depth and area of the source is available, minimum values for the VF under site-specific conditions can be calculated using Equation 14, the Mass-Limit Equation for Volatiles (USEPA 1996a,b, 2001b). The formula used in the default equation (Equation 11) assumes that contamination at the site extends from the surface to an infinite depth. Equation 14 provides a method for testing whether this assumption violates mass-limitations at the site. The mass-limit equation is applicable when contamination extends from the surface for a known fixed thickness in the soil column. Thus, application of the model requires site-specific information about the thickness of the contamination and contaminant concentrations.

If the VF calculated using Equation 11 for a contaminant is less than the VF calculated using Equation 14, then the assumption that the contamination extends from the surface to an infinite depth may be too conservative, and the site-specific VF from Equation 14 may be substituted for the default VF in Equations 1 through 4.

Finite Source Model for Volatiles

The USEPA has also identified the Finite Source Model for Volatiles (Equation 15) as a suitable model for addressing finite contaminant sources (USEPA, 1996a). The model is based on a flux model developed by Jury (Jury et al., 1990) that estimates flux of a contaminant from a finite source. The model is applicable when contamination extends from the surface for a known fixed thickness in the soil column. The model requires site-specific information about the thickness of the contamination and contaminant concentrations.

Application of the model to determine a VF value requires an average flux over the exposure period. To estimate the average contaminant flux over 30 years, the time-dependent contaminant flux must be solved for various times and the results averaged. A simple computer program or spreadsheet can be used to calculate the instantaneous flux of contaminants at set intervals and numerically integrate the results to estimate the average contaminant flux. The time-step interval must be small enough (e.g., 1-day intervals) to ensure that the cumulative loss through volatilization is less than the total initial mass. Inadequate time steps can lead to mass-balance violations (USEPA 1996a).

Alternatively, EMSOFT (Exposure Model for Soil-Organic Fate and Transport), a computer program developed by USEPA’s Office of Research and Development National Center for Environmental Assessment (NCEA) may be used to estimate average flux. The computer program provides an average emission flux over time by using an analytical solution to the integral, thereby eliminating the problem of establishing adequate time steps for numerical integration. The EMSOFT User’s Guide is available through the USEPA NCEA at <http://www.epa.gov/ncea/pdfs/emsoft.pdf> (USEPA, 1997c). The EMSOFT is available on the NCEA website as a zip file.

When using the finite source model, the risk assessor should recognize the uncertainties inherent in site-specific estimates of subsurface contaminant distributions and use conservative estimates of source size and concentrations to allow for such uncertainties.

3.1.1.2 Soil Exposure Summary

In summary, the options that may be considered when evaluating soil exposure include:

- Modifying the standard default exposure equations to eliminate incomplete exposure pathways;
- Substituting site-specific soil properties in the default soil equations to obtain site-specific exposure estimates;

- Using the default particulate emission and volatilization factor equations, the mass-limit equation, or the finite source model and site-specific characteristics to calculate alternative exposure estimates; and
- Using alternative equations for the construction scenario to calculate screening/initial remediation levels, PEFs, VFs, and Q/Cs for the on-site construction worker and off-site resident.

3.1.2 Tap Water

MCLs may be used as screening/initial remediation levels for contaminants in tap water. The AAWQS may also be used as screening/initial remediation levels for contaminants in aquifers that are actual or potential sources of drinking water. Site-specific risk-based screening/initial remediation levels for drinking water may be used in the following circumstances: 1) when an MCL or AAWQS are not available for a specific chemical; 2) when it is not feasible to remediate to the AAWQS; 3) for aquifers that are not actual or potential sources of drinking water and are not connected to an aquifer that is a drinking water source; 4) other reasons.

Screening/initial remediation levels for tap water may be calculated using Equations 5 and 6 taken from the USEPA Region 9 PRG Update (USEPA, 2002d). Dermal exposure is not addressed in the current default tap water equations but may be significant at some sites for some contaminants. The USEPA Region 9 is currently considering the inclusion of a dermal component in its default tap water equations. In the interim, parties calculating risk-based screening/remediation levels for tap water should consider all relevant exposure pathways.

Intakes of chemicals from inhalation or from dermal contact with water during household use such as bathing or showering may be calculated using the residential exposure equation for inhalation of airborne vapor-phase chemicals and the residential exposure equation for dermal contact with chemicals in water contained in *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A)* (USEPA, 1989) at <http://www.epa.gov/superfund/programs/risk/ragsa/index.htm>. *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) Interim, Review Draft* (USEPA, 2001c) at <http://www.epa.gov/superfund/programs/risk/ragse/index.htm> also contains information for calculating dermal exposure to household water.

3.1.3 Air

Ambient Air

The NAAQS should be used as the screening and remediation levels for the six criteria air pollutants in ambient air, which are: Carbon Monoxide (CO); Nitrogen Dioxide (NO₂); Ozone; Lead, Particulate Matter (PM₁₀); and Sulfur Dioxide (SO₂). HBGLs for HAPS may be calculated using Equations 7 through 10 in Part A which are taken from *Arizona Ambient Air Health-based Guidance Levels (HBGLs)* (ADHS 1999, Unpublished). HBGLs are not air quality standards but non-binding guidance levels for screening and establishing initial remediation levels for HAPs. The Arizona HBGL equations assume residential exposure to contaminants in air via inhalation and provide annual, 24-hour, and 1-hour screening values. The annual HBGLs are the most protective based upon carcinogenicity and systemic toxicity. The 24-hour HBGLs specifically protect against systemic toxicity (noncarcinogens) from acute exposure to toxic or irritating compounds. One-hour HBGLs are protective of irritating and toxic effects from transient exposures to systemic toxicants and irritants.

The USEPA Region 9 PRG air equations for calculating annual screening values for HAPs are the same as the HBGL equations for calculating annual values for HAPs. USEPA Region 9 equations and

generic risk-based levels for chemicals in ambient air can be found at <http://www.epa.gov/region09/waste/sfund/prg/index.htm> (USEPA, 2002d).

Indoor Air

Concerns have been raised about the potential for sub-surface contamination in soil and/or groundwater to adversely impact indoor air quality. For example, exposures may occur as the result of subsurface soil gas entering basements, crawl spaces, or elevator shafts. The USEPA has developed draft vapor intrusion guidance that includes a screening strategy and screening levels for soil gas, groundwater and indoor air concentrations entitled *Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion)* (USEPA, 2002f) and *Draft Supplemental Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway* (USEPA, 2001d). Both documents are located at <http://www.epa.gov/epaoswer/hazwaste/ca/eis/vapor.htm>.

3.1.4 Special Considerations

The USEPA has no consensus reference dose (RfD) or cancer slope factor (CSF) for inorganic lead. Therefore, it is not possible to calculate site-specific screening/initial remediation levels for lead as for other chemicals. The USEPA recommends that the Integrated Exposure Uptake Biokinetic (IEUBK) model for lead in children 7 years of age and less be used as the primary tool to generate risk-based soil cleanup levels for current or future residential land use. The USEPA also recommends that the cleanup levels be designed to reduce risk to no greater than a 5% chance of exceeding a 10 ug/dl blood-lead level for a full-time child resident. Since the IEUBK Model is specifically designed to be applied to children, the USEPA recommends using its Adult Lead Model (ALM) for calculating the non-residential (adult) screening level for lead. Information on these models can be found at <http://www.epa.gov/superfund/programs/lead/ieubk.htm> (USEPA, 2003a).

Regulatory standards recommended for purposes of screening and establishing initial remediation levels for lead are: the Arizona SRLs for residential soils (400 mg/kg) and nonresidential soils (2000 mg/kg); the USEPA Action Level for water (15 ug/l); and the NAAQS for air (1.5 ug/m³).

The USEPA Region 9 indicates there are some additional chemicals for which the standard soil, tap water, and air default equations do not apply and/or adjustments to the toxicity values are recommended. These chemicals include: cadmium; chromium 6; manganese; nitrates/nitrites; thallium; vinyl chloride; and lead as previously mentioned. Further information on these special situations can be found at <http://www.epa.gov/region09/waste/sfund/prg/index.htm> (USEPA, 2002d).

3.2 Default Exposure Factors

General Discussion

The USEPA has established default human exposure factors for the default equations described above in an effort to establish consistency. The standard USEPA default exposure factors for soil, tap water, and air are given in Table 1, with a reference for each value. Site-specific human exposure information; for example, exposure frequency, duration, or intake data, may be substituted for the default values (e.g. the exposure duration should be 40 years instead of the standard default of 30 years).

In addition to the exposure factors in Table 1, the *Exposure Factors Handbook* (USEPA, 1997a) at <http://www.epa.gov/ncea/pdfs/efh/front.pdf> also provides statistical data on exposure factors for the general population and for segments of the population who may have characteristics different from the general population. In September 2002, the USEPA published the *Child-specific Exposure Factors Handbook* which is also available on the USEPA NCEA website.

Default age-adjusted exposure factors are also shown in Table 1. Because contact rates with residential soil, tap water, and ambient air are different for children and adults, carcinogenic risks during the first 30 years of life are calculated using age-adjusted factors. These factors integrate exposure from birth until age 30 (with 6 years as a child and 24 years as an adult), combining contact rates, body weights, and exposure durations for small children and adults. Use of age-adjusted factors is especially important for residential soil ingestion which is higher during childhood and decreases with age. Site-specific age-adjusted factors may be calculated using Equations 16 - 18 taken from the USEPA Region 9 PRGs Table Update. Age-adjusted factors are not used in evaluating noncarcinogenic systemic toxicity.

3.2.1 Residential Soil Default Exposure Factors

Exposure Frequency, Exposure Duration, and Body Weight

Site-specific screening/initial remediation levels for carcinogens at a residential site are based on combined childhood and adult exposure. The default exposure factors for residential soils can be found in Table 1. The applicable default exposure factors for carcinogens are as follows: Exposure Frequency (350 days/year); Exposure Duration (30 years); Adult Body Weight (70 kg); Child Body Weight (15 kg); and Averaging Time (25,550 days).

Site-specific screening/initial remediation levels for noncarcinogens are calculated separately for children and adults. The applicable default exposure factors are as follows: Exposure Frequency (350 days/year); Exposure Duration Adult (30 years); Exposure Duration Child (6 years); Adult Body Weight (70 kg); Child Body Weight (15 kg); and Averaging Time Child (2,190 days); Averaging Time Adult (10,950 days). In order to remain adequately protective, the USEPA bases screening/remediation levels for noncancer residential exposure on a conservative “childhood only” scenario. The focus on children is protective of the higher daily rates of soil intake by children and their lower body weight.

Ingestion Exposure

The default residential values for soil ingestion are 100 mg/day for adults and 200 mg/day for children. The default age-adjusted factor for soil ingestion is 114 [mg-yr]/[kg-d].

Inhalation Exposure

The default residential soil inhalation rates are 20 m³/day for adults and 10 m³/day for children. The default age-adjusted inhalation factor is 11 [m³/yr]/[kg/d].

As stated in Section 3.1.1.1, VFs are used in the denominator of the inhalation term of both the residential and nonresidential soil equations (Equations 1-4) for volatile compounds and PEFs are used in the denominator for semi-volatile and non-volatile constituents. Table 1 shows the default PEF value of 1.396×10^{-9} and indicates that the default VFs and soil saturation concentrations (sats) are chemical specific. Default VFs and sats for individual chemicals can be found in the USEPA Region 9 PRG Phys-Chem Tables at <http://www.epa.gov/region09/waste/sfund/prg/index.htm> (USEPA, 2002d).

The site-specific equations for calculating VFs and PEFs (Equations 11, 13-15) can be broken into two separate models: a model to estimate the emissions of volatiles and dusts, and an air dispersion model (reduced to the term Q/C) that simulates the dispersion of contaminants in the atmosphere. The default Q/C for the VF equations (Equations 11, 14, and 15) is 68.81 g/m² - s per kg/m³ for a 0.5-acre default site (Los Angeles, CA). The default Q/C for the PEF equation (Equation 13) is 90.80 g/m² -s per kg/m³ for a 0.5-acre default site (Minneapolis, MN). Information on calculating site-specific Q/C values (e.g. for Phoenix, AZ) that that can be used in lieu of the default values can be found in *Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites* (USEPA, 2001b) at <http://www.epa.gov/superfund/resources/soil/ssgmarch01.pdf>. A site-specific value for “sat” may be calculated using Equation 12.

Dermal Contact

According to the USEPA’s *Risk Assessment Guidance for Superfund, Volume I: Human Health*

Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) Interim, Review Draft (USEPA, 2001c) at <http://www.epa.gov/superfund/programs/risk/rage/index.htm>. The recommended RME defaults for surface skin areas (SA) are 5700 cm²/day for adult residents and 2800 cm²/day for child residents. The default adherence factor (AF) is 0.07 mg/cm² for adult residents and 0.2 mg/cm² for children. The default dermal absorption factor (ABS) for semi-volatile organics is 0.1 for adults and children. The default age-adjusted dermal factor is 361 [m³/yr]/[kg/d].

The USEPA did not recommend default dermal absorption factors for volatiles and inorganics in USEPA (2001c); consequently, the previously recommended default dermal absorption factors of 0.1 for volatiles and 0.01 for inorganics have been removed from the standard default table. USEPA (2001c) contains chemical-specific dermal absorption factors for arsenic, cadmium, chlordane, 2,4-D, DDT, TCDD, lindane PAHs, PCBs, and pentachlorophenol.

3.2.2 Commercial/Industrial Soil Default Exposure Factors

Exposure Frequency, Exposure Duration, and Body Weight

Site-specific screening/initial remediation levels for both carcinogens and noncarcinogens at non-residential (i.e. commercial/industrial) sites are based on exposure to adult workers only; consequently, age-adjusted factors are not used in the carcinogenic nonresidential soil equation. The default exposure factors for nonresidential soils can be found in Table 1. The applicable default exposure factors for both the carcinogenic and noncarcinogenic equations are as follows: Exposure Frequency Indoor Worker (250 days/year); Exposure Frequency Outdoor Worker (225 days/year); Exposure Duration (25 years); Adult Body Weight (70 kg); Averaging Time Cancer (25,550 days); Averaging Time Noncancer (9,125 days).

Ingestion Rates

The soil ingestion rates for non-construction workers are 100 mg/day for outdoor workers and 50 mg/day for indoor workers.

Inhalation Rates

A standard default inhalation rate of 20 m³/workday is assumed for indoor and outdoor adult workers.

Dermal Contact

The default skin surface area for indoor and outdoor workers is 3300 cm². The default skin adherence factor for outdoor workers is 0.2 mg/cm². There is no default adherence factor for indoor workers. Default dermal absorption factors for semi-volatiles, volatile organics and inorganics are the same as the default factors for residential soil.

3.2.3 Construction Soil Default Exposure Factors

Exposure Frequency, Exposure Duration, and Body Weight

Site-specific screening/initial remediation levels for carcinogens and noncarcinogens are calculated for the ingestion, dermal, and inhalation pathways for the on-site construction workers and the inhalation pathway for off-site residents during construction. Default exposure factors for the construction worker are: Exposure Frequency (250 days/year); Exposure Duration (365 days or site-specific); Body Weight (70 kg); Averaging Time Cancer (25550 days); Averaging Time Noncancer (365 days).

Default exposure factors for the off-site resident are: Exposure Frequency (350 days/year); Exposure Duration (site-specific); Body Weight Child (15 kg); Body Weight Adult (70 kg); Averaging Time Cancer (70 years); Averaging Time Noncancer (site-specific).

Ingestion Exposure

The standard default soil ingestion rate for construction workers is 330 mg/d. Ingestion is not evaluated in the default equations for off-site residents.

Inhalation Exposure

The standard default inhalation rate for construction workers and off-site adult residents is 20 m³/day and 10 m³/day for off-site child residents.

Dermal Exposure

A standard default skin adherence factor of 0.3 mg/cm² and an adult worker skin surface area of 3300 cm²/day should be assumed for construction workers. Dermal contact is not evaluated in the default equations for off-site residents.

3.2.4 Tap Water Default Exposure Factors

Exposure Frequency, Exposure Duration, and Body Weight

Risk-based screening/initial remediation levels for tap water for carcinogenic and noncarcinogenic contaminants should generally be based on residential exposures. Site-specific screening/initial remediation levels for carcinogens in drinking water are based on combined childhood and adult exposure; consequently, age-adjusted factors are used in the carcinogenic equation. Default exposure factors for tap water exposure can be found in Table 1. The applicable default exposure factors for carcinogens are: Exposure Frequency (350 days/year); Exposure Duration Child (6 years); Exposure Duration Adult (30 years); Adult Body Weight (70 kg); Child Body Weight (15 kg); Averaging Time (25,550 days).

Screening/initial remediation levels for noncarcinogens in drinking water are calculated separately for children and adults. Therefore, age-adjustment factors are not used in evaluating systemic toxicity. An exposure frequency of 350 days/year, exposure duration of 30 years for an adult and 6 years for children, and a default body weight of 70 kg for adults and 15 kg for children should be assumed.

Ingestion Exposure

A standard default drinking water ingestion rate of 2 L/day for adults and 1L/day for children is assumed. The default age-adjusted factor for water ingestion is 1.1 [L-yr]/[kg-d]. Ingestion of drinking water is an appropriate pathway for all chemicals.

Inhalation Exposure

A standard default inhalation rate of 20m³/day for adults and 10m³/day for children is assumed. The default age-adjusted factor for inhalation is 11 [m³-yr]/[kg-d]. Inhalation of volatile chemicals from water is considered routinely only for chemicals with a Henry's Law constant of 1 x 10⁻⁵ atm-m³/mole or greater with a molecular weight of less than 200 g/mole.

In calculating the PRGs for tap water, the USEPA Region 9 used an upperbound volatilization constant (VF_w) that is based on all uses of household water (e.g. showering, laundering, and dish washing). Region 9 assumed in their calculations that the volume of water used in a residence for a family of four is 720 L/day, the volume of the dwelling is 150,000L, and the air exchange rate is 0.25air changes/hour. Furthermore, it was assumed that the transfer efficiency weighted by water use is 50 percent (i.e. half of the concentrations of each chemical in water will be transferred in air by all water uses). (The range of transfer efficiencies extends from 30% for toilets to 90% for dishwashers.)

Dermal Exposure

As stated in Section 3.1.2, dermal contact is not addressed in the current USEPA equations (Equations 5 and 6) but may be significant at some sites. Parties calculating risk-based screening levels for tap water should consider all relevant exposure pathways. Default factors used to assess dermal contact with water may be found in USEPA's *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)* (USEPA, 1989) at <http://www.epa.gov/superfund/programs/risk/ragsa/index.htm> and *Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) Interim Review Draft* (USEPA, 2001c) at <http://www.epa.gov/superfund/programs/risk/ragse/index.htm>.

3.2.5 Air Default Exposure Factors

Annual HBGLs

The HBGL default exposure factors for residential inhalation exposure can be found in Table 1. The default exposure factors for the annual HBGLs for carcinogens in air are: Exposure Frequency (350 days/year); Exposure Duration (30 years); Averaging Time (25,550 days); Body Weight (70 kg). Cancer risks during the first 30 years of life are calculated using an age-adjusted exposure factor for inhalation of 11 [m³-yr]/[kg-d].

Annual HBGLs for noncarcinogenic systemic toxicity in air are calculated only for children. Therefore, an age-adjusted factor is not used in evaluating systemic toxicity. Exposure assumptions reflect childhood inhalation rates and body weight. The focus on children is protective of the higher daily intake rates by children relative to their body weight. For systemic toxicity, the exposure duration is assumed to be 350 days/year for 6 years. Exposure doses are averaged over a period of 6 years. Air HBGLs use the default childhood inhalation rate of 10 m³/day and default body weight for children of 15 kg.

Twenty-four Hour HBGLs

Twenty-four Hour HBGLs specifically protect against systemic toxicity from acute childhood exposure to noncarcinogens; therefore, no age-adjusted factor is used in the equation. Exposure assumptions reflect childhood inhalation rates (10 m³/day) and body weight (15 kg). The focus on children is protective of the higher daily intake rates by children relative to their body weight.

One-hour HBGLs

One-hour HBGLs are protective of irritating and toxic effects from transient exposures to noncarcinogens. They are calculated by dividing the 24-hour HBGL by 3.8, which represents the proportional difference in the lowest observed adverse effect level for 24-hour and 1-hour exposure to a common irritant (SO₂) in human subjects.

4.0 TOXICITY ASSESSMENT

A toxicity assessment includes a hazard identification and dose-response evaluation for each COPC. The hazard identification evaluates what types of health effects are caused by exposure to a chemical. The dose-response evaluation identifies the appropriate quantitative chemical-specific toxicity values (i.e. reference doses for noncarcinogens and cancer slope factors for carcinogens).

4.1 Hazard Identification

Information on the health effects of individual chemicals may be found in the USEPA's *Integrated Risk Information System* at <http://www.epa.gov/iris/> (USEPA, 2003b) and elsewhere on the USEPA website. Toxicological profiles of individual chemicals are also available from the Agency for Toxic Substances and Disease Registry (ATSDR, 2003a) at <http://www.atsdr.cdc.gov/>. Draft and final toxicological profile reports or a CD-ROM of the toxicological profiles for a given year can be obtained by contacting the ATSDR Information Center at 1-888-422-8737.

4.2 Dose-Response Evaluation

Oral Toxicity Values

A reference dose, or RfD (expressed in mg/kg/day), is the toxicity values used most often in evaluating noncarcinogenic effects resulting from exposure to individual chemicals. The USEPA defines a chronic reference dose as a daily exposure level that is likely to be without deleterious effects over a lifetime (USEPA, 1989). A subchronic reference dose is defined as a provisional estimate that is likely to be without

deleterious effects during a portion of a lifetime, usually an exposure period between two weeks and seven years (USEPA, 1989).

The cancer slope factor, or CSF (expressed in mg/kg-day) is the toxicity value most commonly used in evaluating carcinogenic effect posed by exposure to individual chemicals. The CSF represents the probability of carcinogenic response per unit daily intake of a substance over a lifetime. Only chronic CSFs are available. Slope factors should be accompanied by the weight-of-evidence classification (discussed below) to indicate the strength of the evidence that the agent is a human carcinogen.

Chronic oral RfDs may be obtained from IRIS (USEPA, 2003b) at <http://www.epa.gov/iris/>, the Health Effects Summary Tables (HEAST) (USEPA, 1997b), or by contacting the USEPA National Center for Environmental Assessment (NCEA) which develops provisional RfDs and cancer slope factors (CSFs) on request for contaminants not in IRIS and HEAST.

Subchronic oral RfDs are not as available as chronic values. A limited number of oral subchronic values are available from HEAST. Additionally, the ATSDR publishes Minimal Risk Levels (MRLs) that may be suitable for use as subchronic RfDs. The MRLs are derived for acute (1-14 days), intermediate (>14-364 days), and chronic (365 days and longer) exposure durations for both the oral and inhalation routes of exposure. The MRLs can be found at <http://www.atsdr.cdc.gov/mrls.html> (ATSDR, 2003b).

Inhalation Toxicity Values

The IRIS and the NCEA (including HEAST) databases no longer present RfDs or CSFs for the inhalation exposure route. These criteria have been replaced by reference concentrations (RfCs) for noncarcinogenic effects and by unit risk factors (URFs) for carcinogenic effects. According to the USEPA Region 9, inhalation RfDs and inhalation CSFs are preferred for risk analysis purposes. Equations which may be used to calculate an inhalation RfD from an RfC and an inhalation CSF from a URF are presented in the USEPA Region 9 PRG Table 2002 Update at <http://www.epa.gov/region09/waste/sfund/prg/index.htm> (USEPA, 2002d). The Update also describes route-to-route extrapolation methods in which oral RfDs and CSFs may be used for inhalation RfDs and CSFs (and visa versa) in the case of organic but not inorganic compounds. The ATSDR MRLs also contain acute, intermediate, and chronic inhalation RfCs.

Dermal Toxicity Values

Neither the USEPA nor ATSDR provide dermal RfDs or CSFs. The USEPA Region 9 indicates that, route extrapolation may be used in which oral toxicity values may be used as dermal RfDs and CSFs.

Subchronic Toxicity Issues

Adult exposure durations may be relatively short. The construction worker is the most widely used example. Subchronic RfDs (where available) should be used for exposure periods for adults lasting from 2 weeks to 7 years (USEPA, 1989). If a subchronic value is not available, the chronic RfD may be used.

On the other hand, chronic RfDs should be used for childhood exposure (which the USEPA defines as from 0 to 6 years) as the subchronic values may not be sufficiently protective of children.

4.3 Hierarchy of Toxicity Values

The priority among sources of toxicity values is as follows: (1) IRIS, (2) HEAST, (3) provisional values developed by NCEA, (4) withdrawn values or values under review from IRIS or HEAST, (5) other USEPA documents; and (6) other sources such as the ATSDR MRLs. Each source is used only if values from higher-priority sources are unavailable, unless NCEA indicates a newer provisional value is superior to an older HEAST value.

4.4 Weight-of-Evidence Classifications

CSFs should always be accompanied by a weight-of-evidence (WoE) classification to indicate the

strength of the evidence that the agent is a human carcinogen. The WoE system classifies chemicals into five groups based on the extent to which the agent has been shown to be a carcinogen in humans or experimental animals:

- Group A Proven Human Carcinogen
- Group B Probable Human Carcinogen
- Group C Possible Human Carcinogen
- Group D Not Classified as to Human Carcinogenicity
- Group E Evidence of Noncarcinogenicity for Humans

Human carcinogens for which there is sufficient evidence of carcinogenicity in humans are included in Group A. Probable human carcinogens are designated as B1, indicating that studies in humans are strongly suggestive but not conclusive, or B2, indicating the chemical has been conclusively carcinogenic in repeated animal studies but not conclusive in human studies. A chemical may be classified as a C possible human carcinogen if a single high-quality animal study or several low-quality animal studies suggest carcinogenicity. Chemicals are classified as D if there is insufficient human and animal evidence to determine the carcinogenicity of the chemical. Class E chemicals have been conclusively demonstrated to be non-carcinogenic to humans.

Site-specific screening/initial remediation levels usually limit excess lifetime cancer risk to one-in-one million (10^{-6}) for Class A proven human carcinogens and to one-in-one-hundred-thousand (10^{-5}) for Class B probable and Class C possible human carcinogens.

The USEPA is considering adopting a new weight-of-evidence classification system which uses three categories of descriptors for human carcinogenic potential: 1) Known/likely; 2) Cannot be determined; and 3) Not likely. Information on the new proposed system was first given in *Proposed Guidelines for Carcinogenic Risk Assessment* (USEPA, 1996) which can be found at <http://cfpub.epa.gov/ncea/raf/cancer.cfm>.

5.0 UNCERTAINTY ANALYSIS

An assessment of the uncertainties associated with the calculated risk-based screening/initial remediation levels should be conducted to place the screening levels in proper perspective and to serve as a basis for recommending further modifications to the levels prior to setting final remediation goals. Each component of risk-based screening/initial remediation levels discussed in Part A should be examined, and the major areas of uncertainty discussed in the required summary report discussed in Section 1.3 of Part A. For example, the discussion could include uncertainty associated with the selected future land use, the accuracy of the equations and technical models to reflect site-specific conditions, the relevance of the selected exposure factors to potentially exposed populations, and assumptions concerning the RME individual(s).

The uncertainty analysis of the risk-based screening/initial remediation levels is similar to that conducted for a baseline risk assessment described in *Risk Assessment Guidance for Superfund, Part A* (USEPA, 1989). Further general information on uncertainty analyses can be found in *Guidance on Risk Characterization for Risk Managers and Risk Assessors* (USEPA, 1992d) at <http://www.epa.gov/superfund/programs/risk/habicht.htm> and *Guidance for Risk Characterization* (USEPA, 1995c) at <http://www.epa.gov/osp/spc/rcguide.htm>.

6.0 SUMMARY

Site-specific screening and initial remediation levels for soil, tap water, and air may be calculated using a combination of standard default equations, standard default or site-specific exposure factors, and toxicity criteria (reference doses or cancer slope factors).

The standard default screening level equations are presented in Part A as follows: Equations 1-4 for soil; Equations 5 and 6 for tap water; and Equations 7-12 for air. Default equations for calculating the VFs and PEFs used in the screening equations are presented in Equations 13-17. Default exposure factors for soil, water, and air used in the screening level equations are given in Table 1. References on where to obtain reference doses and cancer slope factors are given in Section 3.3 of Part A. Site-specific screening/initial remediation levels may be developed by substituting site-specific properties for default parameters and/or by using alternative equations and models for evaluating inhalation. Site-specific screening/initial remediation levels may also eliminate incomplete exposure pathways if the CSM supports such a decision.

Parties developing site-specific screening/initial remediation levels should prepare a summary document for submittal to the reviewing agency as described in Section 1.3. The summary document should contain:

- X A conceptual site model;
- X An exposure component that quantifies the exposure from each complete pathway;
- X A toxicity component that presents reference doses and cancer slope factors and the WoE classification;
- X An uncertainty analysis; and
- X A narrative summary and tables that display the equations, calculations, exposure factors, and final proposed site-specific screening/initial remediation levels.
- X References for all equations and default/site-specific exposure factors.

Table 1: STANDARD DEFAULT FACTORS

<u>Symbol</u>	<u>Definition (units)</u>	<u>Default</u>	<u>Reference</u>
CSFo	Cancer slope factor oral (mg/kg-d) ⁻¹	--	IRIS, HEAST, or NCEA
CSFi	Cancer slope factor inhaled (mg/kg-d) ⁻¹	--	IRIS, HEAST, or NCEA
RfDo	Reference dose oral (mg/kg-d)	--	IRIS, HEAST, or NCEA
RfDi	Reference dose inhaled (mg/kg-d)	--	IRIS, HEAST, or NCEA
TR _A	Target cancer risk (WoE = A) ^a	10 ⁻⁶	--
TR _{B,C}	Target cancer risk (WoE = B1, B2, C) ^b	10 ⁻⁵	--
THQ	Target hazard quotient	1	--
BW _a	Body weight, adult (kg)	70	RAGS (Part A), USEPA 1989 (EPA/540/1-89/002)
BW _c	Body weight, child (kg)	15	Exposure Factors USEPA 1991b (OSWER No. 9285.6-03)
AT _c	Averaging time - carcinogens (days)	25550	RAGS (Part A), USEPA 1989 (EPA/540/1-89/002)
AT _n	Averaging time - noncarcinogens (days)	ED*365	
SA _a	Exposed surface area for soil/dust (cm ² /day)		Dermal Assessment, EPA 2001 (EPA/540/R-99/005)
	- adult resident	5700	
	- adult worker	3300	
SA _c	Exposed surface area, child in soil (cm ² /day)	2800	
AF _a	Adherence factor, soils (mg/cm ²)		Dermal Assessment, EPA 2001 (EPA/540/R-99/005)
	- adult resident	0.07	
	- adult worker	0.2	
	- construction worker	0.3	Soil Screening Guidance (EPA 2001a)
AF _c	Adherence factor, child (mg/cm ²)	0.2	Dermal Assessment, EPA 2001 (EPA/540/R-99/005)
ABS	Skin absorption defaults (unitless):		Dermal Assessment, EPA 2001 (EPA/540/R-99/005)
	- semi-volatile organics	0.1	
	- volatile organics	----	
	- inorganics	----	
IRA _a	Inhalation rate - adult (m ³ /day)	20	Exposure Factors, USEPA 1991b (OSWER No. 9285.6-03)
IRA _c	Inhalation rate - child (m ³ /day)	10	Exposure Factors, EPA 1997 (EPA/600/P-95/002Fa)
IRW _a	Drinking water ingestion-adult (L/day)	2	RAGS (Part A), EPA 1989 (EPA/540/1-89/002)
IRW _c	Drinking water ingestion-child (L/day)	1	PEA, Cal-EPA (DTSC, 1994)
IRS _a	Soil ingestion - adult (mg/day)	100	Exposure Factors, USEPA 1991b (OSWER No. 9285.6-03)
IRS _c	Soil ingestion - child (mg/day),	200	Exposure Factors, USEPA 1991b (OSWER No. 9285.6-03)
IRS _o	Soil ingestion - occupational (mg/day)		
	- outdoor worker	100	Soil Screening Guidance (EPA 2001a)
	- indoor worker	50	Soil Screening Guidance (EPA 2001a)
	- construction worker	330	Soil Screening Guidance (EPA 2001a)
EFr	Exposure frequency - residential (d/y)	350	Exposure Factors, USEPA 1991b (OSWER No. 9285.6-03)
	- off-site resident	350	Soil Screening Guidance (EPA 2001a)
EF _o	Exposure frequency - occupational (d/y)		
	- outdoor worker	225	Soil Screening Guidance (EPA 2001a)
	- indoor worker	250	Soil Screening Guidance (EPA 2001a)
	- construction worker	250	Soil Screening Guidance (EPA 2001a)
ED _r	Exposure duration - residential (years)	30 ^c	Exposure Factors, USEPA 1991b (OSWER No. 9285.6-03)
	- off-site resident	site-specific	
ED _c	Exposure duration - child (years)	6	Exposure Factors, USEPA 1991b (OSWER No. 9285.6-03)
ED _o	Exposure duration - occupational (years)		
	- outdoor worker	25	Soil Screening Guidance (EPA 2001a)
	- indoor worker	25	Soil Screening Guidance (EPA 2001a)
	- construction worker	1	Or site-specific, Soil Screening Guidance (EPA 2001a)
IFS _{adj}	Age-adjusted factors for carcinogens: Ingestion factor, soils ([mg/yr]/[kg/d])	114	RAGS (Part B), USEPA 1991 (OSWER No. 9285.7-01B)
SFS _{adj}	Dermal factor, soils ([mg/yr]/[kg/d])	361	By analogy to RAGS (Part B)

InhFadj	Inhalation factor, air ([m ³ /yr]/[kg/d])	11	By analogy to RAGS (Part B)
IFWadj	Ingestion factor, water ([L-yr]/[kg-d])	1.1	By analogy to RAGS (Part B)
VFw	Volatilization factor for water (L/m ³)	0.5	RAGS(Part B), EPA 1991 (OSWER No. 9285.7-01B)
PEF	Particulate emission factor (m ³ /kg)	1.396 x 10 ⁺⁹	Soil Screening Guidance (USEPA 1996a,b)
VF _s	Volatilization factor for soil (m ³ /kg)	Chem. Specific	Soil Screening Guidance (USEPA 1996a,b)
sat	Soil saturation concentration (mg/kg)	Chem. Specific	Soil Screening Guidance (USEPA 1996a,b)

See Below

Footnotes:

^a USEPA Carcinogenic Weight of Evidence (WoE) Classification for Known Human Carcinogens

^b USEPA Carcinogenic Weight of Evidence (WoE) Classification for Probable Human Carcinogens (WoE = B1 or B2) and Possible Human Carcinogens (WoE = C)

^c Exposure duration for lifetime residents is assumed to be 30 years (total). For carcinogens, exposures are integrated for childhood (6 years) and adults (24 years).

EQUATIONS – PART A

Equation 1: Combined Exposures to Carcinogenic Contaminants in Residential Soil (USEPA, 2002d)

$$C(\text{mg/kg}) = \frac{\text{TR} \times \text{AT}_c}{\text{EF}_r \left[\left(\frac{\text{IFS}_{\text{adj}} \times \text{CSF}_o}{10^6 \text{ mg/kg}} \right) + \left(\frac{\text{SFS}_{\text{adj}} \times \text{ABS} \times \text{CSF}_o}{10^6 \text{ mg/kg}} \right) + \left(\frac{\text{InhF}_{\text{adj}} \times \text{CSF}_i}{\text{VF}_s^a} \right) \right]}$$

Equation 2: Combined Exposures to Noncarcinogenic Contaminants in Residential Soil (USEPA, 2002d)

$$C(\text{mg/kg}) = \frac{\text{THQ} \times \text{BW}_c \times \text{AT}_n}{\text{EF}_r \times \text{ED}_c \left[\left(\frac{1}{\text{RFD}_o} \times \frac{\text{IRS}_c}{10^6 \text{ mg/kg}} \right) + \left(\frac{1}{\text{RFD}_o} \times \frac{\text{SA}_c \times \text{AF} \times \text{ABS}}{10^6 \text{ mg/kg}} \right) + \left(\frac{1}{\text{RFD}_i} \times \frac{\text{IRA}_c}{\text{VF}_s^a} \right) \right]}$$

Equation 3: Combined Exposures to Carcinogenic Contaminants in Nonresidential Soil (USEPA, 2002d)

$$C(\text{mg/kg}) = \frac{\text{TR} \times \text{BW}_a \times \text{AT}_c}{\text{EF}_o \times \text{ED}_o \left[\left(\frac{\text{IRS}_o \times \text{CSF}_o}{10^6 \text{ mg/kg}} \right) + \left(\frac{\text{SA}_a \times \text{AF} \times \text{ABS} \times \text{CSF}_o}{10^6 \text{ mg/kg}} \right) + \left(\frac{\text{IRA}_a \times \text{CSF}_i}{\text{VF}_s^a} \right) \right]}$$

Equation 4: Combined Exposures to Noncarcinogenic Contaminants in Nonresidential Soil (USEPA, 2002d)

$$C(\text{mg/kg}) = \frac{\text{THQ} \times \text{BW}_a \times \text{AT}_n}{\text{EF}_o \times \text{ED}_o \left[\left(\frac{1}{\text{RfD}_o} \times \frac{\text{IRS}_o}{10^6 \text{ mg/kg}} \right) + \left(\frac{1}{\text{RfD}_o} \times \frac{\text{SA}_a \times \text{AF} \times \text{ABS}}{10^6 \text{ mg/kg}} \right) + \left(\frac{1}{\text{RfD}_i} \times \frac{\text{IRA}_a}{\text{VF}_s^a} \right) \right]}$$

Equation 5: Ingestion and Inhalation Exposures to Carcinogenic Contaminants in Water (USEPA, 2002d)

$$C(\text{ug/L}) = \frac{\text{TR} \times \text{AT}_c \times 1000 \text{ ug/mg}}{\text{EF}_r \left[\left(\text{IFW}_{\text{adj}} \times \text{CSF}_o \right) + \left(\text{VF}_w \times \text{InhF}_{\text{adj}} \times \text{CSF}_i \right) \right]}$$

Equation 6: Ingestion and Inhalation Exposures to Noncarcinogenic Contaminants in Water (USEPA, 2002d)

$$C \text{ (ug/L)} = \frac{\text{THQ} \times \text{BW}_a \times \text{AT}_n \times 1000 \text{ ug/mg}}{\text{EF}_r \times \text{ED}_r \left[\left(\frac{\text{IRW}_a}{\text{RfD}_o} \right) + \left(\frac{\text{VF}_w \times \text{IRA}_a}{\text{RfD}_i} \right) \right]}$$

Equation 7: Annual HBGL for Exposure to Carcinogens in Air (ADHS Unpublished, 1999; USEPA, 2002d)

$$C \text{ (ug/m}^3\text{)} = \frac{\text{TR} \times \text{AT}_c \times 1000 \text{ ug/mg}}{\text{EF}_r \times \text{InhF}_{\text{adj}} \times \text{CSF}_i}$$

Equation 8: Annual HBGL for Systemic Toxicity of Exposure of Noncarcinogens in Air (ADHS Unpublished, 1999; USEPA, 2002d)

$$C \text{ (ug/m}^3\text{)} = \frac{\text{THQ} \times \text{RfD}_i \times \text{BW}_a \times \text{AT}_n \times 1000 \text{ ug/mg}}{\text{EF}_r \times \text{ED}_r \times \text{IRA}_a}$$

Equation 9: Twenty-four hour HBGL for Systemic Toxicity of Exposure of Noncarcinogens in Air (ADHS Unpublished, 1999)

$$C \text{ (ug/m}^3\text{)} = \frac{\text{THQ} \times \text{SubChrRfD}_i \times \text{BW}_c \times 1000 \text{ ug/mg}}{\text{IRA}_c}$$

Equation 10: One-hour HBGL for Systemic Toxicity of Exposure of Noncarcinogens in Air (ADHS Unpublished, 1999)

$$C \text{ (ug/m}^3\text{)} = 24\text{Hour HBGL (ug/m}^3\text{)} \times 3.8$$

Equation 11: Derivation of the Volatilization Factor (USEPA, 2002d)

$$VF_s \text{ (m}^3 \text{ / kg)} = (Q/C) \times \frac{(3.14 \times D_A \times T)^{1/2}}{2 \times \rho_b \times D_A} \times 10^{-4} \text{ (m}^2 \text{ / cm}^2)$$

where:

$$D_A = \frac{\left(\frac{\Theta_a^{10/3} D_i H' + \Theta_w^{10/3} D_w}{n^2} \right)}{\rho_B K_d + \Theta_w + \Theta_a H'}$$

Parameter	Definition (units)	Default
VF _s	Volatilization Factor (m ³ /kg)	--
D _A	Apparent diffusivity (cm ² /s)	--
Q/C	Inverse of the mean concentration at the center of a 0.5-acre square source (g/m ² -second per kg/m ³)	68.18
T	Exposure interval (seconds)	9.5x10 ⁸
ρ _b	Dry soil bulk density (g/cm ³)	1.5 (or site-specific)
Θ _a	Air-filled soil porosity (L _{air} /L _{soil})	0.28 (or site-specific)
N	Total soil porosity (L _{pore} /L _{soil})	0.43 (or site-specific)
Θ _w	Water-filled soil porosity (L _{water} /L _{soil})	0.15 (or site-specific)
ρ _s	Soil particle density (g/cm ³)	2.65 (or site-specific)
D _i	Diffusivity in air (cm ² /s)	Chemical-specific
H	Henry's Law constant (atm-m ³ /mol)	Chemical-specific
H'	Dimensionless Henry's Law constant	H x 41 (USEPA 1991a)
D _w	Diffusivity in water (cm ² /s)	Chemical-specific
K _d	Soil-water partition coefficient (cm ³ /g) = K _{oc} f _{oc}	Chemical-specific
K _{oc}	Soil organic carbon-water partition coefficient (cm ³ /g)	Chemical-specific
f _{oc}	Fraction organic carbon in soil (g/g)	0.006 (or site-specific)

Equation 12: Derivation of the Soil Saturation Limit (USEPA, 2002d)

$$\text{sat} = \frac{S}{\rho_b} (K_d \rho_b + \Theta_w + H' \Theta_a)$$

Parameter	Definition (units)	Default
sat	Soil saturation concentration (mg/kg)	--
S	Solubility in water (mg/L-water)	Chemical-specific
ρ_b	Dry soil bulk density (kg/L)	1.5 (or site-specific)
n	Total soil porosity ($L_{\text{pore}}/L_{\text{soil}}$)	0.43 (or site-specific)
ρ_s	Soil particle density (kg/L)	2.65 (or site-specific)
K_d	Soil-water partition coefficient (L/kg)	$K_{oc} \times f_{oc}$ (chemical-specific)
k_{oc}	Soil organic carbon/water partition coefficient (L/kg)	Chemical-specific
f_{oc}	Fraction organic carbon content of soil (g/g)	0.006 (or site-specific)
Θ_w	Water-filled soil porosity ($L_{\text{water}}/L_{\text{soil}}$)	0.15 (or site-specific)
Θ_a	Air-filled soil porosity ($L_{\text{air}}/L_{\text{soil}}$)	0.28 (or site-specific)
w	Average soil moisture content kg _{water} /kg _{soil} or $L_{\text{water}}/\text{kg}_{\text{soil}}$	0.1 (or site-specific)
H	Henry's Law constant (atm-m ³ /mol)	Chemical-specific
H'	Dimensionless Henry's Law constant	H x 41, where 41 is a units conversion factor

Equation 13: Derivation of the Particulate Emission Factor (USEPA, 2002d)

$$\text{PEF}(\text{m}^3/\text{kg}) = Q/C \times \frac{3600\text{s/h}}{0.036 \times (1-V) \times (U_m/U_t)^3 \times F(x)}$$

Parameter	Definition (units)	Default
PEF	Particulate emission factor (m ³ /kg)	1.316 x 10 ⁹
Q/C	Inverse of the mean concentration at the center of a 0.5-acre-square source (g/m ² -s per kg/m ³)	90.80
V	Fraction of vegetative cover (unitless)	0.5 (or site-specific)
U_m	Mean annual wind speed (m/s)	4.69 (or site-specific)
U_t	Equivalent threshold value of windspeed at 7 m (m/s)	11.32 (or site-specific)
F(x)	Function dependent on U_m/U_t derived using Cowherd (1985) (unitless)	0.194

Equation 14: Mass-Limit Model of the Inhalation of Volatiles (USEPA, 1996a)

$$VF = Q / C \times \frac{T \times (3.15E + 7s / yr)}{\rho_b \times d_s \times 10^6 \text{ g / Mg}}$$

Parameter	Definition (units)	Default
VF	Volatilization factor (m ³ /kg)	-
Q/C	Inverse of the mean concentration at the center of a 0.5-acre source (g/m ² -s per kg/m ³)	68.18
T	Exposure interval (years)	30
ρ _b	Dry soil bulk density (kg/L)	1.5 (or site-specific)
d _s	Thickness of the contaminated soil (meters)	Site-specific

Equation 15: Finite Source Model of the Inhalation of Volatiles (Jury et. al., 1990; USEPA,1996a)

$$VF = \frac{Q}{C} \times \frac{C_o}{\rho_b} \times \frac{1}{J_s^{ave}} \times \frac{10^{-4} \text{ m}^2}{\text{cm}^2}$$

Parameter	Definition (units)	Default
VF	Volatilization factor (m ³ /kg)	
Q/C	Inverse of the mean concentration at the center of a 0.5 acre square source (g/m ² -s per kg/m ³)	68.18
C _o	Uniform contaminant concentration at t=0 (g/cm ³)	Site-specific
ρ _b	Soil dry bulk density (g/cm ³)	1.5 (or site-specific)
J _s ^{ave}	Average contaminant flux at ground surface (g/cm ² -s)	Equation 15a

where $J_s = C_o (D_A / \pi \tau)^{1/2} [1 - \exp(-d_s^2 / 4D_A \tau)]$ (Equation 15a)

and where

$$D_A = \frac{(\Theta_a^{10/3} D_i H' + \Theta_w^{10/3} D_w)}{\rho_B K_d + \Theta_w + \Theta_a H'} \quad \text{(Equation 15b)}$$

Parameter	Definition (units)	Default
J _s ^{ave}	Average contaminant flux over exposure period (g/cm ² -s)	--
C _o	Uniform contaminant concentration at t=0 (g/cm ³)	Site-specific
D _A	Apparent diffusivity (cm ² /s)	Equation 15b
Π	Pi	3.14
τ	Time(s)	Solve daily from τ =0 to 30

		years
d_s	Depth from the soil surface to the base of contamination at $t=0$ (cm)	Site-specific
Θ_a	Air-filled soil porosity (L_{air}/L_{soil}) = $n - \Theta_w$	0.28 (or site-specific)
N	Total soil porosity (L_{pore}/L_{soil}) = $1 - (\rho_b/\rho_s)$	0.43 (or site-specific)
Θ_w	Water-filled soil porosity (L_{water}/L_{soil}) = $w\rho_b/\rho_w$	0.15 (or site-specific)
ρ_b	Dry soil bulk density (g/cm^3)	1.5 (or site-specific)
ρ_s	Soil particle density (g/cm^3)	2.65 (or site-specific)
D_i	Diffusivity in air (cm^2/s)	Chemical-specific
H	Henry's Law constant ($atm\cdot m^3/mol$)	Chemical-specific
H'	Dimensionless Henry's Law constant = $41 \times H$	Chemical-specific
D_w	Diffusivity in water (cm^2/s)	Chemical-specific
K_d	Soil-water partition coefficient (cm^3/g) = $K_{oc}f_{oc}$	Chemical-specific
K_{oc}	Soil organic carbon partition coefficient (cm^3/g)	Chemical-specific
f_{oc}	Fraction organic carbon content of soil (g/g)	0.006 (or site-specific)

Equation 16: Age-adjustment Factor for Inhalation (USEPA, 2002d)

$$InhF_{adj} = \frac{ED_c \times IRA_c}{BW_c} + \frac{(ED_r - ED_c) \times IRA_a}{BW_a}$$

Equation 17: Age-Adjustment Factor for Ingestion (USEPA, 2002d)

$$IFS_{adj} = \frac{ED_c \times IRS_c}{BW_c} + \frac{(ED_r - ED_c) \times IRS_a}{BW_a}$$

Equation 18: Age-adjustment Factor for Dermal Contact (USEPA, 2002d)

$$SFS_{adj} = \frac{ED_c \times AF \times SA_c}{BW_c} + \frac{(ED_r - ED_c) \times AF \times SA_a}{BW_a}$$

PART B

DETERMINISTIC RISK ASSESSMENT GUIDANCE

1.0 INTRODUCTION

This section provides guidance for parties using a complete risk assessment to develop site-specific cleanup standards. The approach outlined in Part B provides more flexibility in characterizing risks and setting site-specific remediation levels than the options available in Part A.

1.1 Organization

Risk assessments should use the standard USEPA approach (USEPA 1989). The organizational format should be as follows:

Chapter 1 *Introduction*- overview of the site, objectives of the risk assessment, site background, scope, conceptual site model, and study design;

Chapter 2 *Site Assessment*- sample design, sample locations, number, and media, analytical methods, quality assurance methods, contaminant boundaries;

Chapter 3 *Identification of Chemicals of Concern (COCs)*- data evaluation and presentation, selection methodology, identification of COCs, data uncertainties;

Chapter 4 *Exposure Assessment*- Identification of complete exposure pathways and quantification of current and potential future intakes;

Chapter 5 *Toxicity Assessment*- Identification of hazard and dose response data for the constituents selected as COCs;

Chapter 6 *Risk Characterization*- Presentation and discussion of actual and potential human health risks and discussion of uncertainties.

1.2 Overview and Objectives

1.2.1 Overview of the Site

Present an overview of the site including a summary of the investigations and remedial activity that has been conducted at the site. The discussion should include a description of the general problem at the site.

1.2.2 Risk Assessment Objectives

The risk assessment objectives should be clearly stated and should indicate the specific areas, media, and contaminants that will be addressed.

The objective of most risk assessments is to determine whether residual chemical levels are protective of human health, and to provide a basis for comparing the potential health impacts of various remedial alternatives.

1.3 Site Background

Present information on the known or potential source areas, and concentrations of hazardous substances involved in the release. Discuss other relevant records such as inspection data, photographs, and any removal actions conducted at the site. Describe the basic characteristics of the contamination in air, soil, soil gas and water at the site. The document should establish potential exposure pathways.

1.3.1 Site Description

The site should be described in detail. The general location of the site, the proximity to populated areas, and the possible routes of contaminant migration should be stated. Land uses in the surrounding area should be discussed.

1.3.2 Maps

A map that shows the site boundaries and surface topography with features such as fences, ponds, and structures should be included. The map should display the current layout of the site including the geographical relationship between potential receptors and the site.

1.3.3 History

Discuss the history of specific chemical use at the site including the methods by which chemicals were used and disposed. This section should include a chronology of land use, including the types of chemicals used at the site and operations at the site that may have resulted in the presence of residual contamination. The nature of the past uses of the site should help determine the types of contamination and impacted areas.

The nature of the contamination should be documented and linked to prior ownership and use, and specific site areas, where known. This section should also discuss the magnitude of the scoping activities undertaken to identify all potential site-related contaminants and how the results influenced the sampling plan.

1.4 Conceptual Site Model

A conceptual site model (CSM) is developed by conducting an extensive records search and site visit, and by compiling all of the existing data including site sampling data, historical records, aerial photographs, hydrogeologic information and population locations. Once this information is organized, the risk assessment team develops a CSM that identifies the sources of contamination, the types and concentrations of chemicals detected in various media, potential exposure pathways and exposure points. The CSM links contaminant sources, release mechanisms, exposure pathways and routes, and receptors.

The development of a CSM is usually interactive. Model development should begin as early in the site investigation process as possible. It is developed to identify data gaps and determine data needs. The preliminary model should be revised following additional data collection efforts to refine the potential

sources, transport media, exposure pathways, and receptors identified. The pathways and receptors in the final model will be those evaluated throughout the remainder of the risk assessment. The ASTM Standard E 1689-95: Guide for Developing Conceptual Site Models for Contaminated Sites provides additional information to develop a CSM (ASTM 1995).

1.5 Scope and Design of the Risk Assessment

Present the scope of the report and a summary of the study design.

1.5.1 Scope

Discuss the scope and complexity of the risk assessment. Include whether the assessment is intended to apply to a small area on site, the entire facility, or the area around the facility including surrounding residential or nonresidential properties. Discuss the complexity of the report. For example, the assessment may use screening level assumptions or may use an approach that is more complex. The rationale for the selection of the approach should be discussed.

1.5.2 Study Design

Present an overview of the risk assessment methodology and study design. The discussion should include the sources of contamination, potentially complete exposure pathways, and potential receptors. Specific elements that influence the study design include:

- X The sample collection and analytical results including the selection of target compounds of concern and an evaluation of the confidence that all potential chemicals of concern have been identified;
- X The degree of confidence that all locations that may be contaminated have been identified;
- X An exposure evaluation including physical and chemical characteristics at the site including contaminant fate and transport;
- X The types and numbers of potential receptors that may potentially be exposed to contaminants at the site.

2.0 SITE ASSESSMENT

Data collection efforts conducted at the site should be identified in this section. The discussion should include the rationale for the sample design, a description of sample locations and media, the analytical methods used, the quality control procedures used, and a definition of the boundaries of the contamination.

2.1 Detailed Rationale for Sampling Design

State the rationale for the sampling design and include topics such as sample size and location, types of samples, choice of analytical methods, temporal and meteorological factors, and field screening analyses. Discuss how sample sizes and location were chosen, including the number of areas of concern investigated, the statistical methods used, and statistical performance standards (i.e. degree of confidence that the true mean is less than the mean from the sample data set). The sampling strategy should be adequate to characterize the site. The number of samples that need to be analyzed will depend upon site-specific conditions.

2.2 Sample Locations, Number, and Media

Identify the media sampled and provide information regarding sampling locations.

2.3 Definition of Modeling Parameters

Site-specific characteristics that may need to be quantified for use in fate/transport models include air filled and total porosity of the soil, soil bulk density, soil moisture, soil organic carbon content and average wind speed and direction. This section should include a discussion and a determination of the necessary parameters.

2.4 Analytical Methods for Sampling and Analysis

The procedures for sample collection, preservation, handling, and transport, and the laboratory analytical methods used should be discussed. The method detection limits for the contaminants for which analyses are conducted should be lower than the applicable SRL (ie. residential or non-residential) or an alternative site-specific risk-based concentration.

2.5 Quality Assurance/Quality Control (QA/QC) Methods

Discuss the data quality objectives, sampling methods, sampling devices, QC samples, collection procedures, and sample preservation methods. QC samples include field blanks, trip blanks, duplicates, and split samples. Collection procedures should not alter the samples which should be preserved to prevent any change in concentration. An appendix should contain the laboratory results for all QA/QC results including percent recovery of spike samples and results of sample blanks. The QA/QC results should be used to conclude whether the data quality objectives for the site have been satisfied. The USEPA has published a guidance document entitled *Guidance for Data Useability in Risk Assessment* (USEPA 1990a) which outlines proper procedures.

2.6 Definition of Contaminant Boundaries

In order to accurately evaluate risks, the horizontal and vertical extent of the contamination should be determined. The boundaries of the contamination should be identified or referenced in this section. The characterization should be adequate to estimate exposure concentrations at the site.

3.0 IDENTIFICATION OF CHEMICALS OF CONCERN

This section identifies the chemicals of concern (COCs) in each media. This section summarizes the criteria recommended for selecting COCs.

3.1 Evaluation of Chemical Data

Summarize the sampling results from each area of concern. The presentation should include both a narrative summary, and tables of the analytical results. Separate tables should be included for each media of concern. Each table should display the range and frequency of detection, and the mean and upper 95% confidence limit (UCL).

The distribution of the data with respect to the layout of the site should be included. The text should also mention whether the concentrations of chemicals were close to the detection limits, or whether there are areas that contain hotspots. Any areas that contain hotspots should be identified. Hotspots are areas that have one or more samples that contain concentrations of contaminants that exceed the relevant SRL by a factor of ten or more.

3.2 Identification of Chemicals of Potential Concern

The methodology used to select COCs in each media should be presented in this section. The recommend the approach presented in this section.

3.2.1 Soil

All chemicals detected in at least one soil sample should be considered COCs unless **one** of the following criteria are met:

- X if the highest detected concentration in soil is less than the applicable SRL (i.e. residential or nonresidential);
- X if the compound was detected in less than 5% of the soil samples and no hotspots exist;
- X if the compound is present at similar levels under natural ambient conditions in the area (ie. background), and the contaminant concentration has not been increased by anthropogenic sources.

The USEPA document entitled *Establishing Background Levels* (USEPA 1995a) may be used to determine background levels of naturally occurring contaminants.

3.2.2 Soil Gas

All chemicals detected in at least one soil gas sample should be considered COCs unless **one** of the following criteria are met:

- X if the highest detected concentration is less than the current USEPA Reference Concentration (RfC) or the Unit Risk at the one-in-one-million risk level (1E-6) for carcinogens with a WoE classification of □A□ or at the one-in-one-hundred-thousand risk level (1E-5) for

carcinogens with a WoE classification of □B or C□. Details regarding these criteria are included in Chapter 4.

- X if the compound was detected in less than 5% of the soil gas samples collected and no hotspots exist.

3.2.3 Surface Water/Sediment

All chemicals detected in at least one surface water/sediment sample should be considered COCs unless **one** of the following criteria are met:

- X if the highest detected value downstream of the site is less than the highest detected value upstream of the site;
- X if the highest detected concentration is less than the Aquifer Water Quality Standard.

3.2.4 Air

All chemicals detected in at least one sample should be considered COCs unless one of the following criteria are met:

- X if the highest detected value upwind of the site is less than the highest detected value downwind of the site;
- X if the highest detected concentration is less than the current USEPA Reference Concentration (RfC) or the Unit Risk at the one-in-one-million risk level (1E-6) for carcinogens known human carcinogens (WoE classification of □A□) or at the one-in-one-hundred-thousand risk level (1E-5) for probable and possible carcinogens (WoE classification of □B or C□).

3.2.5 Groundwater

All chemicals detected in at least one groundwater sample should be considered COCs unless if the highest detected concentration is less than the Aquifer Water Quality Standard (AWQS). In some cases, COCs should remain in the risk assessment even if their maximum concentration is present at less than the AWQS. For example, arsenic can significantly contribute to overall site risk even if it is present at less than the AWQS. A risk assessor should carefully evaluate site conditions before eliminating COCs in groundwater.

3.3 Data Uncertainties

Uncertainties in the sampling and laboratory procedures should be summarized and discussed in a qualitative and quantitative manner for each media. The discussion should include the uncertainties that may exist if data from multiple investigations were used. The QA/QC procedures used should be discussed including the results of sample blanks and spikes.

4.0 EXPOSURE ASSESSMENT

The exposure assessment expands upon and quantifies exposures discussed in the CSM. The CSM initially identifies the sources of contamination, the concentrations of chemicals detected in various media, potential exposure pathways and exposure points. The exposure assessment quantifies exposures identified in the CSM.

The exposure assessment integrates information on chemical releases, environmental measurements, and human activity to estimate the type and magnitude of exposure to COCs received. This is done by characterizing the exposure setting, exposure pathways, exposed populations (receptors), and by quantifying exposure concentrations and intakes.

4.1 Characterization of Exposure Setting

4.1.1 Physical Setting

The risk assessment should describe site-specific surface features that may influence human exposure such as geologic setting, vegetation, and types and locations of structures at the site. The following physical characteristics may influence exposure:

Geology and Soils-vegetation, underlying strata, air-filled and total porosity of the soil, soil moisture, soil bulk density, organic carbon content, and the depth of the contaminants below the ground surface

Meteorology- temperature, precipitation, and wind speed and direction

Hydrology- distance from the surface to groundwater, the direction of flow, surface hydrologic features and potential surface transport of contaminants

4.1.2 Characterization of Potentially Exposed Populations

This section should describe the number and location of people who could be exposed to contaminants at the site including those who reside or work at or near the site, and sensitive subgroups such as children and elderly people. These sensitive receptors may be at higher risk due to higher exposures or greater susceptibility to the COCs.

4.1.2.1 Populations Relative to the Site

Using information from a site visit, population surveys, and maps, establish the number of people with potential exposure and their location relative to the site.

4.1.2.2 Current Land Use

Using zoning maps, census information, aerial photographs, and information from a site visit, characterize the activities and activity patterns of potentially exposed populations. Potential current land uses include residential, commercial/industrial, agricultural and recreational. Sites may have more than one land use. Identify any land use controls that may be in effect.

Determine the human activity patterns at the site, estimate the number of hours spent in these

activities by the population and identify any site-specific characteristics influencing exposure. Important activity issues include the amount of time spent outdoors versus indoors, seasonal changes in activities, soil excavations, access restrictions, and paths showing activity trends.

4.1.2.3 Future Land Use

The risk assessment should identify any foreseeable future land uses, and should include the likelihood of each alternative future use. If future land uses may be residential, then future land uses should be assumed to be residential. Numerous future land uses may be evaluated in the risk assessment, however, the risk assessment team should keep in mind the objectives of the risk assessment when selecting future use exposure scenarios.

4.2 Exposure Pathways and Routes of Exposure

Summarize the potentially complete exposure pathways at the site. An exposure pathway is the course a contaminant takes from its source to a receptor or to a potential receptor, and consists of four elements:

- X a source and mechanism of chemical release;
- X a retention or transport medium;
- X a point of potential human contact with contaminated medium;
- X an exposure route at the point of contact (inhalation, ingestion, dermal contact).

All potential migration pathways including natural pathways such as volatilization of contaminants through soil and man made pathways such as conduits should be identified. All potential exposure routes should be explored including ingestion of soil, dermal absorption, and inhalation of vapors and dust. Engineering and institutional controls may be considered when identifying complete exposure pathways.

4.2.1 Source Identification

This section should identify potential release mechanisms and receiving media at the site. In some instances, the source itself is the exposure point. However, a contaminated medium from a past release can be a contaminant source for other media (e.g., contaminated surface soil contaminated may be a source to surface water or air).

4.2.2 Fate and Transport Evaluation

Exposure may be determined more precisely with a knowledge about the fate (i.e. behavior of a contaminant when released into a specific media) and transport (i.e. bioconcentration, soil adsorption/mobility, and volatilization) of a contaminant. An analysis of the fate and transport is conducted to identify media that may be receiving site-related chemicals. Following release of a chemical to the environment, it may be:

- X transported (through soil, water, or air);
- X physically transformed (volatilization, etc.);
- X chemically transformed (photolysis, hydrolysis, oxidation, reduction);
- X biologically transformed (biodegradation);
- X accumulated in one or more media.

The above fate and transport mechanisms may be affected by physical characteristics such as moisture content, organic carbon content, bulk density, and soil porosity. Site-specific characteristics that may influence transport may include vapor barriers or other engineering controls.

Use all available information to evaluate transport within and between media and retention or accumulation within a single media. Monitoring data should be used to identify media that are currently contaminated and the pathways that may lead to future contamination.

4.2.3 Exposure Points and Routes

An exposure point is any location that serves as a potential contact to the contaminated medium. Any contaminated media should be considered a potential exposure point if the area is currently being used, if the site is not restricted, or if future land use suggests potential human contact to the contaminant. In general, most complete exposure points and routes will occur on-site. However, instances of off-site exposure may occur if contamination extends beyond the property boundaries via a transport mechanism. All exposure points at the site should be identified and discussed in this section. In addition, all potential exposure routes should be explored and discussed, including ingestion of soil, dermal absorption, and inhalation of vapors and fugitive dust.

4.2.4 Synthesis into Complete Exposure Pathways

Based on the information identifying the source, fate and transport of the COCs, and the exposure points and routes, a complete exposure pathway may be established. A summary of all complete exposure pathways, including the potentially exposed populations and the exposure media, points, and routes, should be included in the quantitative risk assessment. Complete exposure pathways should be summarized for current and future land uses. Excluding pathways from quantification should be justified and supported by the CSM.

A table that summarizes all current and potential future exposure pathways should be provided.

4.3 Quantification of Exposure Concentrations

Exposure concentrations in the various media for each exposure area should be calculated and presented in this section. The analysis should include parameters and assumptions in the model and backup documentation to defend the results.

The level of effort used to estimate exposure concentrations depends on the kind of data available, the level of detail in the risk assessment, the objectives of the risk assessment, and the resources available for the project. Estimating exposure concentrations will usually include a simple analysis of the data and application of simple methods that assume steady-state conditions. This section presents models consistent with this strategy. Alternative methods to estimate exposure concentrations may be used if the risk assessment team believes they are warranted. However, alternative methods should be well documented and use peer reviewed literature sources.

4.3.1 Estimating Exposure Concentrations Under Current Conditions

Exposure concentrations in soil should be quantified by calculating the 95% UCL of the arithmetic mean of the concentration of contaminants in each exposure area and media where human activity is occurring.

Surface Soils

The area over which human activity occurs and the spacial distribution of soil matrix data is a critical factor in determining exposure concentrations for surface soil. In general, data from random soil sampling programs or samples from evenly spaced grids can be considered representative of human exposure concentrations when contact with soil in all areas of the site is equally probable (USEPA 1989). At some sites, the contamination will not be evenly distributed and the soils will contain hotspots.

Data sets containing hotspots may be averaged if current contact with soil is spatially random. However, averaging contaminant concentrations from hotspots over a large area is inappropriate if human activity at the site is not spatially random. If a hotspot is near an area that is frequently used, exposure concentrations at the hotspot area should be assessed separately.

Subsurface Soils

The dominant exposure pathway when the primary contaminants are VOCs in subsurface soils is usually vapor phase diffusion into indoor and outdoor air and subsequent inhalation of the contaminants. Vapor phase migration of the COCs to the surface may be estimated using diffusion modeling. Examples of approaches for estimating flux and outdoor air concentrations are presented in the Appendix. A number of acceptable mathematical models are presented in the SEAM (USEPA 1988) and the Air/Superfund National Technical Guidance Study Series Document: *Guideline for Predictive Baseline Emissions Estimation for Superfund Sites* (USEPA 1995b). Other models may be acceptable if the approach has been published in the peer-reviewed literature. Any model that is used should be validated by laboratory, pilot or field studies.

Diffusion models require an estimated or actual concentration of the contaminant in subsurface soil or soil gas. Often, contamination in the subsurface will contain hotspots. The spacial distribution of subsurface contamination may be a factor in evaluating monitoring data to estimate flux over an exposure area. If a hotspot is near an area that currently contains an occupied structure, soil gas or subsurface soil concentrations may be averaged over the area of the current structure to estimate flux when evaluating current exposures. In general, for contamination where no current structure exists, soil concentrations may be averaged over the area of current exposure in order to calculate flux. Acceptable models for calculating flux and air concentrations are provided in the Appendix.

4.3.2 Estimating Exposure Concentrations Under Future Conditions

Surface Soils

Data from random soil sampling programs or samples from evenly spaced grids can be considered representative of future human exposure concentrations if no hotspots were found. Similarly, data from purposive sampling plans may be considered representative of future human exposure concentrations if hotspots do not exist. However, for sites that contain hotspots, averaging hotspot data over a *maximum* area the size of a residential backyard (500 m²) may be the most appropriate way of estimating future residential exposure concentrations for direct exposure pathways (USEPA 1989). In some circumstances, it may be necessary to estimate future exposure concentrations at hotspots, without averaging any of the data, if the area may present a potential future non-cancer hazard to children. If the future use of the property is not residential, it may be appropriate to average surface soil data over the area which human activity currently occurs or over an area such as 2,000m² (0.5 acres).

Subsurface Soils

If a hotspot is near an area that currently contains an occupied structure, soil gas or subsurface soil concentrations may be averaged over the area of the current structure to estimate flux for future exposures if land uses are not anticipated to change. For contaminated areas where no current structure exists, averaging the data to estimate flux from hotspots over an area of a potential future house (200 m²) may be the best approach for estimating future residential exposures. For properties with nonresidential land uses, it may be appropriate to average subsurface data over a larger area (2,000m²) when estimating flux. Acceptable models for calculating flux and air concentrations are provided in the Appendix.

4.3.3 Statistical Procedures

The contaminant concentration that should be used to exposure concentrations for all media is the 95 percent upper confidence limit (95% UCL) of the *arithmetic* mean concentration in each exposure area. Using the 95% UCL provides reasonable confidence that the true site average will not be underestimated. For data sets with limited sample numbers, the 95% UCL may be higher than the maximum detected level in the data set. If this occurs, the maximum detected concentration may be used as the estimate of the exposure concentration. Specific guidance calculating appropriate exposure concentration is provided in the Appendix.

4.4 Estimation of Chemical Intakes for Each Exposure Pathway

Exposure is the contact of a receptor with a chemical or physical agent. When exposure is standardized for time and body weight, it is designated as intake and expressed as a chronic daily intake (CDI) in mg of chemical per kg of body weight per day (mg/kg · day). The CDI is the quantity of a chemical, which is available for absorption at the exchange boundary (e.g., skin, lungs, gastrointestinal tract). It is different from the absorbed dose, which represents the concentration of the chemical in blood.

The reasonable maximum exposure (RME) is the highest exposure (CDI) that may *reasonably* be expected at a site, and applies to both current and future land use. The objective of an RME estimate is to join the upper-bound and mid-range exposure variables into an equation, resulting in an intake level that is reasonable, protective, and not the worse case. While central tendency exposures may be evaluated in the risk assessment, risk management decisions will usually be made using an RME estimate. Therefore, developing RME estimates will be required for all risk assessments, while developing an estimate of central tendency exposure is optional.

All potentially complete exposures should be quantified in this section. Residential exposure should be evaluated for adult and child receptors separately. The presentation should include worksheets that

identify the assumptions and parameters in the evaluation. This section provides guidance for quantifying exposure.

4.4.1 Incidental Ingestion of Soils

The intake equation for incidental ingestion of soil is summarized in Table 4.4.1. Information about the site and professional judgement may be used to determine variable values for current exposure. Potential future residential exposures should incorporate the RME variables identified in Table 4.4.1. Potential future exposures for residential properties should include the residential childhood scenario. The exposure assumptions in the table are recommended for use by the USEPA (USEPA 1989,1991b).

Table 4.4.1 Formula Used to Calculate Intakes from Ingestion of Soils for Residential and Non-Residential (Occupational) Exposure Scenarios.

$$CDI = \frac{(CS)(CF)(IR)(EF)(ED)}{(BW)(AT)}$$

Where:

- CDI = Chronic Daily Intake (mg/kg-day)
 CS = Chemical concentration in soil over exposure area (mg/kg)
 CF = Conversion Factor (kg/10⁶ mg)
 IR = Ingestion rate (mg/day)
 EF = Exposure frequency (days/year)
 ED = Exposure duration (years)
 BW = Body weight (kg)
 AT = Averaging time (period over which exposure is averaged-days)

Variable Values:

	<u>Occupational</u>	<u>Residential Adult</u>	<u>Residential Child</u>
CS:	95% UCL (mg/kg)	95% UCL (mg/kg)	95% UCL (mg/kg)
IR:	50 (mg/day)	100 (mg/day)	200 (mg/day)
EF:	250 (days/year)	350 (days/year)	350 (days/year)
ED:	25 (years)	30 (years)	6 (years)
BW:	70 (kg)	70 (kg)	15 (kg)
AT: (carc.)	25,550 (days)	25,550 (days)	25,550 (days)
AT: (non-carc.)	9,125 (days)	10,950 (days)	2,190 (days)

4.4.2 Inhalation of Vapors and Particulates

The intake equations for inhalation of vapors and particulates are summarized in Tables 4.4.2.1 and 4.4.2.2, respectively. Information about the site and professional judgement may be used to determine variable values for current exposure. Potential future exposures should incorporate the RME variables identified in the tables. The exposure assumptions in the table are recommended for use by the USEPA (USEPA 1989, 1991b).

Acceptable models for estimating indoor and outdoor air concentrations are presented in the Appendix.

Table 4.4.2.1 - Formula Used to Calculate Intakes from Inhalation of Vapors for Residential and Non-Residential (Occupational) Exposure Scenarios.

$$\text{CHRONIC DAILY INTAKE: } \text{CDI} = \frac{(\text{AC})(\text{IR})(\text{EF})(\text{ED})}{(\text{BW})(\text{AT})}$$

where:

- AC = Chemical concentration in air (indoor or outdoor) (mg/m³)
- IR = Inhalation rate (m³/day or workday)
- EF = Exposure frequency (days/year)
- ED = Exposure duration (years)
- BW = Body weight (kilograms)
- AT = Averaging time (days)

Variable Values:

	<u>Occupational</u>	<u>Residential</u> Adult	<u>Residential</u> Child	<u>Residential</u>
AC:	95% UCL (mg/m ³)			
IR:	20 (m ³ /workday)	20 (m ³ /day)	15 (m ³ /day)	15 (m ³ /day)
EF:	250 (workdays/year)	350 (days/year)	350 (days/year)	350 (days/year)
ED:	25 (years)	30 (years)	6 (years)	6 (years)
BW:	70 (kg)	70 (kg)	15 (kg)	15 (kg)
AT: (carc.)	25,550 (days)	25,550 (days)	25,550 (days)	25,550 (days)
AT: (non-carc.)	9,125 (days)	10,950 (days)	2,190 (days)	2,190 (days)

Table 4.4.2.2 - Formula Used to Calculate Intakes from Inhalation of Particulates for Residential and Non-Residential (Occupational) Exposure Scenarios

$$CDI = \frac{(CS)(PEF)(IR)(EF)(ED)}{(BW)(AT)}$$

where:

- CDI = Chronic daily intake (mg/kg-day)
- CS = Chemical concentration in surface soil (mg/kg)
- PEF = Particulate Emission Factor (kg/m³)
- IR = Inhalation rate (m³/day)
- EF = Exposure frequency (days/year)
- ED = Exposure duration (years)
- BW = Body weight (kg)
- AT = Averaging time (period over which exposure is averaged-days)

Variable Values:

	<u>Occupational</u>	<u>Residential</u> Adult	<u>Residential</u> Child	<u>Residential</u>
CS:	95% UCL (mg/kg)	95% UCL (mg/kg)	95% UCL (mg/kg)	95% UCL (mg/kg)
PEF:	7.16E-10 (kg/m ³)			
IR:	20 (m ³ /workday)	20 (m ³ /day)	15 (m ³ /day)	15 (m ³ /day)
EF:	250 (days/year)	350 (days/year)	350 (days/year)	350 (days/year)
ED:	25 (years)	30 (years)	6 (years)	6 (years)
BW:	70 (kg)	70 (kg)	15 (kg)	15 (kg)
AT: (carc.)	25,550 (days)	25,550 (days)	25,550 (days)	25,550 (days)
AT: (non-carc.)	9,125 (days)	10,950 (days)	2,190 (days)	2,190 (days)

4.4.3 Dermal Exposure Estimation Methods

Many inorganic chemicals are poorly absorbed through dermal contact and not all risk assessments will require a quantitative evaluation of intake via dermal absorption. However, for compounds such as pesticides, dermal absorption may significantly contribute to total exposure. Therefore, dermal contact and absorption may be evaluated on a case by case basis. All sites should at least qualitatively evaluate the potential for dermal exposure. At sites where dermal contact may significantly contribute to exposure, dermal exposure should be quantitatively evaluated. Table 4.4.3 provides guidance for quantifying dermal exposure at sites where this is appropriate.

Variables used in the formula are taken from RAGS (USEPA 1989) and the USEPA Dermal Assessment (USEPA 1992a). Skin surface area (SA) available for contact was usually assumed to be 5,000 cm²/day, which is 25% of the surface area of an average adult (USEPA 1992a). The surface area for childhood exposure here assumes an exposed surface area of 2,000 cm²/day (USEPA 1992a). The soil adherence factor (AF) was assumed to be 0.2 mg/cm² (USEPA 1992a).

Table 4.4.3 - Formula Used to Calculate Transient and Occupational CDI From Dermal Absorption of Contaminants in Soil

$$CDI = \frac{(CS)(CF)(SA)(AF)(ABS)(EF)(ED)}{(BW)(AT)}$$

where:

- CDI = Chronic Daily Intake (mg/kg-day)
- CS = Chemical Concentration in Soil (mg/kg)
- CF = Conversion Factor (1E-6 kg/mg)
- SA = Skin Surface Available for Contact (cm²/day)
- AF = Soil to Skin Adherence Factor (mg/cm²)
- ABS = Absorption Factor (unitless)
- EF = Exposure Frequency (days/year)
- ED = Exposure Duration (years)
- BW = Body Weight (kg)
- AT = Averaging Time (period over which exposure is averaged-days)

Variable Values:

	<u>Occupational</u>	<u>Residential Adult</u>	<u>Residential Child</u>
CS:	95%UCL (mg/kg)	95% UCL (mg/kg)	95% UCL(mg/kg)
SA:	5,000 (cm ² /day)	5,000 (cm ² /day)	2,000 (cm ² /day)
AF:	0.2 (mg/cm ²)	0.2 (mg/cm ²)	0.2 (mg/cm ²)
ABS:	chemical specific	chemical specific	chemical specific
EF:	250 (days/year)	350 (days/year)	350 (days/year)
ED:	25 (years)	30 (years)	6 (years)
BW:	70 (kg)	70 (kg)	70 (kg)
AT: (carc.)	25,550 (days)	25,550 (days)	25,550 (days)
AT: (non-carc)	9,125 (days)	10,950 (days)	2,190 (days)

4.5 Identification of Uncertainties

This section should discuss the major assumptions of the exposure assessment, the uncertainties associated with each assumption, and how these uncertainties influence the exposure estimates.

4.6 Summary of the Exposure Assessment

A summary of the exposure assessment should be presented in tabular form. The table presents quantitative estimates of exposure from each pathway. The information should be separated into current and potential future exposures. The summary of potential future exposures should include exposures under a □no action alternative□ but may also include exposures that may occur following potential remedial alternatives such as installation of a vapor barrier or other engineering controls.

5.0 TOXICITY ASSESSMENT

The toxicity assessment provides information about the potential for contaminants to cause adverse health effects in exposed individuals and an estimate of the relationship between exposure and the increased likelihood of adverse effects.

5.1 Information for Noncarcinogenic Effects

Toxicity information about noncarcinogenic effects for each chemical of concern at the site should be summarized and presented in this section. Information that should be provided includes the following:

- X Current chronic reference doses (RfDs) and reference concentrations (RfCs) for each chemical of concern. The uncertainty and modifying factors used in the determination of the toxicity value also should be included.
- X The database from which the toxicity value was taken (IRIS or HEAST)

In general, it is inappropriate to adjust an RfD to account for absorption (ie. bioavailability) unless it is expressed as an absorbed dose. However, dermal exposures are expressed as the amount of the substance absorbed per day, and it will often be appropriate to derive an absorbed dose RfD from an administered dose value for use in calculating non-cancer hazard. Occasionally, it may be appropriate to adjust for relative absorption efficiencies for other pathways such as ingestion if the RfD is based upon a medium of exposure (i.e., soil matrix vs. water or corn oil) that does not exist at the site. However, any such adjustments should be well referenced, and should only be done by a qualified toxicologist (USEPA 1989).

5.2 Information for Carcinogenic Effects

The USEPA has developed carcinogenicity weight of evidence (WoE) classifications for many chemicals. The WoE represents the carcinogenicity evidence from human and animal studies, and indicates the strength of the data. An A classification signifies that the chemical is a known human carcinogen. Probable human carcinogens are designated either B1, showing that studies in humans are strongly suggestive but not conclusive, or B2 if the chemical has been conclusively carcinogenic in repeated animal studies but not conclusive in human studies. A chemical may be classified C, a possible human carcinogen, if a single high-quality animal study or several low-quality animal studies suggest carcinogenicity. If there is insufficient human and animal evidence to determine the carcinogenicity of the chemical, it is classified as D. A chemical conclusively shown to be non-carcinogenic to humans is in group E.

The WoE classification for each of the COCs should be identified. These designations will be used in the Risk Characterization to separate risks presented by known human carcinogens and the possible and probable human carcinogens.

Toxicity information about carcinogenic effects for each chemical of concern at the site should be summarized and presented in this section. Information that should be provided includes the following:

- X Current slope factors (SF) and WoE for all carcinogens for oral and inhalation exposures
- X The database from which the slope factor was taken (IRIS or HEAST)

The chemicals of concern at most sites will generally have toxicity values available. If a site has chemicals of concern without toxicity values, the ADHS should be contacted regarding the use of substitute toxicity values.

In general, it is inappropriate to adjust a SF to account for absorption (i.e., bioavailability) unless the SF is expressed as an absorbed dose. However, dermal exposures are expressed as the amount of the substance absorbed per day, and it will often be appropriate to derive an absorbed dose SF from an administered dose value for use in calculating risk. Occasionally, it may be appropriate to adjust for relative absorption efficiencies for other pathways such as ingestion if the SF is based upon a medium of exposure (i.e., soil matrix vs. water or corn oil) that does not exist at the site. However, any such adjustments should be very well referenced, and should only be done by a qualified toxicologist (USEPA 1989).

5.3 Summary of Toxicity Information

A short description of the toxic effects of each chemical of concern should be included in the text in this section. The summary of toxic effects of a COC should highlight any toxic effect which may be important at the site. For example, if sensitive groups are present, the toxicity for that group should be included in the summary. It should also be noted that most toxicity studies are conducted for acute or subchronic exposure, while chronic exposure is usually being evaluated in risk assessments of this type. If a large number of COCs have been identified, toxicological profiles may be included in an appendix.

5.4 Uncertainties Related to Toxicity Information

The uncertainties inherent in developing RfDs and Slope Factors should be briefly presented in this section. Many of these uncertainties are identified in RAGS.

6.0 RISK CHARACTERIZATION

Current and potential future risks should be characterized in this chapter using the exposure and toxicology information in the risk assessment. The risk characterization should be presented in a quantitative and qualitative format. Calculations should include risks from all chemicals of concern for each identified exposure route and for all exposure routes combined.

The RME is the highest exposure that may *reasonably* be expected at a site, and applies to both current and future land use. While central tendency exposures and risk may be evaluated in the risk assessment, risk management decisions will usually be made using an RME estimate. Therefore, developing RME estimates is required for all risk assessments, while developing an estimate of central tendency exposure is optional.

In most cases, both excess lifetime carcinogenic risk (ELCR) and non-carcinogenic hazard quotients (HQ) should be assumed to be additive when more than one chemical of concern is present. Values for individual chemical specific values are summed to obtain an estimate of ELCR. Hazard Quotients for most chemicals should be summed to develop the Hazard Index (HI). In some cases, it may be appropriate to develop one or more HIs if the toxic endpoint of the individual constituents differ. Details on this procedure are provided in Section 6.1.2.

6.1 Current Land Use and Exposures

6.1.1 Excess Lifetime Cancer Risk Under Current Conditions

This section of the risk assessment should provide a narrative discussion of the methodology and exposure assumptions used to develop the cancer risk estimates. Following this discussion, the risk assessment should present the quantitative results. The risk assessment should then provide explanatory text that interprets and qualifies the results.

Carcinogenic risk is calculated as the incremental probability of an individual developing cancer over a lifetime (70 years) due to exposure to a carcinogenic compound. This is also called ELCR and represents the increased risk of developing cancer above the background rate, estimated at 30%. Total ELCR is expressed as a probability.

Carcinogenic risks are based on calculations developed in the following order. Information on exposure pathways, exposure concentrations, and toxicology are assembled or calculated. CDIs are then calculated using assumptions from the exposure and toxicity values. Chemical specific carcinogenic slope factors (SF) are used to convert estimated CDI, averaged over a lifetime, to incremental risk. The ELCR for each exposure pathway is then summed to estimate total ELCR.

The dose-response relationship is considered linear under the low dose conditions usually encountered in environmental exposures. In consideration of this assumption, the SF is a constant and risk is directly related to intake. The linear low-dose cancer risk equation is:

$$\text{ELCR} = \text{CDI} \times \text{SF}$$

where:

ELCR = a unitless excess probability of an individual developing cancer;
CDI = Chronic Daily Intake averaged over 70 years (mg/kg-day);
SF = Slope Factor, expressed in (mg/kg-day)⁻¹.

The resulting ELCR estimates for current land uses should be summarized and presented in a table. The following tables should be presented in the text:

- X The ELCR for multiple substances for each currently complete exposure pathway. ELCR estimates for known human carcinogens (WoE = A) should be displayed separately.
- X The sum of the ELCR estimates for all currently complete exposure pathways. The total ELCR estimates should be expressed using one significant figure. ELCR contributed by known human carcinogens should be specifically discussed.

6.1.2 Systemic (Noncarcinogenic) Effects Under Current Conditions

This section of the risk assessment should provide a narrative discussion of the methodology and exposure assumptions used to develop the noncarcinogenic health effect results. Following this discussion, the risk assessment should present the quantitative results. The risk assessment should then provide explanatory text that interprets and qualifies the results.

Noncarcinogenic or systemic health effects may include neurotoxic, hepatotoxic, nephrotoxic, teratogenic, reproductive reactions, and any other non-cancer related systemic toxic responses. The potential for an individual to suffer a noncarcinogenic effect is not expressed as a probability, but as a ratio or quotient. The ratio is determined by comparing the CDI to the chemical specific RfD which is not expected to produce toxic effects. The HQ is the ratio of an exposure level over a specified period (CDI) to the experimentally determined toxicity of the chemical RfD. The screening Hazard Index (HI) is the sum of all HQs for each pathway and chemical.

The HQ is calculated as follows:

$$\text{Non-cancer Hazard Quotient (HQ)} = \text{CDI/RfD}$$

where:

CDI = Daily Intake (dose) in mg/kg-day;
RfD = Reference Dose in mg/kg-day.

The screening HI is the sum of all HQs for multiple substances and pathways. This approach assumes that simultaneous subthreshold exposures to several chemicals could result in an adverse health effect. A limitation to this approach is that the assumption of dose additivity is most properly applied to compounds that induce the same effect by the same mechanism of action. Therefore, application of the hazard index equation to substances that do not act by the same mechanism could overestimate the potential for health effects. If the initial screening level HI exceeds 1, it may be appropriate to segregate the compounds by effect and mechanism of action to derive separate HIs for each group. However, the process of segregating HIs by mechanism and effect is complex, and such an analysis should only be done by a qualified toxicologist (USEPA 1989).

The resulting HIs for current land uses should be summarized in tables. The following tables should be presented in the text for current land use:

- X Chronic Hazard Quotients or Indices for all substances for each current exposure pathway;
- X Chronic Hazard Index for all current exposure pathways.

Hazard Quotients and Indices should be expressed using one significant figure.

6.2 Potential Future Land Use and Exposures

6.2.1 Excess Lifetime Cancer Risk Under Potential Future Conditions

This section of the risk assessment should provide a narrative discussion of the methodology and exposure assumptions used to develop the cancer risk estimates. Following this discussion, the risk assessment should present the quantitative results. The risk assessment should then provide explanatory text that interprets and qualifies the results.

The methodology for developing potential future risk estimates are identical to that of developing current risk estimates except that land uses and exposures may change in the future, resulting in different risk estimates. The risk analysis should include potential future risk under a "no action alternative" but may also include exposures that may occur following potential remedial alternatives such as installation of a cap or other actions that reduce potential future exposures.

Future land uses other than residential and commercial/industrial may be evaluated in the risk assessment, however, residential and/or commercial/industrial uses should always be included in the risk assessment.

6.2.2 Systemic (Noncarcinogenic) Effects Under Potential Future Conditions

This section of the risk assessment should provide a narrative discussion of the methodology and exposure assumptions used to develop the noncarcinogenic health effect results. Following this discussion, the risk assessment should present the quantitative results. The risk assessment should then provide explanatory text that interprets and qualifies the results.

The methodology for developing a potential future non-cancer hazard is identical to that of developing current risk estimates except that land uses and exposures may change in the future resulting in different hazard indices. The risk analysis should include potential future non-cancer hazard under a "no action alternative" but may also include exposures that may occur following potential remedial alternatives such as installation of a cap or other actions that reduce potential future exposures.

Future land uses other than residential and commercial/industrial may be evaluated in the risk assessment, however, residential and/or commercial/industrial uses should always be included in the risk assessment.

6.3 Uncertainties

This section addresses the uncertainties in the risk assessment. Possible sources of uncertainty include site-specific uncertainty errors, errors in estimating exposures, and uncertainties in the toxicity evaluation of chemicals.

Risk estimates are based upon a number of assumptions regarding contaminant concentrations, fate and transport, exposures, doses and toxicity information. The uncertainty at each of these stages should be recognized and discussed in a qualitative and quantitative manner. An analysis of risk factors and COCs as they relate to the contribution of total risk can simplify the uncertainty discussion and help identify

meaningful risk assessment refinement strategies.

Uncertainties in the exposure assessment include most of the site-specific uncertainties inherent in risk characterization. Elements that need to be addressed are:

- X Definition of the physical setting, including the likelihood of exposure pathways and land uses actually occurring, and the possible presence of chemicals or degradation products that were not included in the risk assessment;
- X Uncertainties in the diffusion model applicability and assumptions;
- X Uncertainties in the fate, transport and exposure parameter values.

Include a summary of the uncertainty in the toxicity values for the durations of exposure assessed for substances that contribute to estimates of cancer risk and non-cancer hazard indices. Refer to Chapter 8 in RAGS for a checklist of uncertainties that apply to toxicity assessments.

6.4 Summary Discussion and Tabulation of the Risk Characterization

Summarize the risk characterization results. The results of the risk assessment should not be taken as a characterization of absolute risk. An important use of the risk and hazard index estimate is to highlight potential sources of risk at a site so that it may be dealt with effectively in the remedial process. The discussion of the risk characterization results is a key component of this chapter. The discussion of risk should include:

- X Discussion of confidence in site characterization, identification of all site-related contaminants, and contaminant concentrations and distributions;
- X Level of confidence in the quantitative toxicity information used to estimate risks;
- X Level of confidence in the exposure estimates, pathways and exposure parameter assumptions;
- X The magnitude of the cancer risks and non-cancer hazard indices;
- X The major factors driving the site risks such as chemicals, pathways, and pathway combinations;
- X The major factors reducing the certainty in the results and their significance.

A tabular summary of the cancer risks and non-cancer hazard indices should be displayed for all identified exposure pathways and current and potential future land uses for all substances carried through the risk assessment. The tables should be accompanied by text, and should not stand alone as the entire risk characterization.

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